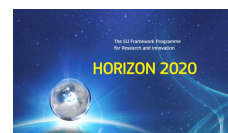




EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR RESEARCH & INNOVATION
Health
Fighting infectious diseases and global epidemics



GRANT AGREEMENT

NUMBER — 634201 — MOCHA

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

*the European Union ('the EU'), represented by the European Commission ('the Commission')*¹,
represented for the purposes of signature of this Agreement by the Director, DIRECTORATE-GENERAL FOR RESEARCH & INNOVATION, Health, Ruxandra DRAGHIA-AKLI,

and

on the other part,

1. 'the coordinator':

IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE (ICL), RC000231, established in Exhibition Road, South Kensington Campus, LONDON SW7 2AZ, United Kingdom, GB649926678, represented for the purposes of signing the Agreement by Project Legal Signatory, Carole MEADS

and the following other beneficiaries, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. **UNIVERSITY COLLEGE DUBLIN, NATIONAL UNIVERSITY OF IRELAND, DUBLIN (UCD)**, established in BELFIELD, DUBLIN 4, Ireland, IE6517386K,

3. **ACADEMISCH ZIEKENHUIS GRONINGEN (UMCG)**, established in HANZEPLEIN 1, GRONINGEN 9713 GZ, Netherlands, NL800866393B01,

4. **CONSIGLIO NAZIONALE DELLE RICERCHE (CNR)**, CF80054330586, established in PIAZZALE ALDO MORO 7, ROMA 00185, Italy, IT02118311006,

5. **UNIVERSITY OF SURREY (SURREY)** GB22, RC000671, established in Stag Hill, GUILDFORD GU2 7XH, United Kingdom, GB688953065,

6. **KAROLINSKA INSTITUTET (KI)**, 2021002973, established in Nobels Vag 5, STOCKHOLM 17177, Sweden, SE202100297301,

7. **NEDERLANDSE ORGANISATIE VOOR TOEGEPAST NATUURWETENSCHAPPELIJK ONDERZOEK - TNO (TNO)**, 27376655, established in SCHOEMAKERSTRAAT 97, DELFT 2628 VK, Netherlands, NL002875718B01,

8. **KING'S COLLEGE LONDON (KCL)**, RC000297, established in Strand, LONDON WC2R 2LS, United Kingdom, GB627403551,

9. **UNIVERSITEIT MAASTRICHT (UM)**, WHW ARTIKEL 1.8 LID, established in Minderbroedersberg 4-6, MAASTRICHT 6200 MD, Netherlands, NL003475268B01,

¹ Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

10. **UNIWERSYTET MEDYCZNY W LUBLINIE (MUL)**, 000288716, established in AL RACLAWICKIE 1, LUBLIN 20 059, Poland, PL7120106911,
11. **HOGSKOLEN I HARSTAD (HIH)**, 971512512, established in HAVNEGATA 5, HARSTAD 9480, Norway, NO971512512MVA,
12. **HASKOLI ISLANDS (UI)**, 600169-2039, established in Sudurgata, REYKJAVIK IS 101, Iceland, IS19133,
13. **AS CYPRUS COLLEGE LIMITED (EUC) EPE**, HE83353, established in DIOGENES STREET 6 ENGOMI, NICOSIA 22006, Cyprus, CY10083353J,
14. **UNIVERSITEIT TWENTE (UTwente)**, 387, established in DRIENERLOLAAN 5, ENSCHEDE 7522 NB, Netherlands, NL002946725B01,
15. **SYDDANSK UNIVERSITET (SDU)**, 29283958, established in CAMPUSVEJ 55, ODENSE M 5230, Denmark, DK29283958,
16. **UNIVERSITY OF KEELE (KEELE) GB22**, RC000655, established in KEELE UNIVERSITY FINANCE DPT, KEELE ST5 5BG, United Kingdom, GB279783684,
17. **CHILDREN'S HOSPITAL CORPORATION (CHB) US8**, EIN042774441, established in LONGWOOD AVENUE 300, BOSTON 02115, United States,
18. **HOSPICES CANTONAUX CHUV (CHUV)**, established in Rue du Bugnon 21, LAUSANNE 1005, Switzerland, CH369716, as 'beneficiary not receiving EU funding' (see Article 9),
19. **MURDOCH CHILDRENS RESEARCH INSTITUTE (MCRI) AU3**, 006566972, established in FLEMINGTON ROAD RCH, PARKVILLE 3052, Australia, AU21006566972, as 'beneficiary not receiving EU funding' (see Article 9),

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

- | | |
|---------|---|
| Annex 1 | Description of the action |
| Annex 2 | Estimated budget for the action |
| Annex 3 | Accession Forms |
| Annex 4 | Model for the financial statements |
| Annex 5 | Model for the certificate on the financial statements |
| Annex 6 | Model for the certificate on the methodology |

TERMS AND CONDITIONS

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CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the action entitled '*Models of Child Health Appraised — MOCHA*' ('**action**'), as described in Annex 1.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be **42 months** as of *01/06/2015* ('**starting date of the action**').

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and budget category (see Articles 5, 6). *It also contains the estimated costs of the beneficiaries not receiving EU funding (see Article 9).*

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR 6,821,232.25** (six million eight hundred and twenty one thousand two hundred and thirty two EURO and twenty five eurocents).

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **100% of the action's eligible costs** (see Article 6) (**'reimbursement of eligible costs grant'**) (see Annex 2).

The estimated eligible costs of the action are EUR **6,962,265.00** (six million nine hundred and sixty two thousand two hundred and sixty five EURO).

Eligible costs (see Article 6) must be declared under the following forms (**'forms of costs'**):

(a) for **direct personnel costs**:

- as actually incurred costs (**'actual costs'**) or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (**'unit costs'**).

Personnel costs for **SME owners or beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs for subcontracting**: as actually incurred costs (**actual costs**);

(c) for **direct costs of providing financial support to third parties**: *not applicable*;

(d) for **other direct costs**: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E (**'flat-rate costs'**);

(f) *specific cost category(ies): not applicable.*

5.3 Final grant amount — Calculation

The **'final grant amount'** depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *Commission* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) declared by the beneficiaries (see Article 20) and approved by the *Commission* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

‘**Profit**’ means the surplus of the amount obtained following Steps 1 and 2 plus the action’s total receipts, over the action’s total eligible costs.

The ‘**action’s total eligible costs**’ are the consolidated total eligible costs approved by the *Commission*.

The ‘**action’s total receipts**’ are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

- (a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;
- (b) financial contributions given by third parties to the beneficiary specifically to be used for the action, and
- (c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

- (a) income generated by exploiting the action’s results (see Article 28);
- (b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);
- (c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *Commission* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *Commission* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the ‘**revised final grant amount**’ for the beneficiary concerned by the findings.

This amount is calculated by the *Commission* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *Commission* for the beneficiary concerned;
- in case of **reduction of the grant**: by calculating the concerned beneficiary’s share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

‘**Eligible costs**’ are costs that meet the following criteria:

(a) for **actual costs**:

- (i) they must be actually incurred by the beneficiary;
- (ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);
- (iii) they must be indicated in the estimated budget set out in Annex 2;
- (iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;
- (v) they must be identifiable and verifiable, in particular recorded in the beneficiary’s accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary’s usual cost accounting practices;
- (vi) they must comply with the applicable national law on taxes, labour and social security, and
- (vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) for **unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, Point A)

multiplied by

the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18);

(c) for **flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

- A. direct personnel costs;
- B. direct costs of subcontracting;
- C. *not applicable*;
- D. other direct costs;
- E. indirect costs;
- F. *not applicable*.

‘Direct costs’ are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

‘Indirect costs’ are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

A. Direct personnel costs

Types of eligible personnel costs

A.1 **Personnel costs** are eligible, if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action (‘**costs for employees (or equivalent)**’). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the **remuneration**, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities² may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

- (a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;
- (b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

- (a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;
- (b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or
- (c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

- (a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;
- (b) the result of the work carried out belongs to the beneficiary, and
- (c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs, if the conditions in Article 11.1 are met.

² For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises (**‘SME owners’**) who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of ‘beneficiaries that are natural persons’** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{hourly rate

multiplied by

the number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant is:

{the number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary for that person in that year for other EU or Euratom grants}.

The **‘hourly rate’** is one of the following:

(a) for personnel costs declared as **actual costs**: the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the ‘number of annual productive hours’, the beneficiaries may choose one of the following:

(i) ‘fixed number of hours’: 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

- (ii) ‘individual annual productive hours’: the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

‘Annual workable hours’ means the period during which the personnel must be working, at the employer’s disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

- (iii) ‘standard annual productive hours’: the ‘standard number of annual hours’ generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the ‘standard annual workable hours’.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

- (b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

- (i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or
- (ii) for personnel costs declared on the basis of the beneficiary’s usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:
- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;
 - the hourly rate is calculated using the actual personnel costs recorded in the beneficiary’s accounts, excluding any ineligible cost or costs included in other budget categories.

The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating

the personnel costs, reasonable and correspond to objective and verifiable information;

and

- the hourly rate is calculated using the number of annual productive hours (see above).

B. Direct costs of subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

C. Direct costs of providing financial support to third parties *not applicable*.

D. Other direct costs

D.1 Travel costs and related subsistence allowances (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

D.2 *The depreciation costs of equipment, infrastructure or other assets (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

The costs of renting or leasing equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.*

The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.

D.3 Costs of other goods and services (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

- (a) purchased specifically for the action and in accordance with Article 10.1.1 or
- (b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

D.4 Capitalised and operating costs of ‘large research infrastructure’³ directly used for the action are eligible, if:

- (a) *the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure⁴);*
- (b) *the beneficiary’s methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission (‘ex-ante assessment’);*
- (c) *the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and*
- (d) *they comply with the conditions as further detailed in the annotations to the H2020 grant agreements.*

E. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

- (a) costs of subcontracting and
- (b) costs of in-kind contributions provided by third parties which are not used on the beneficiary’s premises;
- (c) *not applicable;*
- (d) *not applicable.*

Beneficiaries receiving an operating grant⁵ financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

³ ‘**Large research infrastructure**’ means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

⁴ For the definition, see Article 2(6) of Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013 p.104)-(**‘Horizon 2020 Framework Programme Regulation No 1291/2013’**): ‘**Research infrastructure**’ are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be ‘single-sited’, ‘virtual’ or ‘distributed’.

⁵ For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 218, 26.10.2012, p.1) (**‘Financial Regulation No 966/2012’**): ‘**operating grant**’ means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

F. Specific cost category(ies)

Not applicable

6.3 Conditions for costs of linked third parties to be eligible

not applicable

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary), if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

6.5 Ineligible costs

‘**Ineligible costs**’ are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

- (i) costs related to return on capital;
- (ii) debt and debt service charges;
- (iii) provisions for future losses or debts;
- (iv) interest owed;
- (v) doubtful debts;
- (vi) currency exchange losses;
- (vii) bank costs charged by the beneficiary’s bank for transfers from the *Commission*;
- (viii) excessive or reckless expenditure;
- (ix) deductible VAT;
- (x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *Commission* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *Commission* and the other beneficiaries for implementing the action.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

Beneficiaries not receiving EU funding must implement the action tasks attributed to them in Annex 1 according to Article 7.1.

Their costs are estimated in Annex 2 but:

- *will not be reimbursed and*

- *will not be taken into account for the calculation of the grant (see Articles 5.2, 5.3 and 5.4, and 21).*

Chapter 3, Articles 10 to 15, 18.1.2, 20.3(b), 20.4(b), 20.6, 21, 23a, 26.4, 27.2, 28.1, 28.2, 30.3, 31.5, 40, 42, 43, 44, 47 and 48 do not apply to these beneficiaries.

They will not be subject to financial checks, reviews and audits under Article 22.

Beneficiaries not receiving EU funding may provide in-kind contributions to another beneficiary. In this case, they will be considered as a third party for the purpose of Articles 11 and 12.

9.2 Consequences of non-compliance

If a beneficiary not receiving EU funding breaches any of its obligations under this Article, its participation of the Agreement may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6 that are applicable to it.

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

The beneficiaries must ensure that the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are ‘contracting authorities’ within the meaning of Directive 2004/18/EC⁶ or ‘contracting entities’ within the meaning of Directive 2004/17/EC⁷ must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

⁶ Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

⁷ Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

The beneficiaries may declare costs related to the payment of in-kind contributions as eligible (see Article 6.1 and 6.2), up to the third parties' costs for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The third parties and their contributions must be set out in Annex 1. The *Commission* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties free of charge.

The beneficiaries may declare costs incurred by the third parties for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *Commission* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *Commission* may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are ‘contracting authorities’ within the meaning of Directive 2004/18/EC or ‘contracting entities’ within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

Not applicable

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

Not applicable

15.2 Financial support in the form of prizes

Not applicable

15.3 Consequences of non-compliance

Not applicable

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

Not applicable

16.2 Rules for providing virtual access to research infrastructure

Not applicable

16.3 Consequences of non-compliance

Not applicable

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any information requested in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the 'Beneficiary Register' (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *Commission* and the other beneficiaries — of any of the following:

- (a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:
 - (i) changes in its legal, financial, technical, organisational or ownership situation
- (b) **circumstances** affecting:
 - (i) the decision to award the grant or
 - (ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of *five* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Articles 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *Commission* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

- (a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;
- (b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for **direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions (**'certificate on the methodology'**). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

- (c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, for **personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *Commission* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the ‘**deliverables**’ identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *Commission* may apply any of the measures described in Chapter 6.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the *Commission* (see Article 52) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following ‘**reporting periods**’:

- RP1: from month 1 to month 18
- RP2: *from month 19 to month 36*
- RP3: *from month 37 to month 42*

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a ‘**periodic technical report**’ containing:

- (i) an **explanation of the work carried out** by the beneficiaries;
- (ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated ‘**plan for the exploitation and dissemination of the results**’;

- (iii) a **summary** for publication by the *Commission*;

- (iv) the answers to the ‘**questionnaire**’, covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a ‘**periodic financial report**’ containing:

- (i) an ‘**individual financial statement**’ (see Annex 4) from each beneficiary, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *Commission*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary must **certify** that:

- the information provided is full, reliable and true;
 - the costs declared are eligible (see Article 6);
 - the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
 - for the last reporting period: that all the receipts have been declared (see Article 5.3.3);
- (ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary, for the reporting period concerned;
- (iii) *not applicable*;
- (iv) a ‘**periodic summary financial statement**’ (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

- (a) a '**final technical report**' with a **summary** for publication containing:
 - (i) an overview of the results and their exploitation and dissemination;
 - (ii) the conclusions on the action, and
 - (iii) the socio-economic impact of the action;
- (b) a '**final financial report**' containing:
 - (i) a '**final summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and
 - (ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the *Commission* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *Commission*, the Agreement may be terminated (see Article 50).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment**;
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the *EU* until the payment of the balance.

The amount of the pre-financing payment will be EUR **2,273,744.08** (two million two hundred and seventy three thousand seven hundred and forty four EURO and eight eurocents).

The *Commission* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR **341,061.61** (three hundred and forty one thousand sixty one EURO and sixty one eurocents), corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the *Commission* from the pre-financing payment and transferred into the '**Guarantee Fund**'.

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *Commission* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *Commission* in the following steps:

Step 1 – Application of the reimbursement rates

Step 2 – Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs ; see Article 6) declared by the beneficiaries (see Article 20) and approved by the *Commission* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *Commission* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *Commission* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;

- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
 - is positive, it will be paid to the coordinator
 - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by the beneficiary to the Commission or an executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *Commission* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *Commission* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *Commission* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

- (a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and
- (b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: NATIONAL WESTMINSTER BANK PLC

Address of branch: SILBURY HOUSE: 300, SILBURY BOULEVA CHATHAM, United Kingdom

Full name of the account holder: IMPERIAL COLLEGE LONDON

Full account number (including bank codes):

IBAN code: GB42NWBK60721167649297

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *Commission* bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *Commission* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *Commission* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Commission

22.1.1 Right to carry out checks

The Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the Commission may be assisted by external persons or bodies.

The Commission may also request additional information in accordance with Article 17. The Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

22.1.2 Right to carry out reviews

The Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

22.1.3 Right to carry out audits

The Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The Commission may request beneficiaries to provide such information to it directly.

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the Commission in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013¹⁵ and No 2185/96¹⁶ (and in accordance with their provisions and procedures) the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012¹⁷, the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

22.4 Checks, reviews, audits and investigations for international organisations

Not applicable

22.5 Consequences of findings in checks, reviews, audits and investigations —Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions (**‘extension of findings from this grant to other grants’**).

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

¹⁵ Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

¹⁶ Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

¹⁷ Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (**‘Financial Regulation No 966/2012’**) (OJ L 298, 26.10.2012, p. 1).

22.5.2 Findings in other grants

The Commission may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

- (a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and
- (b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

- (a) an invitation to submit observations on the list of grants affected by the findings;
- (b) the request to submit **revised financial statements** for all grants affected;
- (c) the **correction rate for extrapolation** established by the Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:
 - (i) considers that the submission of revised financial statements is not possible or practicable or
 - (ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the Commission in justified cases.

The amounts to be rejected will be determined on the basis of the revised financial statements, subject to their approval.

If the Commission does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements, it will formally notify the beneficiary concerned the application of the initially notified correction rate for extrapolation.

If the Commission accepts the alternative correction method proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative correction method.

22.5.3.2 If the findings concern **improper implementation** or a **breach of another obligation**: the formal notification will include:

- (a) an invitation to submit observations on the list of grants affected by the findings and
- (b) the flat-rate the Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

If the Commission does not receive any observations or does not accept the observations or the proposed alternative flat-rate, it will formally notify the beneficiary concerned the application of the initially notified flat-rate.

If the Commission accepts the alternative flat-rate proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *EU* programme.

Evaluations may be started during implementation of the action and up to *five* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the *Commission* may apply the measures described in Chapter 6.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities¹⁸.

This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *Commission* may apply any of the measures described in Chapter 6.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action (**‘agreement on background’**).

‘Background’ means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

- (a) is held by the beneficiaries before they acceded to the Agreement, and
- (b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

¹⁸ Commission Recommendation C (2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing (**‘request for access’**).

‘Access rights’ means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

- (a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or
- (b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

‘Fair and reasonable conditions’ means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) —

to affiliated entities¹⁹ established in an EU Member State or ‘**associated country**’²⁰, if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

Not applicable

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

‘**Results**’ means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

¹⁹ ¹⁹ For the definition, see Article 2.1(2) of the Rules for Participation Regulation No 1290/2013: ‘**affiliated entity**’ means any legal entity that is under the direct or indirect control of a participant, or under the same direct or indirect control as the participant, or that is directly or indirectly controlling a participant.

‘Control’ may take any of the following forms:

- (a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
- (b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However the following relationships between legal entities shall not in themselves be deemed to constitute controlling relationships:

- (a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
- (b) the legal entities concerned are owned or supervised by the same public body.

²⁰ For the definition, see Article 2.1(3) of the Rules for Participation Regulation No 1290/2013: ‘**associated country**’ means a third country which is party to an international agreement with the Union, as identified in *Article 7 of Horizon 2020 Framework Programme Regulation No 1291/2013*. *Article 7 sets out the conditions for association of non-EU countries to Horizon 2020*.

- (a) they have jointly generated them and
- (b) it is not possible to:
 - (i) establish the respective contribution of each beneficiary, or
 - (ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership (**'joint ownership agreement'**), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

- (a) at least 45 days advance notice and
- (b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 EU ownership, to protect results

26.4.1 *The EU* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

- (a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);
- (b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or
- (c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *Commission* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *Commission* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may before the end of this period or, if the *Commission* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *The EU* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

- (a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;
- (b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *Commission* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *Commission* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

- (a) the results can reasonably be expected to be commercially or industrially exploited and
- (b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 EU ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *The EU* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *Commission* requests or agrees otherwise or unless it is impossible — include the following:

“The project leading to this application has received funding from the *European Union’s Horizon 2020 research and innovation programme* under grant agreement No 634201”.

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure ‘**exploitation**’ of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

- (a) using them in further research activities (outside the action);
- (b) developing, creating or marketing a product or process;
- (c) creating and providing a service, or
- (d) using them in standardisation activities.

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

If results are incorporated in a standard, the beneficiary concerned must — unless the *Commission* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

“Results incorporated in this standard received funding from the *European Union’s Horizon 2020 research and innovation programme* under grant agreement No 634201”.

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — ‘**disseminate**’ its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *Commission* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

- (a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

- (b) ensure open access to the deposited publication — via the repository — at the latest:
 - (i) on publication, if an electronic version is available for free via the publisher, or

- (ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.
- (c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms “*European Union (EU)*” and “*Horizon 2020*”;
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

Not applicable

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the *Commission* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

- (a) display the EU emblem and
- (b) include the following text:

“This project has received funding from the *European Union’s Horizon 2020 research and innovation programme* under grant agreement No 634201”.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *Commission*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *Commission* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *Commission* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licenses

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

- (a) this does not impede the rights under Article 31 and
- (b) *not applicable*.

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *Commission* right to object to transfers or licensing

Not applicable

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.

Such access rights are limited to non-commercial and non-competitive use.

This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).

31.6 Access rights for third parties

Not applicable

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers²², in particular regarding:

- working conditions;
- transparent recruitment processes based on merit, and
- career development.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *Commission* may apply any of the measures described in Chapter 6.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote equal opportunities between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *Commission* may apply any of the measures described in Chapter 6.

ARTICLE 34 — ETHICS

34.1 Obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

²² Commission recommendation (EC) No 251/2005 of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.03.2005, p. 67).

- (a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity²³ — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and
- (b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

- (a) aim at human cloning for reproductive purposes;
- (b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or
- (c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the ‘**ethics requirements**’ set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the *Commission* copy of:

- (a) any ethics committee opinion required under national law and
- (b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out only if:

- they are set out in Annex 1 or

²³ The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.

http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

- the coordinator has obtained explicit approval (in writing) from the *Commission* (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest (**‘conflict of interests’**).

They must formally notify to the *Commission* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *Commission* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed (**‘confidential information’**).

If a beneficiary requests, the *Commission* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

- (a) need to know to implement the Agreement and
- (b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *Commission* may disclose confidential information to its staff, other EU institutions and bodies or third parties, if:

- (a) this is necessary to implement the Agreement or safeguard the EU's financial interests and
- (b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013²⁴, the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

- (a) the disclosing party agrees to release the other party;
- (b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;
- (c) the recipient proves that the information was developed without the use of confidential information;
- (d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or
- (e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

Not applicable

37.2 Classified results

Not applicable

²⁴ Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013 p.81).

37.3 Activities involving dual-use goods or dangerous materials and substances

Not applicable

37.4 Consequences of non-compliance

Not applicable

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *Commission* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *Commission* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

- (a) display the EU emblem and
- (b) include the following text:

For communication activities: “This project has received funding from the *European Union’s Horizon 2020 research and innovation programme* under grant agreement No 634201”.

For infrastructure, equipment and major results: “This [*infrastructure*][*equipment*][*insert type of result*] is part of a project that has received funding from the *European Union’s Horizon 2020 research and innovation programme* under grant agreement No 634201”.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *Commission*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding the *Commission* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *Commission* is not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the *Commission*

38.2.1 Right to use beneficiaries' materials, documents or information

The *Commission* may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material that it receives from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the *Commission's* use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *Commission* not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

- (a) **use for its own purposes** (in particular, making them available to persons working for the *Commission* or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);
- (b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);
- (c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);
- (d) **translation**;
- (e) giving **access in response to individual requests** under Regulation No 1049/2001²⁵, without the right to reproduce or exploit;
- (f) **storage** in paper, electronic or other form;
- (g) **archiving**, in line with applicable document-management rules, and
- (h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b),(c),(d) and (f) to third parties if needed for the communication and publicising activities of the *Commission*.

²⁵ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *Commission* will insert the following information:

“© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the *European Union (EU)* under conditions.”

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the Commission

Any personal data under the Agreement will be processed by the Commission under Regulation No 45/2001²⁶ and according to the ‘notifications of the processing operations’ to the Data Protection Officer (DPO) of the Commission (publicly accessible in the DPO register).

Such data will be processed by the ‘**data controller**’ of the Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the ‘service specific privacy statement(s) (SSPS)’ that are published on the Commission websites.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS).

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the Commission . For this purpose, they must provide them with the service specific privacy statement (SSPS) (see above), before transmitting their data to the Commission .

²⁶ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *Commission* may apply any of the measures described in Chapter 6.

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *COMMISSION*

The beneficiaries may not assign any of their claims for payment against the *Commission* to any third party, except if approved by the *Commission* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *Commission* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *Commission*.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES

41.1 Roles and responsibilities towards the *Commission*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *Commission* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

- (i) keep information stored in the 'Beneficiary Register' (via the electronic exchange system) up to date (see Article 17);
- (ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);
- (iii) submit to the coordinator in good time:
 - individual financial statements for itself and, if required, certificates on the financial statements (see Article 20);

- the data needed to draw up the technical reports (see Article 20);
- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Commission.

(b) The **coordinator** must:

- (i) monitor that the action is implemented properly (see Article 7);
- (ii) act as the intermediary for all communications between the beneficiaries and the *Commission* (in particular, providing the *Commission* with the information described in Article 17), unless the Agreement specifies otherwise;
- (iii) request and review any documents or information required by the *Commission* and verify their completeness and correctness before passing them on to the *Commission*;
- (iv) submit the deliverables and reports to the *Commission* (see Articles 19 and 20);
- (v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);
- (vi) inform the *Commission* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *Commission*.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

41.3 Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must have internal arrangements regarding their operation and co-ordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written ‘consortium agreement’ between the beneficiaries, which may cover:

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

41.4 Relationship with complementary beneficiaries — Collaboration agreement

Not applicable

41.5 Relationship with partners of a joint action — Coordination agreement

Not applicable

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The *Commission* will — at the time of an **interim payment, at the payment of the balance or afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full.

If the *Commission* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the coordinator or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *Commission* of its disagreement and the reasons why.

If the *Commission* rejects costs **with reduction of the grant** or **recovery of undue amounts**, it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the *Commission* rejects costs at the time of an **interim payment or the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *Commission* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *Commission* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The *Commission* may — **at the payment of the balance or afterwards** — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The *Commission* may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the *Commission* will formally notify a ‘**pre-information letter**’ to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification

If the *Commission* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *Commission* reduces the grant at the time of **the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *Commission* reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *Commission* will recover the difference (see Article 44).

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *Commission* will — after **termination of the participation of a beneficiary, at the payment of the balance or afterwards** — claim back any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *Commission* will claim back the undue amount from the beneficiary concerned, by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Commission will **recover** the amount:

- (a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *Commission* may offset before the payment date specified in the debit note;

- (b) *Not applicable*;

- (c) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC²⁷ applies.

44.1.2 Recovery at payment of the balance

²⁷ Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

If the payment of the balance takes the form of a recovery (see Article 21.4), the *Commission* will formally notify a ‘**pre-information letter**’ to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the *Commission* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or
- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *Commission* by the date in the debit note and has not submitted the report on the distribution of payments: the *Commission* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *Commission* by the date in the debit note, but has submitted the report on the distribution of payments: the *Commission* will:

- (a) identify the beneficiaries for which the amount calculated as follows is negative:

$\left\{ \left\{ \left\{ \text{beneficiary's costs declared in the final summary financial statement and approved by the } \textit{Commission} \text{ multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned} \right\} \right\}$

divided by

the EU contribution for the action calculated according to Article 5.3.1 }

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing and interim payments received by the beneficiary} }.

- (b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{ {amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a);

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *Commission* will **recover** the amount:

- (a) by ‘**offsetting**’ it — without the beneficiary’s consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU’s financial interests, the *Commission* may offset before the payment date specified in the debit note;

- (b) by **drawing on the Guarantee Fund**. The Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) *not applicable*;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *Commission*.

The beneficiary’s share of the final grant amount is calculated as follows:

{ {beneficiary’s costs declared in the final summary financial statement and approved by the *Commission* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned}

divided by

the EU contribution for the action calculated according to Article 5.3.1 }

multiplied by

the final grant amount (see Article 5.3) }.

If the coordinator has not distributed amounts received (see Article 21.7), the *Commission* will also recover these amounts.

The *Commission* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *Commission* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *Commission* will **recover** the amount:

- (a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *Commission* may offset before the payment date specified in the debit note;

- (b) by **drawing on the Guarantee Fund**. The Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) *not applicable*;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

45.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the *Commission* may impose **administrative** and **financial penalties** if a beneficiary:

- (a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or
- (b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the Commission may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

45.2 Duration — Amount of penalty — Calculation

Administrative penalties exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the *Commission*.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *Commission* may extend the exclusion period up to 10 years.

Financial penalties will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *Commission* may increase the rate of financial penalties to between 4% and 20%.

45.3 Procedure

Before applying a penalty, the *Commission* will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *Commission* does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Commission may **recover** the amount:

- (a) by ‘**offsetting**’ it — without the beneficiary’s consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the *Commission* may offset before the payment date specified in the debit note;

- (b) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *Commission*

The *Commission* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *Commission* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

46.2 Liability of the beneficiaries

46.2.1 Conditions

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *Commission* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

Each beneficiary is responsible for paying the damages claimed from it.

46.2.2 Amount of damages - Calculation

The amount the *Commission* can claim from a beneficiary will correspond to the damage caused by that beneficiary.

46.2.3 Procedure

Before claiming damages, the *Commission* will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and

- inviting it to submit observations within 30 days.

If the *Commission* does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *Commission* may **recover** the amount:

- (a) by ‘**offsetting**’ it — without the beneficiary’s consent — against any amounts owed to the beneficiary concerned by the *Commission* or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU’s financial interests, the *Commission* may offset before the payment date specified in the debit note;

- (b) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *Commission* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

- (a) it does not comply with the provisions of the Agreement (see Article 20);
- (b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or
- (c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *Commission* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *Commission* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *Commission* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *Commission* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *Commission* may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

- (a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or
- (b) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

48.2 Procedure

Before suspending payments, the *Commission* will formally notify the coordinator:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *Commission* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *Commission*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The *Commission* will formally notify the coordinator.

During the suspension, the periodic report(s) (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned. When the *Commission* resumes payments, the coordinator may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *Commission* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *Commission*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *Commission* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.2 Suspension of the action implementation, by the *Commission*

49.2.1 Conditions

The *Commission* may suspend implementation of the action or any part of it:

- (a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;
- (b) if a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or
- (c) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *Commission* will formally notify the coordinator:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *Commission* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the coordinator (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *Commission* (see Article 46).

Suspension of the action implementation does not affect the *Commission's* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *Commission* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *Commission* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

- (i) a periodic report (for the open reporting period until termination; see Article 20.3) and
- (ii) the final report (see Article 20.4).

If the *Commission* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *Commission* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *Commission* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *Commission* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

- (i) a report on the distribution of payments to the beneficiary concerned and
- (ii) if termination takes effect during the period set out in Article 3, a ‘**termination report**’ from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Articles 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *Commission*, (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *Commission*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *Commission* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary’s EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary and approved by the *Commission*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:
 - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *Commission* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *Commission* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);
 - in all other cases (in particular if termination takes effect after the period set out in Article 3), the *Commission* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *Commission* the amount due and the *Commission* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);
 - if the beneficiary concerned is the former coordinator, it must repay the new coordinator according to the procedure above, unless:
 - termination is after an interim payment and
 - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

In this case, the *Commission* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *Commission* the amount due. The *Commission* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *Commission* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *Commission* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that
- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the *Commission*

50.3.1 Conditions

The *Commission* may terminate the Agreement or the participation of one or more beneficiaries, if:

- (a) one or more beneficiaries do not accede to the Agreement (see Article 56);
- (b) a change to their legal, financial, technical, organisational or ownership situation is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;
- (c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);
- (d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:
 - (i) resumption is impossible, or
 - (ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

- (e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;
- (f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;
- (g) a beneficiary does not comply with the applicable national law on taxes and social security;
- (h) the action has lost scientific or technological relevance;
- (i) *not applicable*;
- (j) *not applicable*;
- (k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the *EU's* financial interests;
- (l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:
 - (i) substantial errors, irregularities, fraud or
 - (ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;
- (m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**'extension of findings from other grants to this grant'**).

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *Commission* will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *Commission* of the measures to ensure compliance with the obligations under the Agreement.

If the *Commission* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification of the confirmation (see above);

- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

- (i) a periodic report (for the last open reporting period until termination; see Article 20.3) and
- (ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *Commission* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *Commission* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiaries may not claim damages due to termination by the *Commission* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

- (i) a report on the distribution of payments to the beneficiary concerned;
- (ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and
- (iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources,

the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *Commission* (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *Commission*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *Commission* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary and approved by the *Commission*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:
 - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *Commission* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *Commission* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);
 - in all other cases, in particular if termination takes effect after the period set out in Article 3, the *Commission* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *Commission* the amount due and the *Commission* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);
 - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:
 - termination takes effect after an interim payment and
 - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

In this case, the *Commission* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee

Fund will pay to the *Commission* the amount due. The *Commission* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *Commission* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *Commission* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that
- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, ‘formal notifications’, etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery (‘formal notification on paper’).

Communications in the electronic exchange system must be made by persons authorised according to the ‘Terms and Conditions of Use of the electronic exchange system’. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a ‘Legal Entity Appointed Representative (LEAR)’. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the Commission websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

<https://ec.europa.eu/research/participants/portal/desktop/en/projects/>

The *Commission* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the Commission** must be sent to the following address:

*European Commission
DIRECTORATE-GENERAL FOR RESEARCH & INNOVATION
Fighting infectious diseases and global epidemics
Directorate Health
B-1049 Brussels Belgium*

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the 'Beneficiary Register'.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

Not applicable

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71²⁸, periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

²⁸ Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8.6.1971, p. 1).

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents;
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *Commission* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *Commission* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58).

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *Commission's* right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium.

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

As an exception, if such a dispute is between the Commission and HOGSKOLEN I HARSTAD, HASKOLI ISLANDS, CHILDREN'S HOSPITAL CORPORATION, HOSPICES CANTONNAUX CHUV, MURDOCH CHILDRENS RESEARCH INSTITUTE, the competent Belgian courts have sole jurisdiction.

If a dispute concerns administrative or financial penalties, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU.

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the *Commission* or the coordinator, depending on which is later.

SIGNATURES

For the coordinator

For the *Commission*



European Commission

DIRECTORATE-GENERAL FOR RESEARCH & INNOVATION

Fighting infectious diseases and global epidemics



ANNEX 1 (part A)

Research and Innovation action

NUMBER — 634201 — MOCHA

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1.1. The project summary

Project Number ¹	634201	Project Acronym ²	MOCHA
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One form per project

General information

Project title ³	Models of Child Health Appraised
Starting date ⁴	01/06/2015
Duration in months ⁵	42
Call (part) identifier ⁶	H2020-PHC-2014-two-stage
Topic	PHC-23-2014 Developing and comparing new models for safe and efficient, prevention oriented health and care systems
Fixed EC Keywords	Health policy and services
Free keywords	Child health, Primary health care, Family Practice, Primary secondary care interface, Optimising services, School health, Adolescent services; population health, efficiency, economics, implementation

Abstract ⁷

Children’s health affects the future of Europe – children are citizens, future workers, parents and carers. Children are dependent on society to provide effective health services (UN Convention on the Rights of the Child). Models of child primary health care vary widely across Europe based on two broad alternatives (primary care paediatricians or generic family doctors), and a variety of models of school health and adolescent direct access services. There is little research to show which model(s) are best, implying that some are inefficient or ineffective, with sub-optimal outcomes. MOCHA will draw on networks, earlier child health projects and local agents to model and evaluate child primary care in all 30 EU/EEA countries. Scientific partners from 11 European countries, plus partners from Australia and USA, encompassing medicine, nursing, economics, informatics, sociology and policy management, will:

- Categorise the models, and school health and adolescent services
- Develop innovative measures of quality, outcome, cost, and workforce of each, and apply them using policy documents, routine statistics, and available electronic data sets
- Assess effects on equality, and on continuity of care with secondary care.
- Systematically obtain stakeholder views.
- Indicate optimal future patterns of electronic records and big data to optimise operation of the model(s).

The results will demonstrate the optimal model(s) of children’s primary care with a prevention and wellness focus, with an analysis of factors (including cultural) which might facilitate adoption, and indications for policy makers of both the health and economic gains possible. The project will have a strong dissemination programme throughout to ensure dialogue with public, professionals, policy makers, and politicians. The project will take 42 months (36 of scientific work plus start up and close), and deliver major awareness and potential benefit for European children’s health and healthy society.

1.2. List of Beneficiaries

Project Number ¹	634201	Project Acronym ²	MOCHA
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List of Beneficiaries

No	Name	Short name	Country	Project entry month ⁸	Project exit month
1	IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE	ICL	United Kingdom	1	42
2	UNIVERSITY COLLEGE DUBLIN, NATIONAL UNIVERSITY OF IRELAND, DUBLIN	UCD	Ireland	1	42
3	ACADEMISCH ZIEKENHUIS GRONINGEN	UMCG	Netherlands	1	42
4	CONSIGLIO NAZIONALE DELLE RICERCHE	CNR	Italy	1	42
5	UNIVERSITY OF SURREY	SURREY	United Kingdom	1	42
6	KAROLINSKA INSTITUTET	KI	Sweden	1	42
7	NEDERLANDSE ORGANISATIE VOOR TOEGEPAST NATUURWETENSCHAPPELIJK ONDERZOEK - TNO	TNO	Netherlands	1	42
8	KING'S COLLEGE LONDON	KCL	United Kingdom	1	42
9	UNIVERSITEIT MAASTRICHT	UM	Netherlands	1	42
10	UNIwersytet medyczny w Lublinie	MUL	Poland	1	42
11	HOGSKOLEN I HARSTAD	HIH	Norway	1	42
12	HASKOLI ISLANDS	UI	Iceland	1	42
13	AS CYPRUS COLLEGE LIMITED	EUC	Cyprus	1	42
14	UNIVERSITEIT TWENTE	UTwente	Netherlands	1	42
15	SYDDANSK UNIVERSITET	SDU	Denmark	1	42
16	UNIVERSITY OF KEELE	KEELE	United Kingdom	1	42
17	CHILDREN'S HOSPITAL CORPORATION	CHB	United States	1	42
18	HOSPICES CANTONNAUX CHUV	CHUV	Switzerland	1	42
19	MURDOCH CHILDRENS RESEARCH INSTITUTE	MCRI	Australia	1	42

1.3. Workplan Tables - Detailed implementation

1.3.1. WT1 List of work packages

WP Number ⁹	WP Title	Lead beneficiary ¹⁰	Person-months ¹¹	Start month ¹²	End month ¹³
WP1	Identification of Models of Children's Primary Health Care	1 - ICL	150.00	1	42
WP2	Safe and Efficient Interfaces of Models of Primary Health Care with Secondary, Social and Complex Care	2 - UCD	176.00	1	42
WP3	Effective Models of School Health Services and Adolescent Health Services	3 - UMCG	55.00	1	42
WP4	Identification and Application of Innovative Measures of Quality and Outcome of Models	4 - CNR	64.00	1	42
WP5	Identification and Use of Derivatives of Large Data Sets and Systems to Measure Quality	5 - SURREY	35.00	1	42
WP6	Economic and Skill Set Evaluation and Analysis of Models	5 - SURREY	56.00	1	42
WP7	Ensuring Equity for all Children in all Models	6 - KI	55.00	1	42
WP8	Use of Electronic Records to Enable Safe and Efficient Models	1 - ICL	72.00	1	42
WP9	Validated Optimal Models of Children's Prevention-Orientated Primary Health Care	7 - TNO	53.00	1	42
WP10	Dissemination	1 - ICL	34.00	1	42
WP11	Project Management	1 - ICL	50.00	1	42
Total			800.00		

1.3.2. WT2 list of deliverables

Deliverable Number ¹⁴	Deliverable Title	WP number ⁹	Lead beneficiary	Type ¹⁵	Dissemination level ¹⁶	Due Date (in months) ¹⁷
D1.1	Systematic Review and Meta-analysis of the Literature	WP1	1 - ICL	Report	Confidential, only for members of the consortium (including the Commission Services)	9
D1.2	Final Report on Current Models of Primary Care for Children, including sections on Context, Operation, and Effects, and related Business Models	WP1	1 - ICL	Report	Public	21
D2.1	Final report on the current approach to managing the care of children with complex care needs in Member States	WP2	2 - UCD	Report	Public	26
D2.2	Final report on models of children's social care support across the EU and the relationship with primary health care.	WP2	2 - UCD	Report	Public	26
D2.3	Report on requirements and models for supporting children with complex mental health needs and the primary care interface	WP2	2 - UCD	Report	Public	30
D2.4	Report on needs and future visions for care of children with complex conditions	WP2	2 - UCD	Report	Public	30
D3.1	Final report on the description of the various models of school health services and adolescent health services, including quality assessments and costs.	WP3	3 - UMCG	Report	Public	36
D4.1	Final report on interface between primary and complex	WP4	4 - CNR	Report	Public	24

Deliverable Number ¹⁴	Deliverable Title	WP number ⁹	Lead beneficiary	Type ¹⁵	Dissemination level ¹⁶	Due Date (in months) ¹⁷
	care for all European country primary care models for children and young people.					
D5.1	Semantic models of key clinical conditions and outcome measures	WP5	5 - SURREY	Report	Public	18
D5.2	Report of Measures of Quality and Outcomes derived from large data sets	WP5	5 - SURREY	Report	Public	32
D6.1	Short report on financial systems and their impact on outcomes	WP6	5 - SURREY	Report	Public	34
D7.1	Report on national policies for primary care for migrant children in Europe	WP7	6 - KI	Report	Public	15
D7.2	Report on differences in outcomes and performance by SES, family type and migrants of different primary care models for children	WP7	6 - KI	Report	Public	30
D8.1	Description and Analysis of current child health electronic record keeping across Europe	WP8	1 - ICL	Report	Public	15
D8.2	Future Achievable Potential Models of Child Health Electronic Record Systems to Support care Delivery	WP8	1 - ICL	Report	Public	30
D9.1	An e-book showcasing conditions for implementation of examples of best practices in primary child health care in European countries.	WP9	7 - TNO	Report	Public	32
D9.2	A report containing consensus statements on most optimal models with guidance on potential benefits	WP9	7 - TNO	Report	Public	40

Deliverable Number ¹⁴	Deliverable Title	WP number ⁹	Lead beneficiary	Type ¹⁵	Dissemination level ¹⁶	Due Date (in months) ¹⁷
	and how these might be achieved.					
D10.1	Functioning web site, including contact details, News and Publications sections, and private working area.	WP10	1 - ICL	Websites, patents filling, etc.	Public	5

1.3.3. WT3 Work package descriptions

Work package number ⁹	WP1	Lead beneficiary ¹⁰	1 - ICL
Work package title	Identification of Models of Children’s Primary Health Care		
Start month	1	End month	42

Objectives

The objectives of this work package are to:

- Identify the current core models of child primary care and first contact services across Europe and their interface with partner services
- Coordinate the scientific work of the country agents
- Act as the interface between the External Advisory Board and Country Agents#

Description of work and role of partners

WP1 - Identification of Models of Children’s Primary Health Care [Months: 1-42]
ICL, UCD, UMCG, CNR, SURREY, KI, KCL, UM, MUL, EUC, KEELE, MCRI

The description of different models of care provided in member states, Norway and Iceland (Task 4) is a key deliverable for this WP and will be informed by systematic review and meta-analysis of the evidence for different models of care (Task 2), exemplar clinical case scenarios, patient experiences and records, business and incentive systems (Tasks 5,6) and finally cultural-political context (Task 7)

Task 1 – Establish Operational Arrangements for the Country Agents Function
 Led by the Project Leader and Deputy, this task will initially establish the working arrangements to act as the communications and verification methods for requesting actions of the Country Agents, and getting the endorsement of the Expert Panel.
 Initially this will involve briefing all parties, then establishing protocols for effective operational working. It will then settle into a systematic process, collecting and harmonising requests from WP leaders, passing them through to the External Advisory Board, then on to country agents in a phased manner, and monitoring the return of replies and the handling of supplementary queries.

Task 2 – Systematic review and meta-analysis
 Led by Dr Nadia Minicuci CRN-IN (IT), this will collate the published scientific evidence of European models of primary care delivery to inform the development of a framework describing model type and key characteristics.

Task 3 – Coordination of Work Packages
 The project will operate on the basis already established in the preparation of the proposal, entrusting the individual WP Leaders for their work package, having first imbued a strong sense of corporate ethos. There will be WP Leaders Meetings at the start of the project, and then every six months – where possible linked to other activities such as topic workshops. By this means business functioning, scientific activities and any problems arising will be handled corporately. There will be WP Leader teleconferences monthly to discuss key issues and progress.

Task 4 – Current Models of Child Primary Care
 The core scientific task of this WP will be to collate, identify and map the current models of care across all Member States, Norway and Iceland. This will not only form a key deliverable, but it will set the foundations for the remainder of the project. Information will be gathered on the basic model and its regulation through the country agents, and after analysis shared with all the Work Packages as a basis for their work.

Task 5 – Business Models
 This work package and WP 2 will address the topics of ‘models of care’ both from the word picture description of a model of care, but also using business modelling. Dr. Daniela Luzi and Dr. Fabrizio Pecoraro, CNR-IRPPS (IT), will narrate the underlying models using UML (Unified Modelling Language) to give a functional diagrammatic picture as well as the word description of each primary health delivery model.

Task 6 –Current Model infrastructure and responsivity
 Evidence from Case Studies: Dr. Ingrid Wolfe, King’s College, London (UK) – will lead on case studies to identify how the services operate in the light of specific presentation scenarios that are universal and illustrate aspects of primary

care. Case studies are likely to include acute mild illness, acute severe illness, single or simple long-term condition, complex long term conditions, social vulnerability, learning difficulties, and mental health problems. Aspects examined will include mode of presentation (unplanned/planned), access and setting (gatekeeping, choice, co-location, booking system, in hours/out of hours, point of care testing) workforce, and interface with other health and other social services. This work will also draw on her previous work with the European Observatory on Health Systems and Policies, and with work ongoing with, and funded by, the European Paediatric Association.

Records and Data: Linking with WP 8, Prof. Simon de Lusignan, University of Surrey (UK) will look at core record systems and data use as agents of care delivery and coordination.

Incentives, Penalties and Societal Effects

Health care models incorporate in many cases incentives and penalties for compliance and non-compliance respectively, to seek to ensure their coverage and reach. Both approaches (perhaps problematically) assume rational actors operating in 'logical' ways but this will often penalise groups of disadvantaged and vulnerable individuals (such as single mothers or families with an ill parent). For Providers additional efforts may be required by providers and may well lead to less remuneration and a reluctance to engage fully with such groups. Incentives for Service Users may include requirements for complete immunisation or preventive care clinic attendance as pre-requisites to school admission or child welfare payments but little is known about whether or not the most challenged are simply further disadvantaged. Dr. Helen Wells, of Keele, UK, a criminologist working on the intended and unintended effects of sanctions, will link these aspects to WPs 4, 6, 7 and 9 in particular.

Patient Experience: For five countries that are part of the DIPEX network analysing patient experiences, Czech Republic, Germany, Spain, UK, and The Netherlands, Dr. Manna Alma, Groningen (NL) and Dr. Auke Wieggersma will work with their DIPEX local partners to obtain patient views of the current services. For this, the qualitative research methodology about patient experiences developed by the Oxford Health Experiences Group will be used(Ziebland S, Herxheimer A. How patients' experiences contribute to decision making: illustrations from DIPEX (personal experiences of health and illness). Journal of Nursing Management, 2008; 16:433-439.).

Task 7 Context and Culture

Political / Constitutional Context: Prof. Helmut Brand and. Timo Clemens, Maastricht (NL) will use their expertise and linkages to place the models and other findings into political and constitutional contexts, recognising that ultimately as a national competence health systems are decided by local political processes, at national, regional, and local levels.

National Health and Policy Culture: To complement the political context, Dr. Kinga Zdunek, Medical University of Lublin (PL) will analyse the health policy patterns from the angle of four elements: content, actors, contexts and processes (Buse K, Mays N, Walt G, Making Health Policy, 2005) taking into account strong socio-cultural background of these components.

Participation per Partner

Partner number and short name	WP1 effort
1 - ICL	36.00
2 - UCD	12.00
3 - UMCG	19.00
4 - CNR	18.00
5 - SURREY	4.00
6 - KI	10.00
8 - KCL	10.00
9 - UM	2.00
10 - MUL	24.00
13 - EUC	10.00
16 - KEELE	3.00

Partner number and short name	WP1 effort
19 - MCRI	2.00
Total	150.00

List of deliverables

Deliverable Number ¹⁴	Deliverable Title	Lead beneficiary	Type ¹⁵	Dissemination level ¹⁶	Due Date (in months) ¹⁷
D1.1	Systematic Review and Meta-analysis of the Literature	1 - ICL	Report	Confidential, only for members of the consortium (including the Commission Services)	9
D1.2	Final Report on Current Models of Primary Care for Children, including sections on Context, Operation, and Effects, and related Business Models	1 - ICL	Report	Public	21

Description of deliverables

1.1 (Internal) Systematic Review and Meta-analysis of the Literature Month 9
 1.2 Final Report on Current Models of Primary Care for Children, including sections on Context, Operation, and Effects and related Business Models Month 21

D1.1 : Systematic Review and Meta-analysis of the Literature [9]
 Systematic Review and Meta-analysis of the Literature

D1.2 : Final Report on Current Models of Primary Care for Children, including sections on Context, Operation, and Effects, and related Business Models [21]
 Final Report on Current Models of Primary Care for Children, including sections on Context, Operation, and Effects, and related Business Models

Schedule of relevant Milestones

Milestone number ¹⁸	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS3	Protocols and Procedures for Country Agents	1 - ICL	7	Document to be agreed by EAB and in WP Leaders meeting
MS4	First draft of current models of children's primary health care	2 - UCD	12	Pertaining to Deliverable 1.3
MS8	Coordination and reconciliation of Final Deliverables	1 - ICL	31	Coordination and reconciliation of Final Deliverables

Work package number ⁹	WP2	Lead beneficiary ¹⁰	2 - UCD
Work package title	Safe and Efficient Interfaces of Models of Primary Health Care with Secondary, Social and Complex Care		
Start month	1	End month	42

Objectives

The overall aim of this work package is to examine the primary physician/specialist interface, the interface between primary and secondary care for children with enduring health issues and the social care interface with families of children who have complex health needs. The specific objectives for this work package are to:

- Investigate the appropriateness and effectiveness of the referral and discharge processes of health care for children and young people with potentially enduring conditions, in conjunction with WP 1.
- Provide an the current models of managing care of children with complex needs, including the three broad types of congenital, acquired (by illness or accident) and mental health complex needs, and the relationship to primary care models.
- Assess how primary care services for children interface with social care services across Europe, recognising the need for a symbiotic relationship within the bounds of respectful personalised support, and identify optimal models or factors.
- Examine undergraduate nursing and postgraduate public health nursing programs related to preparedness for care for the child with complex care needs and their families in the primary/secondary interface, in line with maximising care at home.
- Seek user feedback in conjunction with the DIPEX work in WP 1.
- Build a business model of continuity of complex care that will track events that trigger the interaction among primary, secondary and social care services and the stakeholders involved, linking with WP 1.

Description of work and role of partners

WP2 - Safe and Efficient Interfaces of Models of Primary Health Care with Secondary, Social and Complex Care [Months: 1-42]
UCD, UMCG, CNR, KCL, HIH, SDU, CHB, MCRI

This work package will identify the interface issues between the primary care (in the different core models identified in WP 1) and the models of delivery of complex health and social care, itself a field inadequately addressed or modelled to date. The outputs from Tasks 1 - 5 will inform Task 6, building a model of complex care delivery to illuminate the need for good interfaces as part of the models proposed by WP 9.

Task 1 - Referral/Discharge Interface
 This task, led by Dr. Ingrid Wolfe will explore the boundaries between primary (generalist) and secondary (specialist) care which represents a potential high-risk scenario for quality and timeliness of care and for patient safety, as well as avoidance of unnecessary procedures. This will be a specific dimension of the related Task in WP 1.

Task 2 - Enduring Complex Conditions
 Led by Dr. Maria Brenner the aim of this task is to provide an updated comprehensive analysis of the current approach to managing the care of children with complex care needs at the acute community / primary care interface within each Member State. As shown in Figure 1, complex care includes complex physical and complex mental health issues, defined as health issues requiring a range of additional support services beyond the type and amount required by children generally, and needing a high level of effective integration between specialised and general services.

Data will be gathered on policy, practice, communication procedures for integrated care, care coordination and management of the ongoing community hospital interface. A further specific focus will be on children with complex Mental Health needs. Expertise within this work package (Stine Lundstroem Kamionka), within the project (Professor Ulrike Ravens-Sieberer, German country agent), and the External Advisory Board, will inform specific areas for exploration of complex mental health issues. The primary/secondary care interface will also be compared with that in Australia with an emphasis on family experiences and primary care knowledge, barriers and enablers of support for children with complex mental health issues.

Task 3: Social Care Interface

Children live in a social context and their world. In order to achieve the best outcomes for children with complex social-health status circumstances, or complex health conditions requiring also social care support, interventions need to consider and support children in both health needs and social care needs. Led by Dr Austin Warters the objective of this task is to understand the social care interface with primary care for children and their families, and key success factors and identifiable impediments, and potential effective models explored.

Task 4: Nursing and Skills

Across Europe nursing roles in public health are diverse within the variety of models of health care delivery to children including the following: working in health care teams, and the specific contribution and key role of nurses in each service is often not clearly defined. Led by Dr Anne Clancy this task will link closely to the work in WP 6 in the study of curriculum plans in undergraduate nursing programs and postgraduate public health nursing programs to relate to preparedness for the practice of caring for the child with complex care needs and their families at the primary/secondary interface.

Task 5: Patient and Family Experiences

This task will give insight into the experiences from parents of children with complex needs with the primary/secondary care interface in five European Countries. The task will be lead by Drs Manna Alma and Auke Wiegersma, members of DIPEX-International (<http://www.dipexinternational.org>), as an aspect of the study in WP 1.

Task 6: Business Model of Continuity of Complex Care

Collectively the data from tasks 1-5 will inform the continuing work of Drs Luzi and Pecoraro, which begins in WP 1. The aim is to develop a business model of continuity of care on the different scenarios of integration of primary, secondary and social services using the UML (Unified Modelling Language). This description will be focused on specific scenarios to highlight a) events that trigger the access to primary care, b) actions, tools and data that track the interaction among primary, secondary and social care services, and c) stakeholders involved. This activity will identify strategies used in EU countries to achieve integrated care, and take into account improving continuity of care in terms of communication and messages (e.g. Consorti et al.) (Consorti F, Lalle C, Ricci FL, Rossi-Mori A. Relevance of mandates, notifications and threads in the management of continuity of care; *Studies in Health Technol Inform.* 2000; 77:1035-9.).

Participation per Partner

Partner number and short name	WP2 effort
2 - UCD	84.00
3 - UMCG	5.00
4 - CNR	7.00
8 - KCL	3.00
11 - HIH	40.00
15 - SDU	4.00
17 - CHB	3.00
19 - MCRI	30.00
Total	176.00

List of deliverables

Deliverable Number ¹⁴	Deliverable Title	Lead beneficiary	Type ¹⁵	Dissemination level ¹⁶	Due Date (in months) ¹⁷
D2.1	Final report on the current approach to managing the care of children with	2 - UCD	Report	Public	26

List of deliverables

Deliverable Number ¹⁴	Deliverable Title	Lead beneficiary	Type ¹⁵	Dissemination level ¹⁶	Due Date (in months) ¹⁷
	complex care needs in Member States				
D2.2	Final report on models of children’s social care support across the EU and the relationship with primary health care.	2 - UCD	Report	Public	26
D2.3	Report on requirements and models for supporting children with complex mental health needs and the primary care interface	2 - UCD	Report	Public	30
D2.4	Report on needs and future visions for care of children with complex conditions	2 - UCD	Report	Public	30

Description of deliverables

2.1 Final report on interface between primary and complex care for all European country primary care models for children and young people. Month 24
 2.2 Final report on the current approach to managing the care of children with complex care needs in Member States Month 26
 2.3 Final report on models of children’s social care support across the EU and the relationship with primary health care. Month 26
 2.4 Report on requirements and models for supporting children with complex mental health needs and the primary care interface Month 30
 2.5 Report on needs and future visions for care of children with complex conditions Month 30

D2.1 : Final report on the current approach to managing the care of children with complex care needs in Member States [26]

Final report on the current approach to managing the care of children with complex care needs in Member States

D2.2 : Final report on models of children’s social care support across the EU and the relationship with primary health care. [26]

Final report on models of children’s social care support across the EU and the relationship with primary health care.

D2.3 : Report on requirements and models for supporting children with complex mental health needs and the primary care interface [30]

Report on requirements and models for supporting children with complex mental health needs and the primary care interface

D2.4 : Report on needs and future visions for care of children with complex conditions [30]

Report on needs and future visions for care of children with complex conditions

Schedule of relevant Milestones

Milestone number ¹⁸	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
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Work package number ⁹	WP3	Lead beneficiary ¹⁰	3 - UMCG
Work package title	Effective Models of School Health Services and Adolescent Health Services		
Start month	1	End month	42

Objectives

The objectives of this work package are to:

- To explore the organization, service characteristics and health priorities of various models of school health services and adolescent health services in Europe
- To assess effects and outcomes of the various models of school health services and adolescent health services in Europe for children (≥ 4 years of age) and adolescents
- To assess the costs of the various models of school health services and adolescent health services in Europe for children (≥ 4 years of age) and adolescents

Description of work and role of partners

WP3 - Effective Models of School Health Services and Adolescent Health Services [Months: 1-42]
UMCG, TNO, CHUV

In this work package, the partners led by the Department of Health Sciences of the University Medical Center Groningen (UMCG) will perform an inventory of the approaches and evidence based examples of school health services and adolescent health services within Europe. UMCG, in cooperation with TNO and the Department of Pediatrics of the University Hospital of Lausanne, will analyze the data.

This WP will build upon the findings of WP 1, WP 2 and WP 7, while WP 9 uses the findings. Data on evidence based practices will be combined with research into implementation and transferability of preventive primary child health care services, including stakeholder analyses for future changes, planned in WP 9.

Task 1 – Comparison of the various models of school health services (SHS) and adolescent health services (AHS) in Europe with regard to its organization - and service characteristics and practice features.
 Led by Dr. Danielle Jansen and Dr. Auke Wiegiersma (UMCG), in cooperation with Dr Paul Kocken of TNO and Prof Dr. Pierre-André Michaud (CHUV), this Task will perform a literature review on the characteristics and organizational, and practical features of European school health and adolescent health services, based on the six WHO building blocks that together form the basis of a the well-functioning health system (World Health Organisation. Everybody’s business. Strengthening health systems to improve health outcomes. WHO’s framework for action. 2007.). Practice features will be evaluated on the basis of the work by Kuo et al (Kuo AA, Inkelas M, Lotstein DS, Samson KM, Schor EL, Halfon N: Rethinking well-child care in the United States: an international comparison. Pediatrics 2006, 118:1692-1702) involving among other things: first contact with care system, coordination, comprehensiveness, longitudinality, family centeredness and community centeredness.

Task 2 – Assessment of the outcomes and costs of the various models of school health services and adolescent health services in Europe.
 School health services will be led by Dr. Paul Kocken (TNO); Adolescent health services by Prof Dr. Pierre-André Michaud, both in cooperation with Dr. Danielle Jansen and Dr. Auke Wiegiersma from the UMCG. Within this work package, a first assessment will be conducted on effects and quality of the different school health and adolescent health services in different European countries. Effects of screening, counseling and advice will be studied, SHS tasks that are in some cases performed in the context of whole school approaches and health promoting school interventions. The assessment will be carried out by both conducting a literature review and the use of country agents who will collect country-specific data. Based on the literature, we will define suitable outcomes of effective health services in the broad range of child and adolescent health, education and social domain. Possibly suitable examples of child and adolescent health are: physical (such as diabetes, overweight/obesity), sexual/reproductive, or mental health and substance use. Examples of education indicators are: school enrolment and school completion rates. Examples of social indicators are: social exclusion, bullying, poverty and levels of crime. On the basis of these suitable outcomes, we will assess the effectiveness and quality of the health services.

Task 3 – To assess the costs of the various models of school health services and adolescent health services in Europe for children (≥ 4 years of age) and adolescents Led by Dr Danielle Jansen and Dr Auke Wiegiersma (UMCG), the costs

of the various models of school health services and adolescent health services will be explored by means of gathering data (both in scientific literature and by the use of country agents for data in (inter)national reports and databases) about health care utilization and the costs associated with this health care utilization. The cost-assessment will be consider four key inputs (Kutzin J, Cashin C & Jakab M (2010). Implementing Health Financing Reform. Lessons from countries in transition. World Health Organization 2010, on behalf of the European Observatory on Health Systems and Policies.): human resources, drugs and other supplies, utilities, and facilities and equipment, and there will be liaison with WPs 4 and 5.

Participation per Partner

Partner number and short name	WP3 effort
3 - UMCG	49.00
7 - TNO	4.00
18 - CHUV	2.00
Total	55.00

List of deliverables

Deliverable Number ¹⁴	Deliverable Title	Lead beneficiary	Type ¹⁵	Dissemination level ¹⁶	Due Date (in months) ¹⁷
D3.1	Final report on the description of the various models of school health services and adolescent health services, including quality assessments and costs.	3 - UMCG	Report	Public	36

Description of deliverables

3.1 Final report on the description of the various models of school health services and adolescent health services, including quality assessments and costs. Month 36

D3.1 : Final report on the description of the various models of school health services and adolescent health services, including quality assessments and costs. [36]

Final report on the description of the various models of school health services and adolescent health services, including quality assessments and costs.

Schedule of relevant Milestones

Milestone number ¹⁸	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
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Work package number ⁹	WP4	Lead beneficiary ¹⁰	4 - CNR
Work package title	Identification and Application of Innovative Measures of Quality and Outcome of Models		
Start month	1	End month	42

Objectives

1. To harmonize data on primary care collected through any available large primary care datasets, provided by WP 5 (CNR-IN and CNR-IRPPS).
2. To collect child health validated indicators using existing information (CNR-IN).
3. Analysis of measures of outcome to identify innovative measures and verify their applicability in child primary care models (CNR-IN).
4. Analysis of measures of quality of care to identify innovative measures and verify their applicability in child primary care models (CNR-IRPPS).
5. To apply the SEM/path analysis, using both the harmonised outcome and quality measures and other harmonised predictors, to develop new, or improve on existing, models for health systems (CNR-IN and CNR-IRPPS).

Description of work and role of partners

WP4 - Identification and Application of Innovative Measures of Quality and Outcome of Models [Months: 1-42]
CNR

Task 1. Availability and Harmonisation of Available Data
Lead: CNR-IN. The available consistent and compatible information on primary care will be identified and used with the aim of producing comparable data on the basis of available record systems and large data sets identified in WP 5. Comparable data will be ex-post harmonized, to the greatest extent possible, to facilitate the possibility of investigating on both the cross-national differences of preventive child health programs and the country-specific peculiarities, focusing both on outcome measures (IRPPS) will deal with quality of care (IN).

Task 2. Conceptual Model and Data Availability for Child Health Indicators in Europe
Lead: CNR-IN. The main goal is to build on the compilation of validated health child indicators among the European countries achieved by the RICHE Project (www.childhealthresearch.eu), and update this if necessary. From this to produce an overview of such indicators to produce a model of the topic distribution of current indicators, and key gaps. Further, the availability of data from European and national sources will be studied to model current potential availability of populated indicators of child health in Europe. This will use among other sources the work of the CHILd indicators, PHASE, and Determinants of Obesity projects (with which there is continuity of personnel across the MOCHA project).

Task 3. Outcome Measures
Lead: CNR-IN. The main goal is the exploration of a continuum of feasible outcome measures, from the clinical, health status and satisfaction perspectives, that could be used effectively by the stakeholders within diverse structural models (across countries) and paediatric settings to quantify the impact of the paediatric primary care. First step will describe the currently-used measures of outcomes country-specific; second step will provide an overview of the challenges and opportunities encountered in establishing effective outcomes measurement systems for program evaluation; third step will elaborate recommendations for expanding and enhancing current paediatric primary care outcome measurement efforts to achieve three primary goals: comprehensive service assessment, meaningful data collection and interpretation, and outcomes-driven program design and service provision.

Task 4. Quality of Care Measurement
Lead: CNR-IRPPS. To assess the quality of care it is necessary to identify complex and multidimensional relationships between structural assets, organizational characteristics and clinical procedures adopted in EU countries in paediatric primary care. This analysis will be performed following the steps identified in task 3 to achieve the above mentioned three primary goals. Additional efforts to investigate and improve upon existing methods for both the development of quality measures for children and their testing for reliability and validity will be undertaken, using comparison between methods utilized in the EU, United States and Australia.

Task 5. Exploratory Analysis of Causal Relations

Lead: CNR-IN. A structural equation model (SEM) will be used to reveal any invariant “causal” relations, meaning that it will show whether the causal assumptions embedded in a model match a sample of data. SEMs are best suited for quantitative data and when there is a solid theoretical knowledge on the subject of analysis, using both observed and latent data. Special cases of SEM are: factor analysis, path analysis and regression. This statistical approach will be used to investigate both outcomes (IN) and quality of care (IRPPS) measures.

Participation per Partner

Partner number and short name	WP4 effort
4 - CNR	64.00
Total	64.00

List of deliverables

Deliverable Number ¹⁴	Deliverable Title	Lead beneficiary	Type ¹⁵	Dissemination level ¹⁶	Due Date (in months) ¹⁷
D4.1	Final report on interface between primary and complex care for all European country primary care models for children and young people.	4 - CNR	Report	Public	24

Description of deliverables

4.1 Report on the innovative measures of quality and outcome of child primary care models Month 24
 D4.1 : Final report on interface between primary and complex care for all European country primary care models for children and young people. [24]
 Final report on interface between primary and complex care for all European country primary care models for children and young people.

Schedule of relevant Milestones

Milestone number ¹⁸	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
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Work package number ⁹	WP5	Lead beneficiary ¹⁰	5 - SURREY
Work package title	Identification and Use of Derivatives of Large Data Sets and Systems to Measure Quality		
Start month	1	End month	42

Objectives

The purpose of the WP is to identify unifying common clinical concepts and related data constructs that enable review of the quality and outcome of alternative models of children’s primary health care across Europe, and to seek means of applying these measures using local heterogeneous data sources. To do this we will:

- Develop key use cases that will provide representative scenarios to compare practice. Example use-cases for illustration only are:
 - a. An acute infection: e.g. Meningitis
 - b. A chronic or recurrent infection: e.g. Otitis media /glue ear
 - c. A chronic paediatric disease e.g. Cystic fibrosis
 - d. A behavioural use case e.g. Hyperactivity
 - e. An immunisation use case e.g. Measles and/or a seasonal one such as influenza
 - f. Governance use case e.g. How to share data about perceived failure to thrive
- Identify data concepts and constructs that can provide comparable quality and outcome measures for identified conditions and characteristics across data sets and sources.
- Identify data and datasets from across Europe that have the potential to yield data to inform about the comparative effectiveness of different models of care, including assessing the availability of data to enable analysis by socio-economic or other demographic factors. The structure and nature of local data sets and their governance and access controls will be compiled by the country agents who will also look to identify data owners / analysts willing to participate in action orientated public health, biomedical and social research.

Description of work and role of partners

WP5 - Identification and Use of Derivatives of Large Data Sets and Systems to Measure Quality [Months: 1-42] SURREY

Task 1: Technical requirements analysis (generic) & use-cases (study specific requirements) for using child health data; including the development of ontologies for core clinical concepts within the programme.
 In conjunction with other WPs we will conduct a requirements analysis for measurements of the quality and outcomes of child primary health care:

- Requirements analysis informs what data are needed to fulfil the needs
- Use-cases translate the specific requirements for participation in more detailed quality analysis

The requirements analysis will further develop the process used in the TRANSFoRm project (FP7) (de Lusignan S, Cashman J, Poh N, Michalakidis G, Mason A, Desombre T, Krause P. Conducting requirements analyses for research using routinely collected health data: a model driven approach. *Stud Health Technol Inform.* 2012;180:1105-7.) and the ADVANCE project (monitoring vaccine benefit risk in Europe, IMI funded).

The country agents will catalogue sources of primary care and child health data, the custodians and access regulations. The scope will be broad, following a method developed to look at primary care data (de Lusignan S, Pearce C, Shaw NT, Liaw ST, Michalakidis G, Vicente MT, Bainbridge M, International and European Medical Informatics Association and Federation Primary Care Informatics Working Groups. What are the barriers to conducting international research using routinely collected primary care data? *Stud Health Technol Inform.* 2011;165:135-40.). We will explore key technical requirements at: (1) Macro – legal, policy and business process levels; (2) Meso – data source and data extraction level; and (3) Micro – data.

The focus will be on the development of common quality and outcomes measures. The approach will be broad and inclusive, and include novel data sources (e.g. child protection registries, sentinel practices, etc.), while avoiding a single approach to data. We will seek to look to explore where “Big data” might be utilised in the context of assessing health care models, and where new data processors might be emerging within the health data ecosystem.

Task 2: Identifying candidate data sources

Through the country agents, and other sources such as scientific networks, we will identify and describe databases, registries, and other data sources suitable for participation in child health studies, and seek to ascertain those willing to share data in conjunction with MOCHA. Data sources might include: Immunisation registries, Computerised health care records e.g. hospital discharge registry for ICD diagnoses; Laboratory data, linked to research or other data; Health statistics; Genetic databases; Disease registries e.g. population-based cancer registries; Birth and maternity registries, and associated biobanks; Personal health records; Social care records; and Educational records (for example where immunisation is conditional for school admission).

We will use the framework for health data source identification, profiling and visualisation for implementing this task

Task 3: Development of common descriptors and ontologies

The work package will develop semantic models such as formal ontologies to represent linkage of clinical concepts, applicable and adaptable to individual regions or member states health systems. We will explore the possibilities for representing the key data quality characteristics of data sources as ontological concepts, using standard ontology building tools according OWL (Web Ontology Language) standard. The developed ontologies will be used to identify tracer conditions and occurrences of common concepts that can be used to draw conclusions.

Task 4: Development of Measures of Quality and Outcomes from large data sets

We will work with WP leads and the External Advisory Board to derive measures of quality and outcome. This work will emphasise particularly on developing measures from large data sets.

Task 5: Application of the Measures through Participating Data Sources

Linking the outcomes of the preceding tasks, but particularly Tasks 2, 3 and 4, we will seek to establish a collaborative and cooperative process whereby data custodians, and analysts approved by them, apply the ontologies and measures to local data sets to operationalise the quality measures of the use cases, and seek to produce results on a common analytic basis from heterogeneous data sources to illustrate the effects of the different child primary health care models. This will generate a key input to the project overall, and particularly into WP 9. Results will be shared incrementally internally, and improved with iteration to enable the work of WP 9 while also strengthening the final deliverable of both WPs.

Participation per Partner

Partner number and short name	WP5 effort
5 - SURREY	35.00
Total	35.00

List of deliverables

Deliverable Number ¹⁴	Deliverable Title	Lead beneficiary	Type ¹⁵	Dissemination level ¹⁶	Due Date (in months) ¹⁷
D5.1	Semantic models of key clinical conditions and outcome measures	5 - SURREY	Report	Public	18
D5.2	Report of Measures of Quality and Outcomes derived from large data sets	5 - SURREY	Report	Public	32

Description of deliverables

5.1 Semantic models of key clinical conditions and outcome measures Month 18 5.2 Measures of Quality and Outcomes derived from large data sets Month 32

D5.1 : Semantic models of key clinical conditions and outcome measures [18]

Semantic models of key clinical conditions and outcome measures

D5.2 : Report of Measures of Quality and Outcomes derived from large data sets [32]
 Report of Measures of Quality and Outcomes derived from large data sets

Schedule of relevant Milestones

Milestone number ¹⁸	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS5	Catalogue of child health databases in Europe	5 - SURREY	15	Catalogue of child health databases in Europe
MS6	Quality Measures and Data Sources Workshop Report	5 - SURREY	21	Quality Measures and Data Sources Workshop Report

Work package number ⁹	WP6	Lead beneficiary ¹⁰	5 - SURREY
Work package title	Economic and Skill Set Evaluation and Analysis of Models		
Start month	1	End month	42

Objectives

The overarching objective of this work package is to consider the economic implications of alternative models of child health across Europe. Specifically we will:

- Map and compare the workforce configuration and costs of delivering the alternative models of primary child health care in use in Europe.
- Model the efficiency and effectiveness of alternative models of primary child health care across Europe
- Investigate the impact of reimbursement, payment and incentive systems on the performance of primary child health care systems across Europe

Description of work and role of partners

WP6 - Economic and Skill Set Evaluation and Analysis of Models [Months: 1-42]
SURREY, CNR, HIH
 Different models of primary child health will involve different mixes of staff from medical, nursing, social work and allied health professionals and will take place in differing environments and institutional settings. As staffing is the largest variable cost in delivering health care globally, understanding the optimum staffing levels and skill mix is vital to delivering high quality, cost-effective care. Further, there has also been a desire from many governments across Europe to move care away from secondary care settings into primary and community services, yet this has had limited impact in a number of countries (e.g. UK) where in reality there has been an increase in the amount of acute paediatric care occurring in a hospital setting.

At the same time, there has been a general policy shift away from primary care paediatric services towards general family practice (van Esso D, del Torso S, Hadjipanayis A, et al. Primary-Secondary Working Group (PSWG) of European Academy of Paediatrics (EAP). Paediatric primary care in Europe: variation between countries. Archives of Disease in Childhood 2010;Oct,95(10):791–95).

Finally, the past 20 years has seen a steady change in skill mix with role substitution occurring across medical specialities in Europe. For instance the greater use of unregistered nurses and allied health professionals and the growing number of nurse practitioners or consultants combined with the introduction of non-medical prescribing.

Different models of payment and co-payments exist in Europe, as well as incentivisation through pay per performance schemes (additional to population-targeted incentives). Whilst these are well studied in both general adult primary and secondary care, there is a dearth of studies within the context of paediatric services. This WP will map these changes and their variations across Europe and will then examine the evidence on the cost and effectiveness on child health outcomes.

Lead: Prof. Graham Cookson, University of Surrey (UK)
 Outcomes: Dr. Daniele Luzi, IRPPS (IT)
 Nursing and Skills: Prof. Anne Clancy, Harstad University College, Harstad, Norway
 Labour economics and econometrics: Prof. Graham Cookson, University of Surrey (UK)

Task 1: Map and compare the workforce configuration and costs of delivering the alternative models of primary child health care in use in Europe.

With the support of country agents, and drawing on the emerging models from WP 1, post-doctoral researchers in both Harstad and Surrey this task will be led by Dr. Anne Clancy, Harstad (NO). It will collate and compare the various models of primary child health care delivery across Europe with a focus on the economic aspects of service provision including:

- (i) Workforce: Configuration, training
- (ii) Funding patterns of the different models
- (iii) Payment: provider incentives and payment/reimbursement mechanisms
- (iv) Setting primary care for children in the wider context of secondary and community based services (linking also with WPs 1 and 2),

Harstad will focus on (i) and (iv), Surrey on (i), (ii) and (iii). A combination of data from Country Agents will be required to collate information on the configuration and costs of the alternative models of child health used across Europe. This task is largely descriptive in nature but will inform the models and analysis performed in tasks 2 and 3. This work will take place over months 4-21 with dissemination over months 22-27.

Task 2: Model the efficiency and effectiveness of alternative models of child health care across Europe

This task is dependent upon task 1 from this WP, as well as from tasks from other WPs which will identify and deliver outcome measures and associated control variables. In the framework of the evaluation of alternative models of child health in Europe the evaluation of efficiency and effectiveness of health care delivery services implies the identification of quality indicators pertaining structures, processes and outcomes.

Particular attention will be put on how primary, secondary and social care services are delivered to children with complex care needs, linking with WP 2. This analysis will be based on the scenarios identified in previous WPs, on data available at national level (such as service capacity, epidemiology, personnel involved, etc) as well as on data provided by Country Agents, as harmonized by CNR-IN also in WP 4 and now subject to statistical and economic modelling as well as business modelling. Months 22-27.

Surrey will adopt and adapt the models to consider two further questions: (i) the trade-off between efficiency and effectiveness, and (ii) the relationship between skill-mix and outcomes. Months 19-36

Task 3: Investigate the impact of reimbursement, payment and incentive systems on the performance of child health care systems across Europe

Incentive and payment by results schemes are increasingly common place. The UK has both primary (Quality and Outcomes Framework) and secondary care systems in place. Relatively little is known about their implementation and success across Europe specifically in relation to child health. This task will investigate the impact of these systems on the performance of child health care systems in relation to the outcomes identified in earlier work packages. There will be a link to the strand on this topic led from Keele in WP 1. Surrey will lead this task. (Months 21-33)

Participation per Partner

Partner number and short name	WP6 effort
4 - CNR	12.00
5 - SURREY	40.00
11 - HIH	4.00
Total	56.00

List of deliverables

Deliverable Number ¹⁴	Deliverable Title	Lead beneficiary	Type ¹⁵	Dissemination level ¹⁶	Due Date (in months) ¹⁷
D6.1	Short report on financial systems and their impact on outcomes	5 - SURREY	Report	Public	34

Description of deliverables

6.1 Consolidation of short reports into work package report Month 39
 D6.1 : Short report on financial systems and their impact on outcomes [34]
 Short report on financial systems and their impact on outcomes

Schedule of relevant Milestones

Milestone number ¹⁸	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS6	Quality Measures and Data Sources Workshop Report	5 - SURREY	21	Quality Measures and Data Sources Workshop Report

Work package number ⁹	WP7	Lead beneficiary ¹⁰	6 - KI
Work package title	Ensuring Equity for all Children in all Models		
Start month	1	End month	42

Objectives

Objective 1. To support WP 1 Task 2 by reviewing the literature on socioeconomic and sociocultural differences in outcomes of different primary care models for children.

Objective 2. To compare outcomes and performance with regards to Socio-economic Status (SES), single parent household and a migrant/minority in large primary care datasets, provided by WP 5.

Objective 3. To compare vaccination rates and participation in screening programs with respect to differences in families by SES, single parent household and migrant background in a country with a generalist physician centered primary care model (Denmark) with that of primary care paediatrician centred model (Italy) and with a nurse centered primary care model (Sweden), and the Danish and Swedish models also compared with those in Australia.

Objective 4. To describe the national policies in Europe for primary care for children with different migrant backgrounds (undocumented, asylum seeking, newly settled, born in Europe), with comparison to Australia.

Objective 5. To review the literature on health care models for children in the child welfare system (co-ordinating with WP 2 Task 3 on Social Care Provision).

Objective 6. To describe the diverse health care models for children in the child welfare system in Europe (co-ordinating with WP 2 Task 3 on Social Care Provision).

Description of work and role of partners

WP7 - Ensuring Equity for all Children in all Models [Months: 1-42]
KI, MCRI

Task 1. Literature review of socioeconomic and sociocultural aspects of different primary care models for children.

The scientific literature on studies of outcomes and performance of primary care in different SES groups, single parent household and migrant/minority families will reviewed based on a systematic search strategy in relevant databases and complimented with grey literature from the national representatives of MOCHA. There will be liaison with the overall literature review undertaken in Task 2, WP 1.

Task 2. To compare outcomes and performance by Socio-economic Status (SES), single parent household and migrant background in large primary care datasets.

The intention is to re-analyse key data provided by WP 5 and WP 4 by indicators of SES, family type and migrant/minority background, and also to compare Australian data.

Task 3. To compare vaccination rate and rates of participation in screening programs, as an outcome of primary care for children, with respect to differences in families by SES, single parent household and migrant background in Denmark and Sweden.

Denmark and Sweden have many similarities in terms of welfare policies and standard of living and vaccination policy, but their primary care models for delivery of vaccinations of children are very different. The Danish model is based on general practitioners while the Swedish model is based on nurses who follow each newborn child with regular visits within a defined geographic area until school start. Interestingly in Australia both models exist and both deliver vaccinations. We will compare vaccination rates in a national data set from Denmark and a regional dataset from Sweden with respect to parental education, income, family type and country of birth of parents. By contrast with Denmark, where primary care physicians are generalists, in Italy there are specific paediatric primary care physicians, giving a potentially deeper clinical knowledge but with less family context and different operational support. These will be contrasted with national Australian data of vaccination rates across similar demographic variables and across providers (nurse and physician).

Task 4. To describe national policies and guidelines in Europe for primary care for children with different migrant backgrounds.

We will collect data from government websites, reports from NGO's and information from the MOCHA country agents for all countries in EU, Norway and Iceland on national policies regarding access to care, funding strategies of and special primary health care resources for children in the various migrant categories undocumented families, asylum seeking and newly settled families, and children born in Europe to foreign-born parents. National guidelines for primary care for children in migrant will also be collected and summarized. We will also compare these with Australia where 24% of children starting school speak a language other than English at home.

Task 5. To review the literature on health care models for children in the child welfare system.

Children in the child welfare system often enter care with many unfulfilled needs of care, because of neglected basic health care in their original family as well as mental health problems. For adolescents in the child welfare system disorders related to illicit drug abuse and sexually transmitted disorders are other important concerns. While in care, the children are often far away from their usual primary care services and information about previous primary care is often lacking. We will review the literature on different health care models for child welfare in a systematic search strategy in relevant databases and complimented with grey literature from the national representatives of MOCHA. This work will liaise with, and complement, the work of WP 2 on models of social care support for children with complex needs.

Task 6. To describe health care models and best practices for children in the child welfare system in European countries.

We will collect data from national guidelines, government websites and information from the national representatives of MOCHA for all countries in EU, Norway and Iceland on health care models for children in the child welfare system.

Participation per Partner

Partner number and short name	WP7 effort
6 - KI	38.00
19 - MCRI	17.00
Total	55.00

List of deliverables

Deliverable Number ¹⁴	Deliverable Title	Lead beneficiary	Type ¹⁵	Dissemination level ¹⁶	Due Date (in months) ¹⁷
D7.1	Report on national policies for primary care for migrant children in Europe	6 - KI	Report	Public	15
D7.2	Report on differences in outcomes and performance by SES, family type and migrants of different primary care models for children	6 - KI	Report	Public	30

Description of deliverables

7.1 Report on national policies for primary care for migrant children in Europe Month 15 7.2 Report on differences in outcomes and performance by SES, family type and migrants of different primary care models for children Month 30

D7.1 : Report on national policies for primary care for migrant children in Europe [15]
 Report on national policies for primary care for migrant children in Europe

D7.2 : Report on differences in outcomes and performance by SES, family type and migrants of different primary care models for children [30]
 Report on differences in outcomes and performance by SES, family type and migrants of different primary care models for children

Schedule of relevant Milestones

Milestone number ¹⁸	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
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Work package number ⁹	WP8	Lead beneficiary ¹⁰	1 - ICL
Work package title	Use of Electronic Records to Enable Safe and Efficient Models		
Start month	1	End month	42

Objectives

The objectives of this work package are to:

- Identify the types and models of electronic record system (EHR) supporting child primary health care, and whether these are child health specific EHRs.
- Identify any child health agreed standard data sets which are or have the potential to be included in primary care records, national summary records, data exchanges, or similar, as well as parent and personal child held health records.
- Identify national or collaborative child health registries, cohort studies, or similar.
- Compare the above findings with established coding and standards initiatives at a high level, including SNOMED, ICD-10, DSM5, NANDA and NIC nursing codes, TC251/ISO, and IHTSDO, particularly for areas of omission or conflict.
- Identify examples of added value which can be obtained from integrated use of standard records and controlled secondary use of data.
- Identify effective initiatives in Europe using mobile (mHealth) technologies including apps, social media, and other innovations directed to families.
- Indicate facilitators and barriers to development and maintaining of optimum models of electronic record support to the delivery of primary health care for children, including interface with complex care.

Description of work and role of partners

WP8 - Use of Electronic Records to Enable Safe and Efficient Models [Months: 1-42]
ICL, CNR, SURREY, UI, EUC

In the modern era, models of care should not be islands of isolated activity. Electronic records, and other e-health tools, should be supportive tools but should not dominate practice. At the same time, the availability of such tools can enable new models and paradigms of care; indeed, in the future they can be anticipated to be a cornerstone of effective primary care service provision, and individual workers or facilities can operate above their skill level if supported by on line support. However, child health EHRs have had a mixed history in the face of pressures to conform to adult-dominated e-health strategies with less or no child health functionality.

The Work Package will be led by Professor Rigby, Deputy Project Leader, who has over 40 years’ experience in child health electronic records, with support from Professor Majeed, Professor of Primary Care and Public Health (both Imperial). Professor de Lusignan (Surrey) will provide links with modern standards work, the European Federation of Medical Informatics Primary Care Group which he chairs, and access to derived data sets. Dr. Pecoraro (CNR-IRPPS) will contribute expertise on secondary data analysis, while Dr. Hadjipanayis (EUC) will provide evidence from EAPRASnet (European Academy of Paediatrics Research in Ambulatory Settings network) surveys which he has instigated. Finally, Dr. Gunnlaugsson (University of Iceland) will contribute visioning of what can be achieved with an integrated national data set approach.

Most Tasks will be self-contained but be shared within the work package, and with progress being reported to all WP Leaders. However, the WP will hold a Workshop to cross-link emergent findings in Month 26.

Task 1 – Existing and Planned Future Electronic Records Architecture and Systems
 The first task will be to ascertain the situation regarding EHRs, and references to child health (or lack of) in future national e-health plans, and also the existence of any other key child health records such as neonate parent held records. Other initiatives, such as telemedicine and telehealth, will also be noted where in significant use. The Country Agents and EPRASNet surveys will be important sources of this baseline information.

Task 2 – Mapping to Standards
 These findings will then be studied in more detail to identify agreed data sets and functions, and the degree of commonality or variation, and any rationale including typologies or models of record support to practice. Finally these will be compared at a high topic level across standards such as SNOMED, ICD-10, DSM5, NANDA and NIC nursing codes, the work of TC251/ISO, the International Health Terminology Standards Development Organisation (IHTSDO),

and (particularly for ongoing or complex care) to the work of CONTSys, to identify common solutions, omissions, and possible conflicts.

Task 3 Registries and Added Value Functions

There exist in a number of countries various forms of child register, immunisation register, and the like. These will be identified, and their functions, data sets, and value to child health care identified, both in the context of their current national child primary health care model, and with a view to transferability of best practice. Links will be made to the PARENT and CHICOS EU Projects in particular.

Task 4 – Secondary use and other Added Value from EHR Systems

While electronic records are primarily created by and for doctors and other health professionals to support the care delivery process, increasingly it is recognised that significant new knowledge about care, treatment outcomes, and aetiology can be gained using Large Data and Big Data analyses methods, and there are different successful experiences in the use of EHR systems for secondary purposes, such as clinical research, epidemiology, pharmacovigilance, and comorbidity detection. Coding standards as identified in Task 2 are key to this if cross-system and cross-border aggregations and analyses are to be possible. Major current large scale or innovative examples relating to primary care child health will be sought from current systems in Europe, linking also back to the host primary care models and record support models for child primary care, so as to yield guidance for future best practice.

Task 5 – Whole System Approaches

The new potential of using whole system approaches to target preventive care and stratify other care, using integrated national standards will be explored based on the example of Iceland. This will be compared to other initiatives identified across Europe, from elsewhere in the literature, and from Professor Rigby’s involvement with OECD work on Smarter Health and Welfare Systems (2013), to identify possible future models.

Task 6 – Supporting New Models of Care

This work package will also iterate with Work Package 1, identifying current models of care, and Work Package 9, giving guidance and evidence for future models. Informatics and e-health should support practice not determine it, but conversely these technologies can improve the targeting and efficiency of delivery and enable new models to be developed. This Task will therefore relate the Work Package’s findings to the findings of WP 1 to link models of practice with innovation in electronic record systems. Conversely, in WP 9 the potential of e-health to enable leaner, more responsive, or better outcome models will be input as part of the formulation of WP 9 deliverables.

Participation per Partner

Partner number and short name	WP8 effort
1 - ICL	52.00
4 - CNR	4.00
5 - SURREY	4.00
12 - UI	4.00
13 - EUC	8.00
Total	72.00

List of deliverables

Deliverable Number ¹⁴	Deliverable Title	Lead beneficiary ¹⁴	Type ¹⁵	Dissemination level ¹⁶	Due Date (in months) ¹⁷
D8.1	Description and Analysis of current child health electronic record	1 - ICL	Report	Public	15

List of deliverables

Deliverable Number ¹⁴	Deliverable Title	Lead beneficiary	Type ¹⁵	Dissemination level ¹⁶	Due Date (in months) ¹⁷
	keeping across Europe				
D8.2	Future Achievable Potential Models of Child Health Electronic Record Systems to Support care Delivery	1 - ICL	Report	Public	30

Description of deliverables

8.1 Future Achievable Potential Models of Child Health Electronic Record Systems to Support Care Delivery Month 30

D8.1 : Description and Analysis of current child health electronic record keeping across Europe [15]
Description and Analysis of current child health electronic record keeping across Europe

D8.2 : Future Achievable Potential Models of Child Health Electronic Record Systems to Support care Delivery [30]
Future Achievable Potential Models of Child Health Electronic Record Systems to Support care Delivery

Schedule of relevant Milestones

Milestone number ¹⁸	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS6	Quality Measures and Data Sources Workshop Report	5 - SURREY	21	Quality Measures and Data Sources Workshop Report

Work package number ⁹	WP9	Lead beneficiary ¹⁰	7 - TNO
Work package title	Validated Optimal Models of Children's Prevention-Orientated Primary Health Care		
Start month	1	End month	42

Objectives

The objectives of this work package are:

- Further development of optimal, sustainable and cost-efficient patient-centered and prevention oriented primary child health care models emerging from the analyses of the other WPs.
- Testing of primary child health care models against the needs of addressing specific preventable conditions in European countries and showcasing of existing innovative evaluated practices.
- Estimating the citizens' perceived benefits of primary child health care models, including the existing ones.
- Analysis of views of stakeholders on the vital changes necessary and achievable in policies to improve the primary child health care systems.
- Analysis of the transferability of primary child health care models by means of assessing how best to engender an evidence-based approach to policy making and analysis of governance styles to patient-centered and prevention oriented primary child health care models.

Description of work and role of partners

WP9 - Validated Optimal Models of Children's Prevention-Orientated Primary Health Care [Months: 1-42]
TNO, ICL, UM, MUL, UTwente
 This WP will develop optimal patient-centered and prevention oriented primary child health care models emerging from the analyses of WP 1 and the other WPs. Based on the outcomes of the other WPs optimal models of primary care for children will be chosen. The conditions for implementation of the alternative models, transferability and preferences of general public will be tested at macro, meso and micro level using quantitative and qualitative methods. The potential implementation and transferability of the alternative models on effectiveness, costs and equity of child health services will be postulated based on identified national principles for health systems and for policies relating to children, as well as policy cultures. The results will be promulgated for discussion at high-level European, political and NGO events. This will enable active iteration and development of hypothesised models.

This WP is led by TNO. Maastricht University and Medical University of Lublin are responsible for the analyses at macro level, TNO at meso level and University of Twente at micro level. Imperial College London (leader of WP 1 and the Dissemination WP 10) will supervise the development of optimal primary child health care models.

Task 1 – Organise multidisciplinary workshops to further develop optimal models
 Lead: Imperial College London.
 A starting workshop with WP 1 and leaders of WPs 1-8 will clarify and formulate a set of optimum models that are representative for the child health care systems in the EU and have the highest prospects for sustainability and cost-efficiency. Ensuing workshops, primarily at conferences such as EUPHA and meetings of the European pediatric associations, will ensure iterative development. Special attention will be given to issues of implementation, and sustainability and cost-efficient preventive youth health care models. This will be a major input into the final Project Report of WP 10.

Task 2 – Verification of the implementation conditions of best practices
 Lead: TNO. Medical University of Lublin and Maastricht University contribute.
 Promising primary child health care models as selected in task 1 will be tested on typical issues in public health. A comparative case study between member states will be conducted of a choice of innovative best practices such as prevention of SIDS or mental health screening and promotion in children that are encountered in WPs 1-8. These best practices include good practices on which agreement is reached in generally accepted guidelines or standards. The influence of the models of primary child care on the implementation conditions of the cases will be studied using desk research and a survey among policy makers, professionals and other key figures at the macro and meso level. The framework for the analysis will be theories on diffusion and implementation (Fleuren, M. A., Paulussen, T. G., Van Dommelen, P., & Van Buuren, S. (2014). Towards a measurement instrument for determinants of innovations. *International Journal for Quality in Health Care : Journal of the International Society for Quality in Health Care / ISQua*, doi:mzu060 [pii] ; Greenhalgh, T., Robert, G., Macfarlane, F., Bate, P., & Kyriakidou, O. (2004). Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Quarterly*, 82(4), 581-629)

Task 3 – Assembling the public preferences for primary care models at the micro-level

Lead: University of Twente. TNO contributes.

Public preferences for prevention oriented primary child health care models emerging from the analyses in the other WPs will be tested, based on the expected outcomes, access and patient-centeredness of care. The results will be used to support policy decision making by identifying the important attributes of a high quality primary health care system according to the public, based initially on a qualitative analysis of key differences between proposed patient-centered and prevention oriented primary child health care models emerging from the analyses in the other WPs (task 1).

Task 4 – Analysis of stakeholders’ views at the meso level.

Lead: TNO. Medical University of Lublin and Maastricht University contribute.

This task will seek input of groups of stakeholders on scenarios on how to get to the optimal models as selected in task 1. Based on the influence of primary child care models on the implementation of the examples of best practices of task 2, the necessary changes and expected facilitating and inhibiting factors for implementing the new, optimal models will be included in the scenarios. The acceptance and feasibility of the optimal models will be tested using online focus groups with stakeholders, e.g. policy makers, school health doctors, nurses etc. recruited through the country agents.

Task 5 – Analysis of evidence based policy approaches and governance styles at the macro level in the area of primary child health care models to inform transferability

Lead: Maastricht University. Medical University of Lublin contributes.

This task will start with mapping evidence-based policy making approaches and governance styles to primary child health care models. The transferability analysis will be supported by an assessment of the culture of evidence-based practice. It will focus on how and what kind of evidence is used in decision making processes and how it is implemented to inform policy and practice. It will provide an assessment on knowledge utilization and governance of primary child health care models.

The overall philosophy of the acceptability and preference analysis of WP 9 is based on the understanding of the cascade from optimal theory as study level, through innovation intention at the national policy level, innovation as implemented at the meso level, and innovation is realised at the micro level

Participation per Partner

Partner number and short name	WP9 effort
1 - ICL	8.00
7 - TNO	31.00
9 - UM	2.00
10 - MUL	4.00
14 - UTwente	8.00
Total	53.00

List of deliverables

Deliverable Number ¹⁴	Deliverable Title	Lead beneficiary	Type ¹⁵	Dissemination level ¹⁶	Due Date (in months) ¹⁷
D9.1	An e-book showcasing conditions for implementation of examples of best practices in primary child health care	7 - TNO	Report	Public	32

List of deliverables

Deliverable Number ¹⁴	Deliverable Title	Lead beneficiary	Type ¹⁵	Dissemination level ¹⁶	Due Date (in months) ¹⁷
	in European countries.				
D9.2	A report containing consensus statements on most optimal models with guidance on potential benefits and how these might be achieved.	7 - TNO	Report	Public	40

Description of deliverables

9.1 An e-book showcasing conditions for implementation of examples of best practices in primary child health care in European countries. Month 32
 9.2 A report containing consensus statements on most optimal models with guidance on potential benefits and how these might be achieved. Month 40

D9.1 : An e-book showcasing conditions for implementation of examples of best practices in primary child health care in European countries. [32]
 An e-book showcasing conditions for implementation of examples of best practices in primary child health care in European countries.

D9.2 : A report containing consensus statements on most optimal models with guidance on potential benefits and how these might be achieved. [40]
 A report containing consensus statements on most optimal models with guidance on potential benefits and how these might be achieved.

Schedule of relevant Milestones

Milestone number ¹⁸	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS8	Coordination and reconciliation of Final Deliverables	1 - ICL	31	Coordination and reconciliation of Final Deliverables

Work package number ⁹	WP10	Lead beneficiary ¹⁰	1 - ICL
Work package title	Dissemination		
Start month	1	End month	42

Objectives

The objectives of this work package are to:

- Ensure that stakeholders (policy makers, professionals, and children, young people and families) are fully aware of the project and its aims and how to engage with it from its inception.
- Ensure that methodologies and interim findings are exposed to critical review, and thus refinement and improvement.
- Ensure that the final results of the project, including deliverables but also wider messages, are promoted widely to all stakeholders and those in positions of influence to leverage maximum impact.

Description of work and role of partners

WP10 - Dissemination [Months: 1-42]
ICL, UCD, UMCG, UM, EUC

This work package will be the means of a very active engagement and dissemination programme. This will be formative (disseminating the project’s objectives and methods) as well as summative (disseminating the findings). This work package will work in synergy with each individual work package to facilitate each WP’s own dissemination of specific technical activities, innovations, and findings (with due recognition of the Project context and ownership).

The Dissemination work package itself will focus primarily on leading the dissemination of the holistic and integrated activities and results, but will monitor the wider dissemination activities also.

To maximise the impact of our work, we aim to disseminate two principle sets of communications:

- 1) The Scientific messages which will relate to methods of designing, resourcing, populating, and appraising models of primary health care for children, and their impacts. This will be through conference presentations, stakeholder workshops and peer reviewed journal publication
- 2) Secondly, the policy and adoption implication messages; which are a key end objective of the MOCHA project. However, in full recognition of both the national Member State competence for health systems, and the current groundswell against perceived directional instructions from the European level, these messages will be phrased and delivered in such a way that they are attractive to both national and local policy makers as sound evidence-based advice and not as policy directives.

To achieve these objectives, there will be a number of target populations for the dissemination activities, which will also seek to encourage feedback and further evidence. These will include academic, scientific and professional groups and individuals; policy makers (both political and professional) involved in deciding future health policies; and bodies representing parents, children and young people. Much of the dissemination will be at European level and in professional journals, but materials on the web site (with which other sites will be encouraged to link) will be important, as will targeted national dissemination as recommended by country agents and some publications in selected lay outlets.

To cover these objectives partners in the work package, and members of the Expert Panel supporting this work, include persons directly embedded in a number of key scientific and strategic European organisations including the World Health Organisation, Health Forum Bad Gastein, European Public Health Association, European Health Management Association, European Patients’ Association, European paediatric networks (such as the European Academy of Paediatrics, European Paediatric Associations and European Confederation of Primary Care Paediatrics), Alliance for Childhood (with its network and regular European Parliament meetings) and Eurochild. Other key conferences, such as those of nursing associations at European level, will also be targeted, while the European Union for School and University Health and Medicine has offered collaboration.

The work package will work by initially commissioning the design and delivery of a project logo and design templates, and a common web portal, then linking with other WP leaders and other project partners to set the pattern of the initial formative dissemination programme. Thereafter, the work package will work closely with the Project Management WP 11, and WPs 1 and 9, and in liaison with all WP leaders, to ensure that all key interim and final results are disseminated appropriately at conferences, working meetings (such as European Parliament and NGO meetings), and in scientific

journals – with a balance between dissemination of technical results by WPs and Task leaders, dissemination of higher level policy and choice issues to policy-making stakeholders, and dissemination of integrated project results by this WP.

Every opportunity will be taken, within the project resources, to engage in workshops and presentations at professional and stakeholder high-level events to enrich and validate the emergent processes and findings. Conversely, calls for materials for strategic events will be monitored to ensure that there is an appropriate project presence whenever possible. Links will be encouraged between our portal and all the websites of our stakeholders and all organisations (European and national) that might be interested in the results of the project.

At the end of the project, WP Dissemination will coordinate extensive promulgation of the results, including creation of electronic and printed versions of the final report and recommendations, and the preparation of a lay accessible public version via the project portal and linkage to other key websites, as well as by direct dissemination. Secondly, a final large audience conference is planned to promote all the findings on better child primary health models and the effective deployment. It is intended to seek sponsorship, and to charge a fee for attendees from outside the project, such as to cover most costs

Participation per Partner

Partner number and short name	WP10 effort
1 - ICL	26.00
2 - UCD	2.00
3 - UMCG	2.00
9 - UM	2.00
13 - EUC	2.00
Total	34.00

List of deliverables

Deliverable Number ¹⁴	Deliverable Title	Lead beneficiary	Type ¹⁵	Dissemination level ¹⁶	Due Date (in months) ¹⁷
D10.1	Functioning web site, including contact details, News and Publications sections, and private working area.	1 - ICL	Websites, patents filling, etc.	Public	5

Description of deliverables

10.1 Functioning web site, including contact details, News and Publications sections, and private working area. Month 5

D10.1 : Functioning web site, including contact details, News and Publications sections, and private working area. [5]
 Functioning web site, including contact details, News and Publications sections, and private working area.

Schedule of relevant Milestones

Milestone number ¹⁸	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS2	Web site operational	1 - ICL	5	Development of MOCHA website

Work package number ⁹	WP11	Lead beneficiary ¹⁰	1 - ICL
Work package title	Project Management		
Start month	1	End month	42

Objectives

To manage the project effectively.

Description of work and role of partners

WP11 - Project Management [Months: 1-42]

ICL

The Project Management WP will be central to ensuring the smooth running of the whole project. It will be run by the Project Leader and his Deputy, both of whom are experienced in big projects and in European Commission and other international projects. They will work closely with all the WP leaders, while the strong personnel links with WP 1 (Initial Scientific Coordination, and management of Country Agents throughout) and WP 10 (Dissemination), will ensure the strong cohesion of the project, its dissemination, and its impact. They will be supported by a full-time project officer, who will ensure continuous communication with all WP Leaders.

In months 1-3 WP 11 will liaise with each WP leader to ensure that business processes are established, and necessary staff recruited or others freed up as necessary in each partner, so that in Month 4 the project can commence its 36 month core scientific phase at full capacity from the onset.

There will be three main means of coordination of objectives, processes, and scientific integration:

First, there will be an Annual Meeting of all partners and personnel. This will be a one-day meeting involving all partners and country agents. For sake of efficiency, but also to enable good inter-personal linkage to develop, the meeting will be preceded by half-day meetings of the WP Leaders and of the External Advisory Board; it will be followed by opportunity for each Work Package to have its own working meeting, and for some inter-WP discussions. Thus most members will attend for two days.

Second, there will be a physical meeting of the WP Leaders each intervening six months. For all WP Leaders meetings the agenda will be pre-agreed, and will comprise general business items, discussion of any emergent or possible risks or deviations, and scientific WP linkage topics as appropriate.

Third, there will be a monthly Work Package Leaders' teleconference, with a notified agenda on the same basis, every month that has no physical meeting.

WP 11 will also manage the six-monthly meetings of the External Advisory Board. This has a strong expert and stakeholder membership, as shown (all are confirmed as shown):

Aneela Ahmed Young person from Youth Subgroup of European Patients Forum

Dr. Prerna Banati Chief – Programme and Planning, UNICEF Office of Research (Innocenti Centre), Florence

Vivian Barnekow Lead of Child and Adolescent Health and Development Programme, WHO Regional Office for Europe

Jeni Bremner Director, European Healthcare Management Association

Ragnheiður Ósk Erlendsdóttir Senior Nurse, Primary Healthcare Centre, Iceland

Dr. Katrin Fjeldsted President, Standing Committee of European Doctors (CPME) (a general practitioner)

Jana Hainsworth Secretary General, Eurochild

Dr. Johan Hansen Chair, Health Services Research Group, European Public Health Association (EUPHA)

Dr. Hans Kluge Division of Health Systems, WHO Regional Office for Europe

Prof. Neal Halfon UCLA, USA

Michiel Matthes Secretary-General,

Alliance for Childhood European Network Group

Johanna Pacevicius Coordinator, Social Policy and Public Health Committee, Assembly of European Regions

Prof. Richard Parish, CBE Professor of Health Development, University of Chester

and international expert on prevention-orientated health policy

Lloyd Russell-Moyle Vice President, European Youth Forum

Agreed, nominee awaited European Primary Care Forum

The project administrator will overview administrative arrangements such as resource monitoring. He/she will also prepare agendas for all the meetings listed, and produce notes promptly noting agreements and actions. He/she will

also provide an administrative link point with the Commission Desk Officer, and partner institutions' administration, in support of the project leader.

The Project Leader and Deputy, supported by the administrator, will monitor progress toward each deliverable and milestone, pro-actively monitoring progress towards achievement. Working with the External Advisory Board, and in liaison with WPs 1 and 10, this WP will also hold ultimate responsibility for ensuring the quality assurance, content review, and final house style of all deliverables.

This work package will, in liaison with the Commission's link officer, review the project's progress across scientific objectives, and its use of resources against budget, at the midpoint of the project. It will also coordinate and hold final responsibility for the final project report, drawing from each work package and linking closely with the Dissemination Work Package 10.

Participation per Partner

Partner number and short name	WP11 effort
1 - ICL	50.00
Total	50.00

List of deliverables

Deliverable Number ¹⁴	Deliverable Title	Lead beneficiary	Type ¹⁵	Dissemination level ¹⁶	Due Date (in months) ¹⁷
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Description of deliverables

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Schedule of relevant Milestones

Milestone number ¹⁸	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS1	Initial Annual Meeting	1 - ICL	4	Initial Annual Meeting
MS7	Successful Final Annual Meeting	1 - ICL	28	Successful Final Annual Meeting

1.3.4. WT4 List of milestones

Milestone number ¹⁸	Milestone title	WP number ⁹	Lead beneficiary	Due Date (in months) ¹⁷	Means of verification
MS1	Initial Annual Meeting	WP11	1 - ICL	4	Initial Annual Meeting
MS2	Web site operational	WP10	1 - ICL	5	Development of MOCHA website
MS3	Protocols and Procedures for Country Agents	WP1	1 - ICL	7	Document to be agreed by EAB and in WP Leaders meeting
MS4	First draft of current models of children's primary health care	WP1	2 - UCD	12	Pertaining to Deliverable 1.3
MS5	Catalogue of child health databases in Europe	WP5	5 - SURREY	15	Catalogue of child health databases in Europe
MS6	Quality Measures and Data Sources Workshop Report	WP5, WP6, WP8	5 - SURREY	21	Quality Measures and Data Sources Workshop Report
MS7	Successful Final Annual Meeting	WP11	1 - ICL	28	Successful Final Annual Meeting
MS8	Coordination and reconciliation of Final Deliverables	WP1, WP9	1 - ICL	31	Coordination and reconciliation of Final Deliverables

1.3.5. WT5 Critical Implementation risks and mitigation actions

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
R1	Project leader or Deputy becomes unavailable.		Each can deputise for the other, delegating other roles. This situation was effectively managed in the RICHE FP7 project, by this Deputy Project Leader without detriment to operations
R2	Project administrator becomes unavailable		Within the lead partner, the project Administrator will be housed with the host institution colleagues, so short-term cover can be provided while other cover is recruited.
R3	A Country Agent ceases to be active or effective		All CAs are part of institutions which should be able to provide cover, and a replacement. If a country agent ceases to be effective, this will not undermine the core work given the spread of all EU and EEA Member States' involvement.
R4	Country Agents not able to supply necessary data		If material is not available, or not found, to answer a specific enquiry from a work package, that itself may be a significant finding. Overall, no single unmet enquiry is likely to provide a significant failing to the project.
R5	Tensions between Work Packages		All WP Leaders have met as part of the proposal preparation. There is already a strong corporate commitment, and team spirit. WP Leaders have been chosen partly for their attitude to collaborative project work.
R6	Specialist Task-specific researcher becomes unavailable.		All specialist input is through an institution. In nearly all cases co-workers have already been informally identified, whether or not formally included in the proposal. No single Task or input is

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
			mission critical, though all are important.
R7	Work Packages fall out of synchronisation		The project has a shared plan, monthly WP Leader teleconferences, and half yearly WP Leader meetings also linked to key topic workshops. Problems should be picked up early and resolved.
R8	A Work Package fails to achieve its objectives		This is unlikely in total, though some components might fail to be achieved. While all WPs and their Deliverables are important contributions to the core objective, only WPs 1 and 9 are mission-critical. WPs 1 and 9 have multiple partners, and direct involvement of the Lead partner and the Project Lead and Deputy, providing several means of early detection and speedy resolution of any problems.
R9	Conflict between WPs on methods or findings.		All scientists are known and have been picked in part for their collegiate approach. Any issues arising will be handled by direct discussion by the Project Leader and Deputy; by discussion at the monthly teleconference; by scheduled discussion at the half-yearly WP Leader meeting; and if appropriate and necessary by reference to the External Advisory Board.
R10	Project encounters professional or political opposition		The evaluation of current models of health care provision for children may indeed cause some anxiety by entrenched professional interests not amenable to evidence-based assessment or change, or from politicians opposed to 'external' influences on national policies. The project has a wide range of stakeholders, including

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
			<p>professional bodies and those with access to politicians at all levels, so as to provide reassurance. These stakeholders will be involved at an early stage in the consideration and validation of future care models. Professionals and policy makers provide input making alignment of these models and national standards possible. The project is designed to have many sources of information and views, and should therefore not be vulnerable to blocking measures. Moreover, the core objective – the best health interests of children – is a powerful supporting argument.</p>
R11	<p>DIPEX Studies do not get satisfactory ethical approval / cannot access wide range of service users</p>		<p>DIPEX is an important means of getting user views. Its international standing, and validated methods, put it in a strong position. However, if unsurmountable problems arise the project can still proceed without this dimension.</p>
R12	<p>The consideration of complex care issues becomes too complex and thus diversionary.</p>		<p>This will be managed by the routine progress monitoring. WP 2 will be kept to its core role of examining interface issues, the maintenance of overall health, and the prevention of adverse additional effects.</p>
R13	<p>There are insufficient published national statistics to provide sources of harmonised quality measures.</p>		<p>This would be an important finding in itself. The WP would then define possible ways forward to address the gap in the future.</p>
R14	<p>Insufficient ethically accessible electronic data sources are identified.</p>		<p>This would be a finding. Multiple sources of identifying potential data stores would be used including professional networks in Europe, and</p>

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
			the reasons for non-access identified and a report produced.
R15	Use Case options limited		Though use-cases cover important scientific questions and/topics the data required to answer the research questions might not be available, cannot be accessed within the project timescale, or need more extensive clinical concept or data construct analysis than resources and time allow. In such event the questions will be narrowed to core concepts and data, and modest support be offered if necessary to data sources to help with data extraction.
R16	Custodians of data sources not willing to take part in a collaborative exercise.		Collaboration through MOCHA would be an important and attractive scientific opportunity. The WP Leader has a high scientific profile in General Practice and Health Informatics contexts in Europe. However, failure to produce analyses would not be mission critical to the MOCHA task.
R17	Australian funding is not forthcoming		In this event the Australian lead scientist will contribute to the External Advisory Board, and on other advisory matters, at own expense via telecommunications.

1.3.6. WT6 Summary of project effort in person-months

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	WP10	WP11	Total Person/Months per Participant
1 - ICL	36	0	0	0	0	0	0	52	8	26	50	172
2 - UCD	12	84	0	0	0	0	0	0	0	2	0	98
3 - UMG	19	5	49	0	0	0	0	0	0	2	0	75
4 - CNR	18	7	0	64	0	12	0	4	0	0	0	105
5 - SURREY	4	0	0	0	35	40	0	4	0	0	0	83
6 - KI	10	0	0	0	0	0	38	0	0	0	0	48
7 - TNO	0	0	4	0	0	0	0	0	31	0	0	35
8 - KCL	10	3	0	0	0	0	0	0	0	0	0	13
9 - UM	2	0	0	0	0	0	0	0	2	2	0	6
10 - MUL	24	0	0	0	0	0	0	0	4	0	0	28
11 - HIH	0	40	0	0	0	4	0	0	0	0	0	44
12 - UI	0	0	0	0	0	0	0	4	0	0	0	4
13 - EUC	10	0	0	0	0	0	0	8	0	2	0	20
14 - UTwente	0	0	0	0	0	0	0	0	8	0	0	8
15 - SDU	0	4	0	0	0	0	0	0	0	0	0	4
16 - KEELE	3	0	0	0	0	0	0	0	0	0	0	3
17 - CHB	0	3	0	0	0	0	0	0	0	0	0	3
18 - CHUV	0	0	2	0	0	0	0	0	0	0	0	2
19 - MCRI	2	30	0	0	0	0	17	0	0	0	0	49
Total Person/Months	150	176	55	64	35	56	55	72	53	34	50	800

1.3.7. WT7 Tentative schedule of project reviews

No project reviews indicated

1.4. Ethics Requirements

Ethics Issue Category	Ethics Requirement Description
HUMANS	- Detailed information must be provided on the informed consent procedures that will be implemented.
OTHER ETHICS ISSUES	- More details of proposed questionnaires must be provided
OTHER ETHICS ISSUES	- Detailed information must be provided on the procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation
PROTECTION OF PERSONAL DATA	- There will be comparative existing policy data abstracted for research but no actual research will be carried out in these countries. The applicant must confirm that the ethical standards and guidelines of Horizon2020 will be rigorously applied, regardless of the country in which the research is carried out
OTHER ETHICS ISSUES	- Details on the procedures and criteria that will be used to identify working discussion groups and research participants need to be provided.
OTHER ETHICS ISSUES	- Detailed information must be provided on the informed consent procedures that will be implemented
PROTECTION OF PERSONAL DATA	- Copies of ethical approvals for the collection of personal data by the competent University Data Protection Officer / National Data Protection authority must be submitted to the EU Commission
OTHER ETHICS ISSUES	- In case of data not publicly available, relevant authorisations must be provided
OTHER ETHICS ISSUES	- The applicant must explicitly confirm that the existing data are publicly available

1. Project number

The project number has been assigned by the Commission as the unique identifier for your project. It cannot be changed. The project number **should appear on each page of the grant agreement preparation documents (part A and part B)** to prevent errors during its handling.

2. Project acronym

Use the project acronym as given in the submitted proposal. It can generally not be changed. The same acronym **should appear on each page of the grant agreement preparation documents (part A and part B)** to prevent errors during its handling.

3. Project title

Use the title (preferably no longer than 200 characters) as indicated in the submitted proposal. Minor corrections are possible if agreed during the preparation of the grant agreement.

4. Starting date

Unless a specific (fixed) starting date is duly justified and agreed upon during the preparation of the Grant Agreement, the project will start on the first day of the month following the entry into force of the Grant Agreement (NB : entry into force = signature by the Commission). Please note that if a fixed starting date is used, you will be required to provide a written justification.

5. Duration

Insert the duration of the project in full months.

6. Call (part) identifier

The Call (part) identifier is the reference number given in the call or part of the call you were addressing, as indicated in the publication of the call in the Official Journal of the European Union. You have to use the identifier given by the Commission in the letter inviting to prepare the grant agreement.

7. Abstract

8. Project Entry Month

The month at which the participant joined the consortium, month 1 marking the start date of the project, and all other start dates being relative to this start date.

9. Work Package number

Work package number: WP1, WP2, WP3, ..., WPn

10. Lead beneficiary

This must be one of the beneficiaries in the grant (not a third party) - Number of the beneficiary leading the work in this work package

11. Person-months per work package

The total number of person-months allocated to each work package.

12. Start month

Relative start date for the work in the specific work packages, month 1 marking the start date of the project, and all other start dates being relative to this start date.

13. End month

Relative end date, month 1 marking the start date of the project, and all end dates being relative to this start date.

14. Deliverable number

Deliverable numbers: D1 - Dn

15. Type

Please indicate the type of the deliverable using one of the following codes:

- R Document, report
- DEM Demonstrator, pilot, prototype
- DEC Websites, patent filings, videos, etc.
- OTHER

16. Dissemination level

Please indicate the dissemination level using one of the following codes:

- PU Public

CO Confidential, only for members of the consortium (including the Commission Services)

CI Classified, as referred to in Commission Decision 2001/844/EC

17. Delivery date for Deliverable

Month in which the deliverables will be available, month 1 marking the start date of the project, and all delivery dates being relative to this start date.

18. Milestone number

Milestone number: MS1, MS2, ..., MSn

19. Review number

Review number: RV1, RV2, ..., RVn

20. Installation Number

Number progressively the installations of a same infrastructure. An installation is a part of an infrastructure that could be used independently from the rest.

21. Installation country

Code of the country where the installation is located or IO if the access provider (the beneficiary or linked third party) is an international organization, an ERIC or a similar legal entity.

22. Type of access

VA if virtual access,

TA-uc if trans-national access with access costs declared on the basis of unit cost,

TA-ac if trans-national access with access costs declared as actual costs, and

TA-cb if trans-national access with access costs declared as a combination of actual costs and costs on the basis of unit cost.

23. Access costs

Cost of the access provided under the project. For virtual access fill only the second column. For trans-national access fill one of the two columns or both according to the way access costs are declared. Trans-national access costs on the basis of unit cost will result from the unit cost by the quantity of access to be provided.

History of Changes		
Version	Date	Changes
2.0	03/02/2015	<ul style="list-style-type: none"> • Deliverable Readjustment across WPs • Beneficiary Replacement: University of Reykjavik was replaced by University of Iceland, due to transfer of PI. No change in work and/or budget required. Both institutions in agreement. (Section 4)
Version	Date	Changes
2.1	16/02/2015	<ul style="list-style-type: none"> • Beneficiary Replacement: University of Lausanne was replaced by Lausanne University Hospital, due to transfer of PI. No change in work and/or budget required. Both institutions in agreement (Section 4) • Clarification of Task 1 description in WP3 (Section 3)
2.2	03/03/2015	<ul style="list-style-type: none"> • Specified Subcontracting and Third Party Involvement description in Section 4.2 • Included Tables 3.4b under “Resources to be Committed”
2.3	09/03/2015	<ul style="list-style-type: none"> • Accommodated latest EC feedback on 05/03

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1. Excellence

1.1 Objectives

This proposal seeks to compare and appraise existing national models of primary care for children, and to bring multi-disciplinary and multi-stakeholder views and approaches, to *develop new, or improve on existing, approaches to prevention, primary care and treatment, and their integration into health services*, specifically for this very important population group. Children form some 20% of the European population, but are recipients of different models of care whose relative merits have not been scientifically studied, and most of which have evolved opportunistically and not necessarily optimally, which means that many children must be recipients of the services of models which are not optimal in prevention, early detection, or effectiveness. Children are thus the inadvertent victims of this lack of scientific study, hence the objectives of this Call provide an ideal and long awaited opportunity which this proposal seek to address energetically.

There are three reasons for focussing specifically on children, who have very different health care prevention and treatment needs from adults, and indeed through the childhood life stages:

- (i) **Societal Duty of Care:** Children are dependent on society to provide their services, as they are not able to advocate for themselves. Letting sub-optimal models perpetuate, through lack of evidence as to how they might be improved, commits millions of Europe's children to less than best primary care, and results in inefficient use of resources.
- (ii) **Children are the Future European Society:** Europe is dependent on an active, healthy workforce, with good mental well-being, as well as future healthy parents and family carers, hence good health and health-enhancing behaviour in childhood have a lasting impact.
- (iii) **Complexity and Variation in Provision:** There is a wide variety of patterns of children's primary healthcare provision in Europe, based on history and tradition but with no scientific evaluation or justification; and known variation in condition-specific mortality (e.g. asthma) and detection related to primary care sensitive health problems (e.g. autism and ADHD), and in coverage by social class, documentation status, gender, and social challenge.

Virtually all preventive programmes for children are undertaken in primary care. Second, many childhood illnesses escalate rapidly and cannot safely wait until normal office hours, so out of hours services are important. Third, programmes aimed at populations, and special access services such as in schools, and for mental and reproductive health services for older children, are part of the primary care preventive picture. The proposal will evaluate models of primary care for children, benefiting from the natural laboratory of the current extensive variety in Europe, defining 'primary care' in the literal sense of 'point of first patient contact', also including the systems of professionals in some countries devoted solely to child public health interventions (such as the *Sozialpädiater* in Germany, and *Jeugdarts* in the Netherlands). Interactively it will raise awareness of the need for change where necessary, and identify the health gain, quality improvement, and economic benefits which could be achieved based on implementing its findings, and convey to public, professionals and policy makers the advantages of the optimal model(s) and how these may be realised. The principal paediatric associations of Europe have already expressed the need for a clear evidence base to distinguish the advantages and disadvantages of the varied current child primary care models, and particularly the dichotomy between national models of either

primary care paediatrician or general family doctors. Additionally, there is little knowledge relevant to 21st. Century Europe of

- the effects on child health of publically funded health systems versus insurance based, and the relative access and provision of services (especially preventive services) to children within these, together with regulatory and governance issues;
- the benefits or otherwise of some direct personal service provision (such as immunisation and screening) by dedicated public sector child health services;
- the role of and provision of different models of school health services;
- models of the availability and adequacy of direct access for adolescents to mental health and reproductive health services in particular, to avoid unnecessary morbidity and mortality;
- models of care for children and their families at the acute-community interface, and at health-social care interface for children at risk or in receipt of social care.

The MOCHA project proposes to:

- provide a description of the different models of children's primary care in Europe;
- devise a range of innovative quality and outcome measures, using statistical and electronic data;
- include children with special needs, are a cause for concern, or have complex needs;
- apply innovative quality measures, and economic assessments, to the models;
- obtain stakeholder experiences, and assess cultural and political contexts;
- assess the current and potential future effect of the models on health inequalities among children;
- model the workforce alternatives of different structures;
- consider models of electronic records as an integral part of a modern effective system;
- obtain stakeholder feedback; and integrating this evidence thus
- identify optimal models of *patient-centred, prevention oriented, efficient, resilient, safe and sustainable* child health system provision, raise awareness of the issues, and disseminate the evidence to stakeholders and policy makers;
- Thereby, through targeted interaction with strategic policy and professional organisations and opinion leaders, to facilitate their realisation in Europe, in policy and practice change, underpinned by identification of the health and economic benefits potentially to be gained.

The project will seek directly to address fully the two evidence-orientated Expected Impacts articulated clearly in the call, holistically in regard to all aspects of primary care for children, and their linkage with partner services for secondary care and social care; and additionally to identify culture and context sensitive means of progressing implementation and achievement of benefits.

1.2 Relation to the work programme

The MOCHA proposal sits very firmly and comfortably within the context of Societal Challenges in health identified in the work programme. It addresses directly issues of improving population health, and increasing the evidence base for health programmes and health delivery. By looking progressively at all age groups of children, particularly through school health and adolescent health, it proposes to shed light on best models for these services to increase self-management of personal health at an early age, thus setting health trajectories for adult and older life. The proposal addresses the challenges of demographic change in two ways – by preparing children as new members of European society to maximise (and be enabled to maximise) their health throughout the life-course and into Active and Healthy Ageing, and by addressing the increasing challenge of skilled human resource availability in health, by looking at necessary professional and skill mix.

The proposal exploits the best of European scientific expertise across many disciplines to give an integrated and cohesive view of the subject – and of development of innovative tools to examine better issues of quality and effectiveness (effectiveness in preventive and early detection services is in effect safety for ensuring health in later life). It also uses the variety of current policy and practice across Europe as a living laboratory, while seeking to stimulate improvement in services for those found to receive sub-optimal models. At the same time the proposal selectively includes world class international experience and scientists from outside Europe. Above all, though, MOCHA seeks to study the services for an important and societally dependent section of the European population – children – who have not had the benefit of significant research attention at the population health and health system levels in recent years, and it addresses research questions which are well articulated, and to rectify the recent lack of study which is unfortunate given the impact of the study areas on European citizens and society.

The proposal addresses the variety of existing models of child health primary care provision in Europe – most noticeably the division between either paediatric primary care provision or general family practice provision – with little existing evidence as to comparative benefits. Overlain on this are different models of school health services, direct access adolescent health services, and varied and often politically driven modernisation drives. Yet at the same time the current variety of provision in Europe, while without scientific justification, will be exploited as a living laboratory by the project.

The approach will be comprehensive, and analyse stakeholder views, health outcomes, workforce implications, and economics. Cultural constraints, and political traditions, will also be assessed as important influences on the nature and pace of change possible (this aspect led from Poland). Health inequalities, gender discrimination, and intra-country variation will be considered. The project will be fully multi-disciplinary, including medical (paediatric and primary care), nursing, statistics, economics, and social sciences among others. The team will combine leadership experienced in European child health projects, specialists in emergent areas, and innovative researchers at early international career stage, thus extending ERA capacity and knowledge. Where necessary, particularly regarding outcome and quality measures, new innovative tools will be developed, based on current pioneering work.

The proposal will therefore directly address the subject of evidence-based modernisation of primary care, focussed specifically on children as a key population group, but one often overlooked in generic health reform. It will draw directly from other European projects including CHILD (on indicators), PHASE (on public health actions for a safer Europe),

EUGLOREH (on state of health), RICHE (on child health research gaps) and TRANSFoRm (on linking health databases), as well from the WHO European Region Child and Adolescent Health and Development Strategy. It shares considerable expertise with all these, facilitating strong team work from the outset. Results will be presented not least in policy making circles, enabling discussion of the nature and direction of change needed in specific settings.

1.3 Concept and approach

The overall concept underpinning the project is that all children are equally entitled to high quality health care (as per the UN Convention on the Rights of the Child, to which all EU Member States are signatories); but that this does not happen in practice (not least identified as a need for action in the Council of Europe's *Strategy on the Rights of the Child 2012-2015*). There is considerable variation in type and levels of provision, and in underlying clinical and societal philosophies, but much of this variety is not justified and is the result of inherited patterns, and on occasion of aspirational or political reforms. Strikingly missing is scientific evaluation of child primary health service patterns, measurement of system performance, outcomes and costs, and modelling of the most effective, affordable and sustainable child-centric provision. MOCHA will seek to address this, involving highly regarded experts in their specific fields. Established methods will be used to analyse the acquired evidence, but where new measures or analytic tools are needed they will be developed – this particularly applies to outcome and quality measures, and to analysis of the systems and utility of electronic records and data sets. Stakeholder views are vital, as services that are not attractive and conducive to children (or for younger children, to their parents) are of compromised utility. Resources will therefore be included for stakeholder interviews, focus groups, and use of the DIPEX method (www.dipexinternational.org) in several countries. And while the focus is on primary care, the interface with secondary care is essential for effective treatment and long-term care, and with social care for children at risk, so this will benefit from a specific work package to feed into the primary care optimisation.

For existing models assessed the project will be operating at Technology Readiness Level TRL 9 – actual system proven in operational environment. New models considered from needs analysis will in general be at TRL 7 – system prototype demonstration in operational environment.

Past European research or projects which will be built on include CHILD (on indicators), PHASE (on public health actions for a safer Europe), EUGLOREH (on state of health), RICHE (on child health research gaps), and TRANSFoRm (on linking health databases); development of the WHO European Region Child and Adolescent Health and Development Strategy; and the study underpinning Wolfe and McKee (2013) *European Child Health Services and Systems: Lessons without Borders*. The paediatric associations of Europe have already met in 2013 (prior to knowledge of the Horizon 2020 call) to seek to progress the core research on evaluating the basic different child primary care models, and that intent is now included in this proposal. The proposal also includes the Chair of the European Federation for Medical Informatics Primary Care Group, and the Chairs of the EUPHA Child and Adolescent Health, and Health System Research, Working Groups, and there will be ongoing synergy. A paper on this research subject need was been accepted by the Health Services Research conference held in May 2014, and the presentation was well-received as an important, needed, and well-framed study of European significance.

The project's scientific work packages will be led by subject experts, iterating with a network of field agents accessing local indigenous material, gathering defined facts and policies from Member States (including EEA States), in a number of cases with additional resources to enable focus groups and stakeholder interviews. This method was used successfully in the CHILD, PHASE, and RICHE projects, so is feasible, though this scale will be larger and more inter-active. The project will be able to draw from:

- Experts who were country representatives in the EU CHILD and RICHE projects;
- Members of DIPEX International (Spain, Czech Republic, UK, Germany, Netherlands);
- The operational membership of the European paediatric societies
- International support (largely self-funding) from international experts from Australia, Switzerland, and the United States of America.

An External Advisory Board will ensure scientific and professional validity. It will comprise members of European medical, paediatric and policy bodies, a senior nurse researcher WHO European Regional Office, UNICEF Innocenti Research Centre, and civil society groups including a young person from the Youth sub-group of the European Patients' Forum.

The Dissemination actions will include awareness raising through policy, professional and stakeholder forums and use of different media. Scientific and policy-oriented results will be compiled in a series of reports including models of primary child health care, the innovative and other tools developed and applied, and statements of effective implementation and change management.

An ethics review will be organised mid-term by the Commission. This review is subject to later confirmation.

1.4 Ambition

This proposal is knowingly ambitious as befits a proposed project which will have benefits throughout their lifetime for all the children of Europe and their successors. It will examine in detail and from relevant dimensions a question which should not remain unanswered – namely what is the most effective model of provision of primary health care for children, an issue which affects not just children but is an essential underpinning to the justified European drive for healthy ageing, and to address the growing crisis of the rise in avoidable chronic illness through non-communicable diseases. It is also ambitious in developing tools relating to quality measurement, skills requirements, economic and financing frameworks, and e-health support to modern models of child health care. It is also ambitious in that it seeks to ensure equity in these future optimised models of care, and also to ensure that complex needs, and complex conditions such as mental health, are adequately supported by the same models which may be optimal for the majority. Thus this proposal therefore seeks support for a large work programme which addresses all issues, and also all stakeholder groups. But this is far more effective, and will lead to a far more robust, justifiable and sustainable set of results and deliverables than a cheaper or one-dimensional project, or one which omitted many countries, either of which would have limited robustness and confidence. This proposal addresses a research issue which has been neglected for at least 25 years, and whose results should endure for a similar period. Realistic funding is therefore needed.

The intent is to provide the first ever full analysis of the different models of child primary health care in Europe, together with other first contact services such as school health and adolescent direct access services. The analysis will use proven tools where they exist, but will develop new tools in areas such as outcome measurement where new data sources or analytic techniques are available to be harnessed. Stakeholder view analysis will be important. The proposal will be original in assessing cultural and political barriers to change, and enhancing factors, recognising that with national subsidiarity for health and strong cultural feelings about health provision that scientific evidence alone may not be enough to change the attitudes of public or professionals; decision-making processes especially at implementation level will also be analysed. The scale is ambitious in covering all first health care contact services, together with population programmes, secondary care interface, and EHR support issues, but only a full horizon study will give meaningful results

and avoid the risks of fragmentation or unknown effects of interfaces and excluded components which would be the adverse consequences of narrower studies. Similarly, it is important to look at the evidence from all countries, as each Member State has unique features, innovations and potential evidence, and to draw in (at low cost) key international comparisons.

While taking a pan-European view of common evidence standards, it will recognise that optimum models need to be flexible to accommodate local factors and needs within countries. It will emphasise the importance of models being able to accommodate the needs of all children equally according to need, including those with long-term conditions, complex needs, or factors militating against health equality. It will produce evidence of the importance of appropriate modern records and information systems to operate the models of care effectively.

Focussed Interlinked Innovation

The project would develop focussed innovation in a number of respects, and place these results into the public and scientific domain in a way which would seek to stimulate their widespread application. Indeed, the very objectives of seeking to bring children's primary health care support to the fore, and to model the structures, mechanisms, and effects of this are innovative yet of profound societal importance.

First, the **modelling of primary care delivery for children** is itself ambitious and innovative. The paediatric associations of Europe have already met in November 2013, prior to this call being known about, to debate the critical lack of understanding of the different philosophies and structures of primary health care provision for children in Europe, and to consider how to address what was considered to be an urgent and indefensible lack of scientific knowledge. The creation of models at the core of this proposal seeks to address that need, and is appropriately ambitious as it includes study of every European Union and European Economic Area country (except Lichtenstein which is not involved in Horizon 2020).

This modelling will be both in words, through analysis and narrative of policies, funding, staffing models, and regulation; and also in construction of technical models, as Unified Modelling Language (UML) models will be created. The related analyses will be linked to both these forms of model. This will also further the models' understanding and use, as there will be products related both to general stakeholder requirements but also to technical modellers.

Secondly, **coverage of the full spectrum of childhood**, but recognising key stages of transition through the early life course – new born, infancy, pre-school years, school years and increasing autonomy and health behaviour development, and adolescence – is ambitious, though fully in line with the policy of the World Health Organisation Regional Office for Europe and its *European Strategy for Child and Adolescent Health and Development*¹. Primary health care services for children must be considered as a whole, since this is their legal and professional framework and thus their model, but the needs of children related to health, and thus the means of providing services, need significant variations of sub-model by developmental stage. Thus this proposal will consider in particular the variations on models of school health services, and in adolescent direct access services, together with recognition that Accident and Emergency services, and direct public health help lines where available, are adjuncts to core primary care services and compensate

¹ WHO Regional Office for Europe (2005). *European Strategy for Child and Adolescent Health and Development Strategy*, WHO Copenhagen.

their deficiencies, and so must be included as adjuncts to the core model. In each case the project analysis will progress from identification and description of current models to recommendations on the benefits of optimum models.

Thirdly, the proposal is innovative in recognising that though for the majority of children their interface with healthcare is straightforward, for a proportion of children this is not the case. Thus the project will **study the interface of core models of children's primary health care with the needs of children with complex conditions or complex needs**. Too often complex needs are overlooked when studying population-wide systems, disadvantaging a group of children with greatest need, while separately complex conditions, or complex needs, are studied in isolation. The MOCHA proposal will include experts in Europe and the USA already involved in modelling children's complex care, to ascertain the optimal interface models with the host primary care systems – both to aid consumer-orientation and efficiency across the many agencies with primary care often having a core but poorly defined role, but also to ensure that basic preventive health delivery and treatment of inter-current childhood conditions are not overlooked in the focus on the special condition. Similarly other complex needs, such as those where children need social care support relating to health issues, are in the care of the state or are resident in institutions, or face other complex conditions such as a parent with mental illness or households where a child is also a carer, will be considered and interface models devised. Again, this will be innovative work in its own right yet is a core feature of the proposal, as models of primary care which do not handle complexity would fail to meet the needs of all children, or the Call's requirement for *patient-centeredness, efficiency, and resilience*.

Fourthly, to achieve this analysis, as the means to achieving the Call's very valid purpose to *develop new, or improve on existing, models for health systems, in order to make these systems more patient-centred, prevention oriented, efficient, resilient to crises, safe and sustainable*, the proposal includes work packages which will develop **new and innovative measures of quality and outcome**, drawing both from published statistical data and from analysis of the increasingly available large data sets and registers, collaborating with those national data systems' custodians to as to ensure that data are analysed in-country by those already authorised in each setting as locally trusted – though applying agreed project-wide questions. The work packages addressing this innovation in measurement of quality and outcome will identify clinical concepts which can be translated across data sources and systems as well as across models, develop and use ontologies to identify the agreed tracer conditions and clinical concepts, and study causal relations analysis though use of Structural Equation Modelling. This development of analytic measures will be innovative and ambitious in itself, and more so when applied to different primary care models, as well as different Member States' systems of recording, of data management, and of statistical systems. However, while ambitious it is also seen as feasible, being led by European experts in these fields.

Fifthly, the proposal does not overlook health workforce issues, particularly in stringent economic times but also recognising that a model may not necessarily need to be medically dominated, and should have a preventive and patient-oriented philosophy. Therefore, the project will have a **significant focus on workforce and skills mix, and on funding patterns**. These two aspects are distinct, but inter-linked. The variety across Europe will provide a natural laboratory function. Different current national systems allocate different functions and responsibilities to different professions, while at the same time there is no European training standard, nor common agreed educational objectives, for doctors practicing paediatrics and child health in primary care, for nurses working with children in primary care or in the community, for school nursing or other school health staff, or for health professionals receiving children in Accident and Emergency settings – and indeed

there is little modern evidence on which to base such standards. But this set of issues also interlinks with funding patterns, and with remuneration, charging and billing systems, which are often based on professions and on medical or organisational models. Thus these two aspects will be studied in their own right to produce intrinsic findings, but will also be a key input into the global objective of the project to recommend *new, improved, sustainable models*.

Sixthly, the project is ambitious and innovative, but necessarily so, in linking the **study of opportunities for support of modern effective primary care models by electronic records**. Electronic records and e-health should not merely automate and digitise older methods of working and care delivery; conversely, now models which are more efficient and effective, and more personalised, may be possible when enabled by e-health. However, Europe has a poor track record in developing and applying electronic recording methods in child health. The lead of the first implementation in Europe over 50 years ago has been lost, while in recent developments the needs of children for specific development-based assessment and recording is all too frequently lost in the rush to generic systems inevitably based on the needs of adults. The project therefore contains a work package specifically focussing on this issue, and with the intent of identifying the best future model of IT support to children's primary health care models.

Seventhly, the proposal is ambitious, but in line with the call, in **involving a wide range of stakeholders**. The proposal recognises and seeks to incorporate the separate, distinct, and important views, and requirements, of three broad types of stakeholder – politicians and policy makers who decide what model to implement; professional interests including the different health professions but also health system organisations who have to bring to life such models efficiently and effectively; and civil society groups, including health-specific and young people's groups, since the core function of children's primary health care models is to support and promote the health of every child in Europe. Each of these stakeholder groups has views and interests, and each have their own drivers for progress and their own instincts for conservatism and the *status quo*. The project is seeking to engage with a wide range of each of these types of stakeholder – through the External Advisory Board, through work package strands and the experts leading these, through the country agents in each country, and above all through an active dissemination policy which will seek interaction with key events and networks for each type of stakeholder – such interaction has already been requested by several key organisations.

The results will thus be ground-breaking in that they will generate the first ever set of interlinked models for proven optimum delivery of primary health care for children, linking also to the issues of school health services, adolescent direct access services, and inter-linking with models of complex care and for complex needs extending beyond health, and showing resource feasibility including professional and skill mix. The methods will also extend the state-of-the-art of health system research, by developing new analyses of quality and outcome, as well as the potential optimal future roles and methods for use of e-health, and for exploitation of large and 'big' data sets, relating to ensuring safe and effective preventive-orientated services for children. It will also stretch the current state-of-the-art in seeking to engage with the three stakeholder interests of policy makers, professions, and civil society groups (including young people themselves).

2. Impact

2.1 Expected impacts

The proposal welcomes the terms of the Expected Impacts specified in the Call, namely:

- *On the basis of quantitative and qualitative indicators, evidence for new or improved patient-centred, prevention oriented, safe and efficient models for health care systems and services.*
- *Evidence to be used by policy makers and decision makers in making improvements to health and care systems, health and other policies.*

It takes these as its vision, as being fully congruent with its proposers' intentions, stemming not just from the call but from discussions among many of the proposers during professional networking in 2013 before the call was known about. The project will address these purposes with evidence from evaluations, and qualitative analysis of how progress may be made pragmatically.

The project sees as its beneficiaries the children and families of Europe and the professionals who care for them currently through varied historically-based service models. It intends to give thorough scientific evidence of optimal models, tools to appraise quality and effectiveness locally, and evidence on how best to effect modernisation in a politico-cultural context. In identifying means of moving to optimal models of primary care delivery, including effective processes of implementation, it aims to stimulate achievement of more effective and efficient services, to reduce late diagnosis and sub-optimal care, and achieve better health in Europe for today's children – tomorrow's adults.

To achieve this it will stimulate dialogue widely – at scientific conferences (health professional, policy, other scientific), through publications, through social media discussion, utilising societal and political contacts such as in the European Parliament, and at high level settings such as the Bad Gastein Forum. It will promote discussion of its findings and their implications, and of the benefits to be gained by introducing the evidence-based models it identifies, recognising State subsidiarity for health and thus the need to influence policy through well-presented scientific and process evidence.

However, the proposers recognise that even robust scientific results alone will not effect change, however theoretically justified. First, health care is a field of national competence within Europe, and the project can only seek to inform, not instruct. Secondly, both professional interests, and public sentiment and cultural traditions make change in health care provision unwelcome unless clear and strong benefits are shown which will justify the upheaval and change. This is particularly so now at a time of economic stringency coinciding with health care systems universally being stretched due to demographic change and increased enduring chronic illness, since as a result the public may well see any proposed change as disguised budget cutting rather than true improvement. Moreover, in a current era of 'Euro scepticism', messages appearing to show 'European' views on systems of national competence and of societal beliefs (even if uninformed) will be poorly received or even rejected, and thus judicious presentation is essential.

For these reasons the project will have a robust validation approach, stakeholder engagement, and critical review not just of its messages but of its presentation of them. It will include reality checks in its proposal for improved models of children's primary health care, through involvement of researchers into the policy making process, and the policy formulation and presentation processes. While the health system science is the driving force of the proposal,

there will be interaction with stakeholder interests, and analysis of how best to present results to trigger stakeholder interest, and more importantly action. Thus the evolution of the final deliverables will be directly influenced by analysis of how to make such results appealing and irresistible. Additionally, the new knowledge (including methods) will be released proactively into the scientific community, within Europe and internationally.

2.2 Measures to maximise impact

a) Dissemination and exploitation of results

Work Package 10 majors on Dissemination, throughout the lifetime of the project. Dissemination is seen as vital, as being two-way with listening being important, and will be *formative* (disseminating the project's objectives and methods) as well as *summative* (disseminating the findings). Each work package will be involved in dissemination of its specific activities and outcomes (including method development and stakeholder views), and each WP will input to overall holistic dissemination led by WP 10.

There will be two principle sets of communications:

- 1) The Scientific messages which will relate to methods of designing, resourcing, populating, and appraising models of primary health care for children, and their impacts. This will be through conference presentations, stakeholder workshops and peer reviewed journal publication
- 2) Secondly, the policy and adoption implication messages; which are a key end objective of the MOCHA project. However, in full recognition of both the national Member State competence for health systems, and the current groundswell against perceived directional instructions from the European level, these messages will be phrased and delivered in such a way that they are attractive to both national and local policy makers as sound evidence-based advice and not seen as policy directives.

There will be a number of target populations for the dissemination activities. These will include academic, scientific and professional groups and individuals; policy makers (both political and professional) involved in deciding future health policies; and bodies representing parents, children and young people. Much of the dissemination will be at European level and in professional journals, but materials on the project web site (with which other sites will be encouraged to link) will be important, as will targeted national dissemination as recommended by country agents and some publications in selected lay outlets.

The project and its External Advisory Board include persons directly embedded in a number of key scientific and strategic European organisations including the World Health Organisation, Health Forum Bad Gastein, European Public Health Association, European Health Management Association, European Patients' Association, European paediatric networks (such as the European Academy of Paediatrics, European Paediatric Associations and European Confederation of Primary Care Paediatrics), Alliance for Childhood (with its network and regular European Parliament meetings) and Eurochild. Additional key conferences, such as those of nursing associations at European level, will also be targeted, while the European Union for School and University Health and Medicine has offered collaboration.

At the end of the project, WP Dissemination will coordinate extensive promulgation of the results, including creation of electronic and printed versions of the final report and recommendations, and the preparation of a lay accessible public version via the project portal and linkage to other key websites, as well as by direct dissemination. Secondly, a final large

audience conference is planned to promote all the findings on better child primary health models and the effective deployment.

It is anticipated that partners will have full credit for work they have done on technical issues within the project, while acknowledging the source of support, while the consortium as a whole will be credited with corporate reports. All project public documents will be available on the project web site. Partnership work with outside contributors will be handled individually, and particularly the analysis of national data sets by the data custodians of those sets will be managed and stored in accord with their regulations since the project itself will not access the data but will have a shared interest in the findings.

b) Communication activities

Communication will be an essential part of Dissemination, and core to several work packages. Most importantly, the national country agents for each country will be active in communication with, and seeking defined information and views from, sources within country. Many European organisations have already expressed commitment to partnership in communication within their significant networks. The budget allows for significant numbers of conference attendances, and scientific papers will be encouraged throughout – with two dissemination strategies being planned as Deliverables (10.3 and 10.5).

3. Implementation

3.1 Work plan — Work packages, deliverables and milestones

The work plan is simple in concept, as shown by the Gantt and PERT Charts in this section.

Work Package 1 will coordinate the scientific work. A list of Work Packages, Tasks within Work Packages, and Scientific Leads is given here, and the full work package descriptions follow:

[NB. The Italian National Research Council (CNR) has two autonomous units contributing different skills – legally they are one partner, but for effective management within Work Packages the constituent units are shown.]

WP 1. Identification of Models of Children’s Primary Health Care

This will coordinate the scientific work, be the interface with the country agents and the scientific analysts, and will identify the core basic models of primary care provision.

Lead: – Dr. Mitch Blair, Visiting Prof. Michael Rigby, Imperial, London;

Country Agents Network: Dr. Mitch Blair, Imperial, London (UK)

Systematic Reviews/Meta Analysis: Dr. Nadia Minicuci, CNR-IN (IT)

Evidence from Case Studies: Dr. Ingrid Wolfe, King’s College London (UK)

Business model analysis: Dr. Daniela Luzi and Dr. Fabrizio Pecoraro, CNR-IRPPS (IT)

Records and Data: Prof. Simon de Lusignan, University of Surrey (UK)

Incentives, Penalties, and Societal Effects: Dr. Helen Wells, Keele University, (UK)

Patient Experience: DIPEX – DR. Auke Wiegiersma, Groningen, (NL)

Political / Constitutional Context: Prof. Helmut Brand / Dr. Timo Clemens, Maastricht (NL)

National Health and Policy Culture: Dr. Kinga Zdunek, Lublin (PO)

WP 2. Interfaces of Models of Primary Health Care with Secondary, Social and Complex Care

Covering both day-to-day referrals, and management of complex conditions, between primary and secondary care, and the collaboration between health and social care.

Lead: Dr. Maria Brenner, University College Dublin, (IE)

Referral/Discharge Interface: Dr. Ingrid Wolfe, LHSTM, London (UK)

Enduring Complex Conditions: Dr. Maria Brenner, University College Dublin, (IE)

Continuity of Care: Daniela Luzi and Dr. Fabrizio Pecoraro, CNR-IRPPS (IT)

Patient and Family Experience: DIPEX / Dr. Auke Wiegiersma, Groningen (NL)

Nursing and Skills: Dr. Anne Clancy, Harstad University College, Harstad (NO)

Mental Health: Dr. Stine Lundstroem Kamionka, University of Southern Denmark (DK)

WP 3. Effective Models of School Health Services and Adolescent Health Services

Lead: Dr. Daniëlle Jansen and Dr. Auke Wiegiersma, Groningen, (NL)

School-based Preventive Health Care: Dr. Paul Kocken, TNO (NL)

Adolescent Services: Dr. Auke Wiegiersma and Dr. Daniëlle Jansen, Groningen

Prof. Pierre-André Michaud, Lausanne (CH)

WP 4. Identification and Application of Innovative Measures of Quality and Outcome

This WP will devise and apply a number of innovative measures of quality and outcome of child primary care models, based on concepts, analysis of available routine statistics.

Lead: Dr. Nadia Minicuci, CNR-IN (IT) (IT)

Quality Indicators: Dr. Daniela Luzi; CNR-IRPPS, (IT)

WP 5. Identification and Use of Derivatives of Large Data Sets and Systems to Measure Quality

This WP will assess the availability of large data sets, using learning from the TIRRE survey tool (developed as part of the 7th Framework TRANSFoRm project to assess the potential to link health databases) to create a set of common descriptors and ontologies.

Lead: Prof. Simon de Lusignan, University of Surrey (UK)

WP 6. Economic and Skill Set Evaluation and Analysis of Models

Lead: Prof. Graham Cookson, University of Surrey (UK)

Outcomes: Daniela Luzi and Dr. Fabrizio Pecoraro, CNR-IRPPS (IT)

Nursing and Skills: Dr. Anne Clancy, Harstad University College (NO)

Models Analysis: Dr. Nadia Minicuci, CNR-IN (IT)

Labour Economics and Econometrics: Prof. Graham Cookson, University of Surrey (UK)

WP 7. Ensuring Equity for All Children in all Models

Equity across socio-economic, ethnic, and cultural divides, regardless of gender. How different health systems address these challenges will be considered, as will other triggers for inequality such as children in care, children from challenged families, and refugee and undocumented children.

Lead: Prof. Anders Hjern, Karolinska (SE)

WP 8. The Role of Electronic Records and Data to Support Safe and Efficient Models

Lead: Prof. Michael Rigby, Imperial (UK)

Dr. Geir Gunnlaugsson, University of Iceland (IS)

Dr. Adamos Hadjipanayis, EAP / European University of Cyprus (CY)

Architectures: Prof. Simon de Lusignan, University of Surrey (UK)

Secondary Use of Electronic Records: Dr Fabrizio Pecoraro, CNR-IRPPS (IT)

WP 9. Validated Optimal Models of Children's Prevention-Orientated Primary Health Care

This WP is an overarching outcome of the other WPs, drawing on the evidence collected by WP 1 and analysed by the specialist WPs 2-8. It will develop optimal patient-centered and prevention oriented primary child health care models emerging from the analyses in the other WPs, and seek public and stakeholder views.

Lead: Dr. Paul Kocken, TNO (NL)

Macro Models: Dr. Mitch Blair, Prof. Michael Rigby, Imperial, London (UK)

Meso and Micro Models: Dr. Paul Kocken, TNO (NL)

Stakeholder Analysis: Dr. S. Detmer, TNO

Public Perspective/Preferences: Dr. Janine van Til, Twente University (NL)

Transferability: Prof. Helmut Brand / Dr. Timo Clemens, Maastricht (NL)

Dr. Kinga Zdunek, Lublin (PL)

WP 10. Dissemination

Dissemination will be active throughout the project, involving all Work Packages and many stakeholder interfaces.

Lead: Dr. Mitch Blair, Prof. Michael Rigby Imperial, London (UK)

Critical Review: Dr. Kinga Zdunek, Lublin (PL)

Paediatric Networks: Dr. Adamos Hadjipanayis, EAP / European University of Cyprus (CY)

Nursing Networks: Dr. Maria Brenner, UCD (IE)

EUPHA Networks: Dr. Daniëlle Jansen, Groningen, (NL)

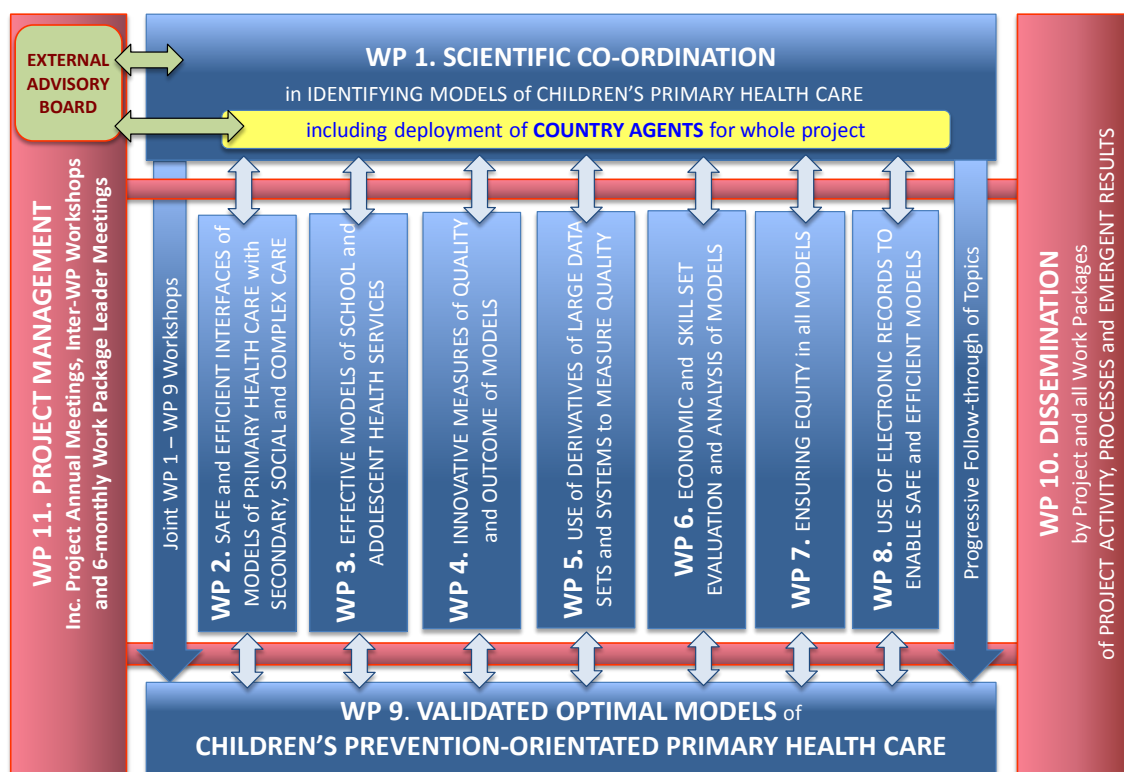
Bad Gastein / Policy Networks: Prof. Helmut Brand / Dr. Timo Clemens, Maastricht (NL)

WP 11. Project Management

Project Leader: Dr. Mitch Blair, Imperial, London (UK)
Deputy Project Leader: Visiting Prof. Michael Rigby, Imperial (UK)

The project will operate on the core basis of 36 months active scientific work. However, to ensure a fast start, there will be a preceding period of 3 months to enable staff to be recruited or freed up, working and business rearrangements to be established, meetings planned and flights booked. Similarly, at the end there will be a further three months for final report writing, and also a final public dissemination conference. Thus the proposal is for 42 months duration, with the full work starting in Month 4. In Months 1-3 there will be only modest preparatory work in work packages, primarily by lead scientists in each work package and institution.

The following PERT diagram shows the relationship between work packages:



The scientific work will be initiated and coordinated by work package 1. This will initiate the process of working with country agents, and will also commence the work of establishing and harmonising across work packages the evidence characteristics for many of the key scientific themes to be developed in each specialist work package – for instance, agreeing the initial scenarios and use cases to be used to illustrate current national models, but also to be used for quality measures and other topics.

Key to WP 1's work will be the management of and interface with the network of Country Agents. Every EU and EEA country is included – 7 are covered by partners, while for the remainder supporting institutions have been identified who will each fulfil a service contract to supply the specified information, and in all but four cases the individual lead scientist or contact has been agreed. The full list is shown here:

MOCHA COUNTRY AGENT TABLE

Country	Institution	Lead Scientist	Status
Austria	Johannes Keppler University, Linz	Dr. Reli Mechtler	Confirmed
Belgium	Université Libre de Bruxelles, School of Public Health	Dr. Sophie Alexander	Confirmed
Bulgaria	National Heart Hospital Sofia	Dr. Vladimir Pilosoff <i>(President of Bulgarian Pediatric Association)</i>	Confirmed
Croatia	LoM	Dr. Ivan Pristas	Confirmed
Cyprus	European University Cyprus (PARTNER)	Dr. Adamos Hadjipanayis <i>(Secretary General, European Academy of Paediatrics)</i>	Confirmed
Czech Republic	Masaryk University	Dr. Ales Bourek	Confirmed
Denmark	Public Health Institute	Hanne Møller	<i>Not yet confirmed</i>
Estonia	National Institute for Health Development	Dr. Toomas Veidebaum	Confirmed
Finland	THL	Prof. Mika Gissler	Confirmed
France	Collège National des Pédiatres Universitaires	Prof. Jean Christophe Mercier <i>(Chair, Collège National des Pédiatres Universitaires)</i> <i>(Chair, European Board of Paediatrics)</i>	Confirmed
Germany	University Clinic Eppendorf, Hamburg	Prof. Ulrike Ravens-Sieberer	Confirmed
Greece	Prolepsis Institute	Dina Zota	Confirmed
Hungary	Institute of Child Health, Hungary	Dr. Gabriella Páll	<i>Not yet confirmed</i>
Iceland	University of Iceland	Dr. Geir Gunnlaugsson	Confirmed
Ireland	UCD (PARTNER)	Dr. Maria Brenner	Confirmed
Italy	CNR-IN (PARTNER)	Dr. Nadia Minicuci	Confirmed
Latvia	Public Health Association of Latvia	Irisa Zile	Confirmed
Lithuania	Centre for Health Education and Disease Prevention	Dr. Diana Mekšriūnaitė <i>(Deputy Head, Division of Noncommunicable Disease Prevention)</i>	Confirmed
Luxembourg	Ministry of Health	Dr. Yolande Wagener	<i>Provisional</i>
Malta	University of Malta	Dr. Natasha Azzopardi-Muscat	Confirmed
Netherlands	University Medical Centre Groningen (PARTNER)	Dr. Auke Wieggersma	Confirmed
Norway	Norwegian Knowledge Centre for the Health Services	Prof. Anne Karin Lindhal <i>(Executive Director)</i>	Confirmed
Poland	Medical University of Lublin (PARTNER)	Dr. Kinga Zdunek	Confirmed
Portugal	University of Lisbon	Prof. Margardia Gaspar de Matos	Confirmed
Romania	University of Cluj	Dr. Maria Roth	Confirmed
Slovakia	tbc	Dr Kvetoslava Prcuchova	<i>Not yet confirmed</i>
Slovenia	Institute of Public Health	Dr. Polonca Truden <i>(Head of Centre for Health and Health Care Research)</i>	Confirmed

Spain	Asociación Española de Pediatría	Prof. Luis Martin Alvarez	Confirmed
Sweden	Karolinska Institute (PARTNER)	Prof. Anders Hjern	Confirmed
United Kingdom	Imperial College London (PARTNER)	Dr. Mitch Blair	Confirmed

To a protocol to be delivered early in the project (Deliverable 1.1) a system will be set up whereby:

- scientists propose questions for the next enquiry period
- these are harmonised by discussion
- a technical sub-group of the External Advisory Board validates the wording
- Country Agents are asked to provide a structured response to a specified timescale
- WP 1 monitors responses
- Commissioning WPs work with the results

It is anticipated that this will work on a monthly cycle.

Work Package 9, responsible for the final report on Validated Optimal Models of Children’s Prevention-Orientated Primary Health Care, will commence work in a small way initially, picking up the scientific themes and early models emerging, and preparing for its subsequent, more intensive work, later in the project.

The specialist scientific Work Packages, WPs 2-8 inclusive, will all work concurrently during Months 4-39. However, though focussed this work will not be undertaken in silos. The project will have three annual meetings attended by all, intervening WP Leaders meetings, and planned special liaison workshops. The structure of the Annual Meeting is intended to maximise cohesion as well as use of travel costs, while ensuring that most personnel only attend for two days. The outline structure of the annual meetings as shown below:

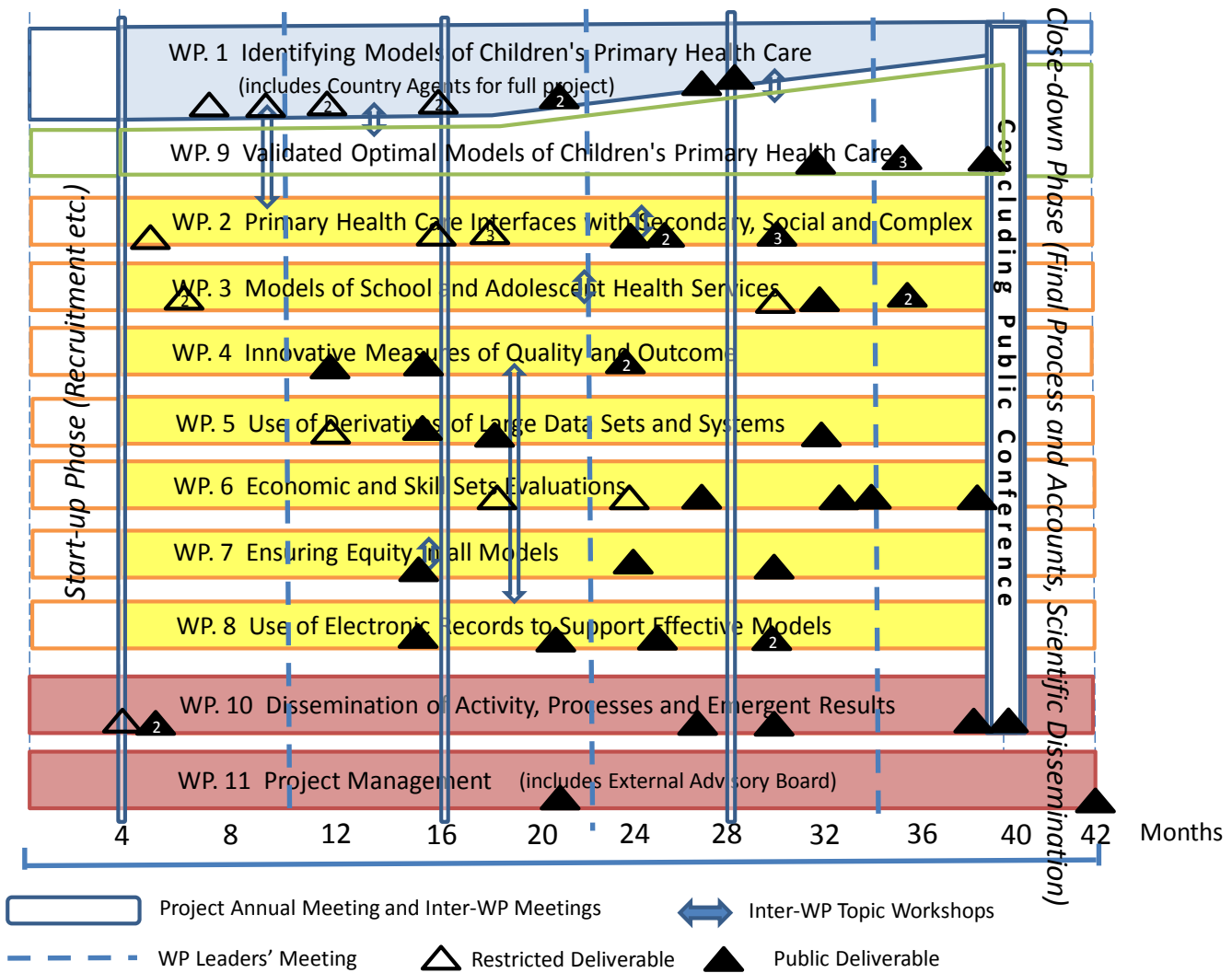
MOCHA Annual Meeting Framework				
Day	Time	Function/ Parallel Functions		People
Day 1	am	WPLs		WPLs
	pm	External Advisory Board (experts)	Country Agents	EAB, CAs
	evening	Optional Informal Meal		
Day 2	am	Annual Meeting		Partners, CAs
	pm	Annual Meeting		Partners, CAs
	Pre-Dinner	Other meetings	WP 8; ad hoc issues	
	evening	Dinner		
Day 3	am	WP Meetings - parallel	1 and 9; 3; 4	Relevant Scientists
	pm	WP Meetings - parallel	2; 5; 6	Relevant Scientists

There is an overall plan of meetings to provide cohesion, and to ensure harmonisation, balancing specialist working with cross-project cohesion and integrated and compatible results. This is shown below, and is accommodated in the budget:

PROJECT-WIDE AND CROSS-PROJECT WORKSHOPS		
Month	Activity	WPs
4	Annual Meeting 1	All, EAB, CAs

6	WP 1	1
10	Expert Panel	EAB
	WP Leaders	WPLs
	WPs 1 + 2 (other WPLs observing)	1, 2, WPLs
14	Coordinating Baseline for 9	1 + 9
15	Exploration of Models of Welfare and Social Care	7 with 2 + 1 + 9
16	Annual Meeting 2	All, EAB, CAs
18	WP 2 Action Planning Workshop	2
19	Quality Measures and Data Sources	4 + 5 + 8
22	Expert Panel	EAB
	WP Leaders	WPLs
	School Health Workshop	3 + reps. from others
26	Mental Health workshop	2 + reps. from other WPs
28	Annual Meeting 3	All, EAB, CAs
30	Coordinating Final Input Verifications for 9	1 + 9
33	Expert Panel	EAB
	WP Leaders	WPLs
37	Expert Panel	EAB
	WP Leaders	WPLs
40	Concluding Conference	All, EAB, CAs

The overall integration of the project, across the 42 months, is shown in this Gantt chart:



As detailed below, the Dissemination Work Package (WP 10) is key to the project. It is intended to be active in dissemination from the start of the project – *Formative* dissemination will advise stakeholder and scientific interests of the intent of the project and its planned methods, and encourage interaction; *Summative* dissemination will share the final results of the project, and of the individual innovative scientific strands. In the middle of the project the intent is that the formative and summative aspects overlap and merge, in that initial methods and emergent findings will be shared and exposed to feedback, which will then influence the later stages of the work.

Dissemination will be aimed at the three broad stakeholder interests of: politicians and policy makers; professional and institutional interests; and civil society and young person interests. Not least, access to their own events will be sought, and in many cases has already been offered; indeed, requested. In particular, one External Advisory Board member represents an NGO which runs regular meetings in the European Parliament on children’s issues, and has made that platform available to the project. Individual project members hold key roles in, for instance, Bad Gastein Health Forum, the European Public Health Association (EUPHA), and many European professional and civil society NGOs, and this will facilitate active and extensive two-way dissemination.

Work Package 11 – Project Management, is the means whereby the project is managed against objectives, budget and timescale. This will be led by the Project Leader and Deputy, each with over 15 years’ experience of European Commission projects, supported by two staff and the technical support of the host institution, Imperial College, London. While the Project Leader is the primary

subject expert as an academic and practicing community paediatrician with extensive project and international experience, the Deputy is a child health expert who has designed and run a number of European projects, all of which have met their full objectives, on time and within budget, as well as producing deliverables over and above those planned. Though based on personal expertise, risk management has been applied and cross-cover deputising is available within WP 11, and with key experienced personnel in other WPs (who in turn could be temporarily replaced).

The following are the individual work package descriptions:

Work package number	1	Start Date or Starting Event	1
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Work package title	Identification of Models of Children’s Primary Health Care
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Participant number	1	2	3	4a	4b	5	6	8	9	10	13	16	19
Short name of participant	ICL	UCD	UMCG	CNR-IN	CNR-IRPDS	Surrey	KI	KCL	UM	MUL	EUC	Keele	MCRI
Person/months per participant Main Scientific work:	36	12	19	14	4	4	10	10	2	24	10	3	2

Objectives
The objectives of this work package are to: <ul style="list-style-type: none"> • Identify the current core models of child primary care and first contact services across Europe and their interface with partner services • Coordinate the scientific work of the country agents • Act as the interface between the External Advisory Board and Country Agents

Description of work (where appropriate, broken down into tasks), lead partner and role of Participants
The description of different models of care provided in member states, Norway and Iceland (Task 4) is a key deliverable for this WP and will be informed by systematic review and meta-analysis of the evidence for different models of care (Task 2), exemplar clinical case scenarios, patient experiences and records, business and incentive systems (Tasks 5,6) and finally cultural-political context (Task 7)
<i>Task 1 – Establish Operational Arrangements for the Country Agents Function</i> Led by the Project Leader and Deputy, this task will initially establish the working arrangements to act as the communications and verification methods for requesting actions of the Country Agents, and getting the endorsement of the Expert Panel. Initially this will involve briefing all parties, then establishing protocols for effective operational working. It will then settle into a systematic process, collecting and harmonising requests from WP leaders, passing them through to the External Advisory Board, then on to country agents in a phased manner, and monitoring the return of replies and the handling of supplementary queries.
<i>Task 2 – Systematic review and meta-analysis</i>

Led by Dr Nadia Minicuci CRN-IN (IT), this will collate the published scientific evidence of European models of primary care delivery to inform the development of a framework describing model type and key characteristics.

Task 3 – Coordination of Work Packages

The project will operate on the basis already established in the preparation of the proposal, entrusting the individual WP Leaders for their work package, having first imbued a strong sense of corporate ethos. There will be WP Leaders Meetings at the start of the project, and then every six months – where possible linked to other activities such as topic workshops. By this means business functioning, scientific activities, and any problems arising will be handled corporately. There will be WP Leader teleconferences monthly to discuss key issues and progress.

Task 4 – Current Models of Child Primary Care

The core scientific task of this WP will be to collate, identify and map the current models of care across all Member States, Norway and Iceland. This will not only form a key deliverable, but it will set the foundations for the remainder of the project. Information will be gathered on the basic model and its regulation through the country agents, and after analysis shared with all the Work Packages as a basis for their work.

Task 5 – Business Models

This work package and WP 2 will address the topics of ‘models of care’ both from the word picture description of a model of care, but also using business modelling. Dr. Daniela Luzi and Dr. Fabrizio Pecoraro, CNR-IRPPS (IT), will narrate the underlying models using UML (Unified Modelling Language) to give a functional diagrammatic picture as well as the word description of each primary health delivery model.

Task 6 – Current Model infrastructure and responsibility

Evidence from Case Studies: Dr. Ingrid Wolfe, King’s College, London (UK) – will lead on case studies to identify how the services operate in the light of specific presentation scenarios that are universal and illustrate aspects of primary care. Case studies are likely to include acute mild illness, acute severe illness, single or simple long-term condition, complex long term conditions, social vulnerability, learning difficulties, and mental health problems. Aspects examined will include mode of presentation (unplanned/planned), access and setting (gatekeeping, choice, co-location, booking system, in hours/out of hours, point of care testing) workforce, and interface with other health and other social services. This work will also draw on her previous work with the European Observatory on Health Systems and Policies, and with work ongoing with, and funded by, the European Paediatric Association.

Records and Data: Linking with WP 8, Prof. Simon de Lusignan, University of Surrey (UK) will look at core record systems and data use as agents of care delivery and coordination.

Incentives, Penalties and Societal Effects

Health care models incorporate in many cases incentives and penalties for compliance and non-compliance respectively, to seek to ensure their coverage and reach. Both approaches (perhaps problematically) assume rational actors operating in ‘logical’ ways but this will often penalise groups of disadvantaged and vulnerable individuals (such as single mothers or families with an ill parent). For *Providers* additional efforts may be required by providers and may well lead to less remuneration and a reluctance to engage fully with such groups. Incentives for *Service Users* may include requirements for complete

immunisation or preventive care clinic attendance as pre-requisites to school admission or child welfare payments but little is known about whether or not the most challenged are simply further disadvantaged. Dr. Helen Wells, of Keele, UK, a criminologist working on the intended and unintended effects of sanctions, will link these aspects to WPs 4, 6, 7 and 9 in particular.

Patient Experience: For five countries that are part of the DIPEX network analysing patient experiences, Czech Republic, Germany, Spain, UK, and The Netherlands, Dr. Manna Alma, Groningen (NL) and Dr. Auke Wieggersma will work with their DIPEX local partners to obtain patient views of the current services. For this, the qualitative research methodology about patient experiences developed by the Oxford Health Experiences Group will be used².

Task 7 Context and Culture

Political / Constitutional Context: Prof. Helmut Brand and Timo Clemens, Maastricht (NL) will use their expertise and linkages to place the models and other findings into political and constitutional contexts, recognising that ultimately as a national competence health systems are decided by local political processes, at national, regional, and local levels.

National Health and Policy Culture: To complement the political context, Dr. Kinga Zdunek, Medical University of Lublin (PL) will analyse the health policy patterns from the angle of four elements: content, actors, contexts and processes³) taking into account strong socio-cultural background of these components.

Deliverables (brief description and month of delivery)

1.1 (Internal) Systematic Review and Meta-analysis of the Literature	Month 9
1.2 Final Report on Current Models of Primary Care for Children, including sections on Context, Operation, and Effects, and related Business Models	Month 21

² Ziebland S, Herxheimer A. How patients' experiences contribute to decision making: illustrations from DIPEX (personal experiences of health and illness). Journal of Nursing Management, 2008; 16:433-439.

³ Buse K, Mays N, Walt G, Making Health Policy, 2005

Work package number	2	Start Date or Starting Event	Month 1
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Work package title	Safe and Efficient Interfaces of Models of Primary Health Care with Secondary, Social and Complex Care
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Participant number	2	3	4b	8	13	15	17	19
Short name of participant	UCD	UMCG	CN-IRPPS	KCL	HIH	SDU	CHB	MCRI
Person/months per participant:	84	5	7	3	40	4	3	30

Objectives

The overall aim of this work package is to examine the primary physician/specialist interface, the interface between primary and secondary care for children with enduring health issues and the social care interface with families of children who have complex health needs. The specific objectives for this work package are to:

- Investigate the appropriateness and effectiveness of the referral and discharge processes of health care for children and young people with potentially enduring conditions, in conjunction with WP 1.
- Provide an the current models of managing care of children with complex needs, including the three broad types of congenital, acquired (by illness or accident) and mental health complex needs, and the relationship to primary care models.
- Assess how primary care services for children interface with social care services across Europe, recognising the need for a symbiotic relationship within the bounds of respectful personalised support, and identify optimal models or factors.
- Examine undergraduate nursing and postgraduate public health nursing programs related to preparedness for care for the child with complex care needs and their families in the primary/secondary interface, in line with maximising care at home.
- Seek user feedback in conjunction with the DIPEX work in WP 1.
- Build a business model of continuity of complex care that will track events that trigger the interaction among primary, secondary and social care services and the stakeholders involved, linking with WP 1.

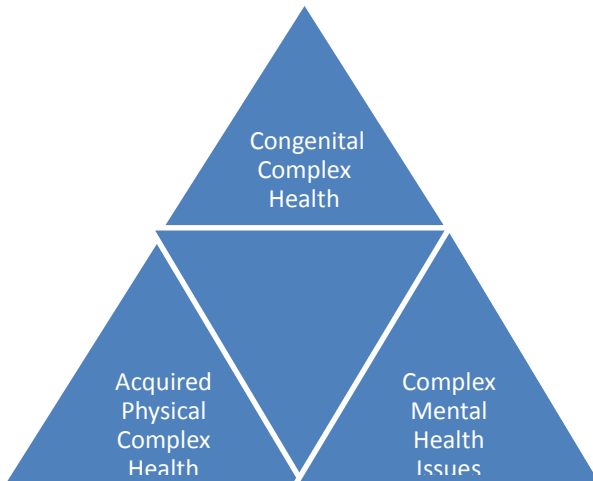
Description of work (where appropriate, broken down into tasks), lead partner and role of Participants)

This work package will identify the interface issues between the primary care (in the different core models identified in WP 1) and the models of delivery of complex health and social care, itself a field inadequately addressed or modelled to date. The outputs from Tasks 1 - 5 will inform Task 6, building a model of complex care delivery to illuminate the need for good interfaces as part of the models proposed by WP 9.

Task 1 - Referral/Discharge Interface

This task, led by Dr. Ingrid Wolfe will explore the boundaries between primary (generalist) and secondary (specialist) care which represents a potential high-risk scenario for quality and timeliness of care and for patient safety, as well as avoidance of unnecessary procedures. This will be a specific dimension of the related Task in WP 1.

Task 2 - Enduring Complex Conditions



Led by Dr. Maria Brenner the aim of this task is to provide an updated comprehensive analysis of the current approach to managing the care of children with complex care needs at the acute community / primary care interface within each Member State. As shown in Figure 1, complex care includes complex physical and complex mental health issues, defined as health issues requiring a range of additional support services beyond the type and amount required by children generally, and needing a high level of effective integration between

Figure 1 Enduring complex care

specialised and general services.

Data will be gathered on policy, practice, communication procedures for integrated care, care coordination and management of the ongoing community hospital interface. A further specific focus will be on children with complex Mental Health needs. Expertise within this work package (Stine Lundstroem Kamionka), within the project (Professor Ulrike Ravens-Sieberer, German country agent), and the External Advisory Board, will inform specific areas for exploration of complex mental health issues. The primary/secondary care interface will also be compared with that in Australia with an emphasis on family experiences and primary care knowledge, barriers and enablers of support for children with complex mental health issues.

Task 3: Social Care Interface

Children live in a social context and their world. In order to achieve the best outcomes for children with complex social-health status circumstances, or complex health conditions requiring also social care support, interventions need to consider and support children in both health needs and social care needs. Lead by Dr Austin Warters the objective of this task is to understand the social care interface with primary care for children and their families, and key success factors and identifiable impediments, and potential effective models explored.

Task 4: Nursing and Skills

Across Europe nursing roles in public health are diverse within the variety of models of health care delivery to children including the following: working in health care teams, and the specific contribution and key role of nurses in each service is often not clearly defined. Led by Dr Anne Clancy this task will link closely to the work in WP 6 in the study of curriculum plans in undergraduate nursing programs and postgraduate public health nursing programs to relate to preparedness for the practice of caring for the child with complex care needs and their families at the primary/secondary interface.

Task 5: Patient and Family Experiences

This task will give insight into the experiences from parents of children with complex needs with the primary/secondary care interface in five European Countries. The task will be lead by Drs Manna Alma and Auke Wiegersma, members of DIPEX-International (<http://www.dipexinternational.org>), as an aspect of the study in WP 1.

Task 6: Business Model of Continuity of Complex Care

Collectively the data from tasks 1-5 will inform the continuing work of Drs Luzi and Pecoraro, which begins in WP 1. The aim is to develop a business model of continuity of care on the different scenarios of integration of primary, secondary and social services using the UML (Unified Modelling Language). This description will be focused on specific scenarios to highlight a) events that trigger the access to primary care, b) actions, tools and data that track the interaction among primary, secondary and social care services, and c) stakeholders involved. This activity will identify strategies used in EU countries to achieve integrated care, and take into account improving continuity of care in terms of communication and messages (e.g. Consorti et al.)⁴.

Deliverables (brief description and month of delivery)

- 2.1** Final report on interface between primary and complex care for all European country primary care models for children and young people. **Month 24**
- 2.2** Final report on the current approach to managing the care of children with complex care needs in Member States **Month 26**
- 2.3** Final report on models of children’s social care support across the EU and the relationship with primary health care. **Month 26**
- 2.4** Report on requirements and models for supporting children with complex mental health needs and the primary care interface **Month 30**
- 2.5** Report on needs and future visions for care of children with complex conditions **Month 30**

⁴ Consorti F, Lalle C, Ricci FL, Rossi-Mori A. Relevance of mandates, notifications and threads in the management of continuity of care; Studies in Health Technol Inform. 2000; 77:1035-9.

Work package number	3	Start Date or Starting Event	1
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Work package title	Effective Models of School Health Services and Adolescent Health Services
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Participant number	3	7	18			
Short name of participant	UMCG	TNO	CHUV			
Person/months per participant:	49	4	2			

<p>Objectives</p> <p>The objectives of this work package are to:</p> <ul style="list-style-type: none"> • To explore the organization, service characteristics and health priorities of various models of school health services and adolescent health services in Europe • To assess effects and outcomes of the various models of school health services and adolescent health services in Europe for children (≥ 4 years of age) and adolescents • To assess the costs of the various models of school health services and adolescent health services in Europe for children (≥ 4 years of age) and adolescents
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<p>Description of work (where appropriate, broken down into tasks), lead partner and role of participants</p> <p>In this work package, the partners led by the Department of Health Sciences of the University Medical Center Groningen (UMCG) will perform an inventory of the approaches and evidence based examples of school health services and adolescent health services within Europe. UMCG, in cooperation with TNO and the Department of Pediatrics of the University Hospital of Lausanne, will analyze the data.</p> <p>This WP will build upon the findings of WP 1, WP 2 and WP 7, while WP 9 uses the findings. Data on evidence based practices will be combined with research into implementation and transferability of preventive primary child health care services, including stakeholder analyses for future changes, planned in WP 9.</p> <p><u><i>Task 1 – Comparison of the various models of school health services (SHS) and adolescent health services (AHS) in Europe with regard to its organization - and service characteristics and practice features.</i></u></p> <p>Led by Dr. Danielle Jansen and Dr. Auke Wieggersma (UMCG), in cooperation with Dr Paul Kocken of TNO and Prof Dr. Pierre-André Michaud (University of Lausanne), this Task will perform a literature review on the characteristics and organizational, and</p>
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practical features of European school health and adolescent health services, based on the six WHO building blocks that together form the basis of a the well-functioning health system (WHO, 2007)⁵ namely service delivery; health workforce; information; medical products; vaccines and technologies; financing and leadership and governance (stewardship). Practice features will be evaluated on the basis of the work by Kuo et al (2006)⁶ involving among other things: first contact with care system, coordination, comprehensiveness, longitudinally, family centeredness and community centeredness. These analyses will inform the detail of the information subsequently requested from Country Agents, which will be compiled and analysed to show each country's service structure against the six WHO building blocks and their operational arrangements against the Kuo practice features.

Task 2 – Assessment of the outcomes and costs of the various models of school health services and adolescent health services in Europe.

School health services will be led by Dr. Paul Kocken (TNO); Adolescent health services by Prof Dr. Pierre-André Michaud, both in cooperation with Dr. Danielle Jansen and Dr. Auke Wiegiersma from the UMCG. Within this work package, a first assessment will be conducted on effects and quality of the different school health and adolescent health services in different European countries. Effects of screening, counseling and advice will be studied, SHS tasks that are in some cases performed in the context of whole school approaches and health promoting school interventions. The assessment will be carried out by both conducting a literature review and the use of country agents who will collect country-specific data. Based on the literature, we will define suitable outcomes of effective health services in the broad range of child and adolescent health, education and social domain. Possibly suitable examples of child and adolescent health are: physical (such as diabetes, overweight/obesity), sexual/reproductive, or mental health and substance use. Examples of education indicators are: school enrolment and school completion rates. Examples of social indicators are: social exclusion, bullying, poverty and levels of crime. On the basis of these suitable outcomes, we will assess the effectiveness and quality of the health services.

Task 3 – To assess the costs of the various models of school health services and adolescent health services in Europe for children (≥ 4 years of age) and adolescents Led by Dr Danielle Jansen and Dr Auke Wiegiersma (UMCG), the costs of the various models of school health services and adolescent health services will be explored by means of gathering data (both in scientific literature and by the use of country agents for data in (inter)national reports and databases) about health care utilization and the costs associated with this health care utilization. The cost-assessment will be consider four key inputs (Kutzin et al, 2010)⁷: human resources, drugs and other supplies, utilities, and facilities and equipment, and there will be liaison with WPs 4 and 5.

Deliverables (brief description and month of delivery)

⁵ World Health Organisation. Everybody's business. Strengthening health systems to improve health outcomes. WHO's framework for action. 2007.

⁶ Kuo AA, Inkelas M, Lotstein DS, Samson KM, Schor EL, Halfon N: Rethinking well-child care in the United States: an international comparison. Pediatrics 2006, 118:1692-1702

⁷ Kutzin J, Cashin C & Jakab M (2010). Implementing Health Financing Reform. Lessons from countries in transition. World Health Organization 2010, on behalf of the European Observatory on Health Systems and Policies.

3.1 Final report on the description of the various models of school health services and adolescent health services, including quality assessments and costs. **Month 36**

Work package number	4	Start Date or Starting Event	1
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Work package title:	Identification and Application of Innovative Measures of Quality and Outcome of Models
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Participant number	4a	4b				
Short name of participant	CNR-IN	CNR-IRPPS				
Person/months per participant:	56	8				

Objectives

1. To harmonize data on primary care collected through any available large primary care datasets, provided by WP-5 (CNR-IN and CNR-IRPPS).
2. To collect child health validated indicators using existing information (CNR-IN).
3. Analysis of measures of outcome to identify innovative measures and verify their applicability in child primary care models (CNR-IN).
4. Analysis of measures of quality of care to identify innovative measures and verify their applicability in child primary care models (CNR-IRPPS).
5. To apply the SEM/path analysis, using both the harmonised outcome and quality measures and other harmonised predictors, to develop new, or improve on existing, models for health systems (CNR-IN and CNR-IRPPS).

Description of work (where appropriate, broken down into tasks), lead partner and role of Participants

Task 1. Availability and Harmonisation of Available Data
 Lead: CNR-IN. The available consistent and compatible information on primary care will be identified and used with the aim of producing comparable data on the basis of available record systems and large data sets identified in WP 5. Comparable data will be ex-post harmonized, to the greatest extent possible, to facilitate the possibility of investigating on both the cross-national differences of preventive child health programs and the country-specific peculiarities, focusing both on outcome measures (IRPPS) will deal with quality of care (IN).

Task 2. Conceptual Model and Data Availability for Child Health Indicators in Europe
 Lead: CNR-IN. The main goal is to build on the compilation of validated health child indicators among the European countries achieved by the RICHE Project (www.childhealthresearch.eu), and update this if necessary. From this to produce an overview of such indicators to produce a model of the topic distribution of current indicators, and key gaps. Further, the availability of data from European and national sources will be studied to model current potential availability of populated indicators of child health in Europe. This will use among other sources the work of the CHILD

indicators, PHASE, and Determinants of Obesity projects (with which there is continuity of personnel across the MOCHA project).

Task 3. Outcome Measures

Lead: CNR-IN. The main goal is the exploration of a continuum of feasible outcome measures, from the clinical, health status and satisfaction perspectives, that could be used effectively by the stakeholders within diverse structural models (across countries) and paediatric settings to quantify the impact of the paediatric primary care. First step will describe the currently-used measures of outcomes country-specific; second step will provide an overview of the challenges and opportunities encountered in establishing effective outcomes measurement systems for program evaluation; third step will elaborate recommendations for expanding and enhancing current paediatric primary care outcome measurement efforts to achieve three primary goals: comprehensive service assessment, meaningful data collection and interpretation, and outcomes-driven program design and service provision.

Task 4. Quality of Care Measurement

Lead: CNR-IRPPS. To assess the quality of care it is necessary to identify complex and multidimensional relationships between structural assets, organizational characteristics and clinical procedures adopted in EU countries in paediatric primary care. This analysis will be performed following the steps identified in task 3 to achieve the above mentioned three primary goals. Additional efforts to investigate and improve upon existing methods for both the development of quality measures for children and their testing for reliability and validity will be undertaken, using comparison between methods utilized in the EU, United States and Australia.

Task 5. Exploratory Analysis of Causal Relations

Lead: CNR-IN. A structural equation model (SEM) will be used to reveal any invariant “causal” relations, meaning that it will show whether the causal assumptions embedded in a model match a sample of data. SEMs are best suited for quantitative data and when there is a solid theoretical knowledge on the subject of analysis, using both observed and latent data. Special cases of SEM are: factor analysis, path analysis and regression. This statistical approach will be used to investigate both outcomes (IN) and quality of care (IRPPS) measures.

Deliverables (brief description and month of delivery)

4.1. Report on the innovative measures of quality and outcome of child primary care models **Month 24**

Work package number	WP 5	Start Date or Starting Event	1
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Work package title	Identification and Use of Derivatives of Large Data Sets and Systems to Measure Quality
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Participant number	5						
Short name of participant	Surrey						
Person/months per participant:	35						

Objectives

The purpose of the WP is to identify unifying common clinical concepts and related data constructs that enable review of the quality and outcome of alternative models of children’s primary health care across Europe, and to seek means of applying these measures using local heterogeneous data sources. To do this we will:

- Develop key use cases that will provide representative scenarios to compare practice. Example use-cases for illustration only are:
 - a. An acute infection: e.g. Meningitis
 - b. A chronic or recurrent infection: e.g. Otitis media /glue ear
 - c. A chronic paediatric disease e.g. Cystic fibrosis
 - d. A behavioural use case e.g. Hyperactivity
 - e. An immunisation use case e.g. Measles and/or a seasonal one such as influenza
 - f. Governance use case e.g. How to share data about perceived failure to thrive
- Identify data concepts and constructs that can provide comparable quality and outcome measures for identified conditions and characteristics across data sets and sources.
- Identify data and datasets from across Europe that have the potential to yield data to inform about the comparative effectiveness of different models of care, including assessing the availability of data to enable analysis by socio-economic or other demographic factors.. The structure and nature of local data sets and their governance and access controls will be compiled by the country agents who will also look to identify data owners / analysts willing to participate in action orientated public health, biomedical and social research.

Description of work (where appropriate, broken down into tasks), lead partner and role of Participants

Task 1: Technical requirements analysis (generic) & use-cases (study specific requirements) for using child health data; including the development of ontologies for core clinical concepts within the programme.

In conjunction with other WPs we will conduct a **requirements analysis** for measurements of the quality and outcomes of child primary health care:

- Requirements analysis informs what data are needed to fulfil the needs
- Use-cases translate the specific requirements for participation in more detailed quality analysis

The requirements analysis will further develop the process used in the TRANSFoRm project (FP7)⁸ and the ADVANCE project (monitoring vaccine benefit risk in Europe, IMI funded). The country agents will catalogue sources of primary care and child health data, the custodians and access regulations. The scope will be broad, following a method developed to look at primary care data.⁹ We will explore key technical requirements at: (1) Macro – legal, policy and business process levels; (2) Meso – data source and data extraction level; and (3) Micro – data. The focus will be on the development of common quality and outcomes measures. The approach will be broad and inclusive, and include novel data sources (e.g. child protection registries, sentinel practices, etc.), while avoiding a single approach to data. We will seek to look to explore where “Big data” might be utilised in the context of assessing health care models, and where new data processors might be emerging within the health data ecosystem.

Task 2: Identifying candidate data sources

Through the country agents, and other sources such as scientific networks, we will identify and describe databases, registries, and other data sources suitable for participation in child health studies, and seek to ascertain those willing to share data in conjunction with MOCHA. Data sources might include: Immunisation registries, Computerised health care records e.g. hospital discharge registry for ICD diagnoses; Laboratory data, linked to research or other data; Health statistics; Genetic databases; Disease registries e.g. population-based cancer registries; Birth and maternity registries, and associated biobanks; Personal health records; Social care records; and Educational records (for example where immunisation is conditional for school admission).

We will use the **framework for health data source identification, profiling and visualisation** for implementing this task (figure 1).

⁸ de Lusignan S, Cashman J, Poh N, Michalakidis G, Mason A, Desombre T, Krause P. Conducting requirements analyses for research using routinely collected health data: a model driven approach. *Stud Health Technol Inform.* 2012;180:1105-7.

⁹ de Lusignan S, Pearce C, Shaw NT, Liaw ST, Michalakidis G, Vicente MT, Bainbridge M, International and European Medical Informatics Association and Federation Primary Care Informatics Working Groups. What are the barriers to conducting international research using routinely collected primary care data? *Stud Health Technol Inform.* 2011;165:135-40.

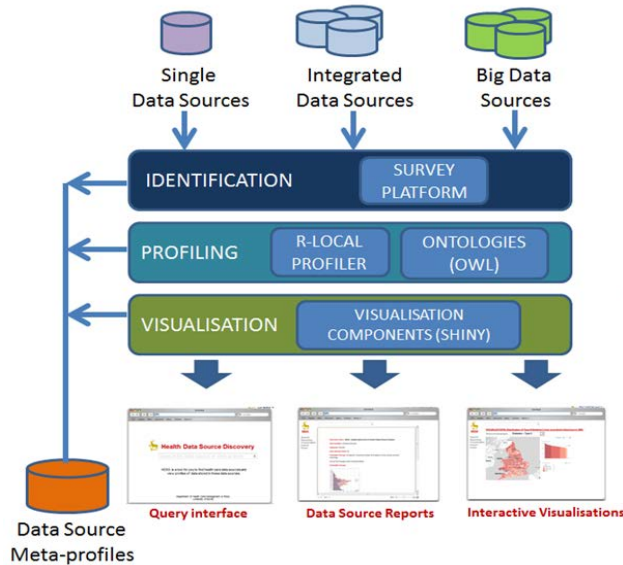


Figure 1: Framework for Identification, Profiling and Visualisation of Health Data Sources

Task 3: Development of common descriptors and ontologies

The work package will develop semantic models such as formal ontologies to represent linkage of clinical concepts, applicable and adaptable to individual regions or member states health systems. We will explore the possibilities for representing the key data quality characteristics of data sources as ontological concepts, using standard ontology building tools according OWL (Web Ontology Language) standard. The developed ontologies will be used to identify tracer conditions and occurrences of common concepts that can be used to draw conclusions.

Task 4: Development of Measures of Quality and Outcomes from large data sets

We will work with WP leads and the External Advisory Board to derive measures of quality and outcome. This work will emphasise particularly on developing measures from large data sets.

Task 5: Application of the Measures through Participating Data Sources

Linking the outcomes of the preceding tasks, but particularly Tasks 2, 3 and 4, we will seek to establish a collaborative and cooperative process whereby data custodians, and analysts approved by them, apply the ontologies and measures to local data sets to operationalise the quality measures of the use cases, and seek to produce results on a common analytic basis from heterogeneous data sources to illustrate the effects of the different child primary health care models. This will generate a key input to the project overall, and particularly into WP 9. Results will be shared incrementally internally, and improved with iteration to enable the work of WP 9 while also strengthening the final deliverable of both WPs.

Deliverables (brief description and month of delivery)

5.1: Semantic models of key clinical conditions and outcome measures	Month 18
5.2: Measures of Quality and Outcomes derived from large data sets	Month 32

Work package number	6	Start Date or Starting Event	Month 1
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Work package title	Economic and Skill Set Evaluation and Analysis of Models
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Participant number	5	4a	4b	11			
Short name of participant	Surrey	CNR-IN	CNR-IPPS	HIH			
Person/months per participant:	40	5	7	4			

Objectives

The overarching objective of this work package is to consider the economic implications of alternative models of child health across Europe. Specifically we will:

- Map and compare the workforce configuration and costs of delivering the alternative models of primary child health care in use in Europe.
- Model the efficiency and effectiveness of alternative models of primary child health care across Europe
- Investigate the impact of reimbursement, payment and incentive systems on the performance of primary child health care systems across Europe

Description of work (where appropriate, broken down into tasks), lead partner and role of Participants

Different models of primary child health will involve different mixes of staff from medical, nursing, social work and allied health professionals and will take place in differing environments and institutional settings. As staffing is the largest variable cost in delivering health care globally, understanding the optimum staffing levels and skill mix is vital to delivering high quality, cost-effective care. Further, there has also been a desire from many governments across Europe to move care away from secondary care settings into primary and community services, yet this has had limited impact in a number of countries (e.g. UK) where in reality there has been an increase in the amount of acute paediatric care occurring in a hospital setting. At the same time, there has been a general policy shift away from primary care paediatric services towards general family practice¹⁰. Finally, the past 20 years has seen a steady change in skill mix with role substitution occurring across medical specialities in Europe. For instance the greater use of

¹⁰ van Esso D, del Torso S, Hadjipanayis A, et al. Primary-Secondary Working Group (PSWG) of European Academy of Paediatrics (EAP). Paediatric primary care in Europe: variation between countries. Archives of Disease in Childhood 2010;Oct,95(10):791-95

unregistered nurses and allied health professionals and the growing number of nurse practitioners or consultants combined with the introduction of non-medical prescribing.

Different models of payment and co-payments exist in Europe, as well as incentivisation through pay per performance schemes (additional to population-targeted incentives). Whilst these are well studied in both general adult primary and secondary care, there is a dearth of studies within the context of paediatric services. This WP will map these changes and their variations across Europe and will then examine the evidence on the cost and effectiveness on child health outcomes.

Lead: Prof. Graham Cookson, University of Surrey (UK)

Outcomes: Dr. Daniele Luzi, IRPPS (IT)

Nursing and Skills: Prof. Anne Clancy, Harstad University College, Harstad, Norway

Labour economics and econometrics: Prof. Graham Cookson, University of Surrey (UK)

Task 1: Map and compare the workforce configuration and costs of delivering the alternative models of primary child health care in use in Europe.

With the support of country agents, and drawing on the emerging models from WP 1, post-doctoral researchers in both Harstad and Surrey this task will be led by Dr. Anne Clancy, Harstad (NO). It will collate and compare the various models of primary child health care delivery across Europe with a focus on the economic aspects of service provision including:

- (i) Workforce: Configuration, training
- (ii) Funding patterns of the different models
- (iii) Payment: provider incentives and payment/reimbursement mechanisms
- (iv) Setting primary care for children in the wider context of secondary and community based services (linking also with WPs 1 and 2),

Harstad will focus on (i) and (iv), Surrey on (i), (ii) and (iii). A combination of data from Country Agents will be required to collate information on the configuration and costs of the alternative models of child health used across Europe. This task is largely descriptive in nature but will inform the models and analysis performed in tasks 2 and 3. This work will take place over months 4-21 with dissemination over months 22-27.

Task 2: Model the efficiency and effectiveness of alternative models of child health care across Europe

This task is dependent upon task 1 from this WP, as well as from tasks from other WPs which will identify and deliver outcome measures and associated control variables. In the framework of the evaluation of alternative models of child health in Europe the evaluation of efficiency and effectiveness of health care delivery services implies the identification of quality indicators pertaining structures, processes and outcomes. Particular attention will be put on how primary, secondary and social care services are delivered to children with complex care needs, linking with WP 2. This analysis will be based on the scenarios identified in previous WPs, on data available at national level (such as service capacity, epidemiology, personnel involved, etc) as well as on data provided by Country Agents, as harmonized by CNR-IN also in WP 4 and now subject to statistical and economic modelling as well as business modelling. Months 22-27.

Surrey will adopt and adapt the models to consider two further questions: (i) the trade-off between efficiency and effectiveness, and (ii) the relationship between skill-mix and outcomes. Months 19-36

Task 3: Investigate the impact of reimbursement, payment and incentive systems on the performance of child health care systems across Europe

Incentive and payment by results schemes are increasingly common place. The UK has both primary (Quality and Outcomes Framework) and secondary care systems in place. Relatively little is known about their implementation and success across Europe specifically in relation to child health. This task will investigate the impact of these systems on the performance of child health care systems in relation to the outcomes identified in earlier work packages. There will be a link to the strand on this topic led from Keele in WP 1. Surrey will lead this task. (Months 21-33)

Deliverables (brief description and month of delivery)

6.1. Report on Economic and Workforce Aspects of New Models

Month 39

Work package number	7	Start Date or Starting Event	1
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Work package title:	Ensuring Equity for all Children in all Models
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Participant number	6	19			
Short name of participant	KI	MCRI			
Person/months per participant:	38	17			

Objectives

Objective 1. To support WP 1 Task 2 by reviewing the literature on socioeconomic and sociocultural differences in outcomes of different primary care models for children.

Objective 2. To compare outcomes and performance with regards to Socio-economic Status (SES), single parent household and a migrant/minority in large primary care datasets, provided by WP-5

Objective 3. To compare vaccination rates and participation in screening programs with respect to differences in families by SES, single parent household and migrant background in a country with a generalist physician centered primary care model (Denmark) with that of primary care paediatrician centred model (Italy) and with a nurse centered primary care model (Sweden), and the Danish and Swedish models also compared with those in Australia.

Objective 4. To describe the national policies in Europe for primary care for children with different migrant backgrounds (undocumented, asylum seeking, newly settled, born in Europe), with comparison to Australia.

Objective 5. To review the literature on health care models for children in the child welfare system (co-ordinating with WP 2 Task 3 on Social Care Provision).

Objective 6. To describe the diverse health care models for children in the child welfare system in Europe (co-ordinating with WP 2 Task 3 on Social Care Provision).

Description of work (where appropriate, broken down into tasks), lead partner and role of Participants

Task 1. Literature review of socioeconomic and sociocultural aspects of different primary care models for children.

The scientific literature on studies of outcomes and performance of primary care in different SES groups, single parent household and migrant/minority families will

reviewed based on a systematic search strategy in relevant databases and complimented with grey literature from the national representatives of MOCHA. There will be liaison with the overall literature review undertaken in Task 2, WP 1.

Task 2. To compare outcomes and performance by Socio-economic Status (SES), single parent household and migrant background in large primary care datasets.

The intention is to reanalyze key data provided by WP 5 and WP 4 by indicators of SES, family type and migrant/minority background, and also to compare Australian data.

Task 3. To compare vaccination rate and rates of participation in screening programs, as an outcome of primary care for children, with respect to differences in families by SES, single parent household and migrant background in Denmark and Sweden.

Denmark and Sweden have many similarities in terms of welfare policies and standard of living and vaccination policy, but their primary care models for delivery of vaccinations of children are very different. The Danish model is based on general practitioners while the Swedish model is based on nurses who follow each newborn child with regular visits within a defined geographic area until school start. Interestingly in Australia both models exist and both deliver vaccinations. We will compare vaccination rates in a national data set from Denmark and a regional dataset from Sweden with respect to parental education, income, family type and country of birth of parents. By contrast with Denmark, where primary care physicians are generalists, in Italy there are specific paediatric primary care physicians, giving a potentially deeper clinical knowledge but with less family context and different operational support. These will be contrasted with national Australian data of vaccination rates across similar demographic variables and across providers (nurse and physician).

Task 4. To describe national policies and guidelines in Europe for primary care for children with different migrant backgrounds.

We will collect data from government websites, reports from NGO's and information from the MOCHA country agents for all countries in EU, Norway and Iceland on national policies regarding access to care, funding strategies of and special primary health care resources for children in the various migrant categories undocumented families, asylum seeking and newly settled families, and children born in Europe to foreign-born parents. National guidelines for primary care for children in migrant will also be collected and summarized. We will also compare these with Australia where 24% of children starting school speak a language other than English at home.

Task 5. To review the literature on health care models for children in the child welfare system.

Children in the child welfare system often enter care with many unfulfilled needs of care, because of neglected basic health care in their original family as well as mental health problems. For adolescents in the child welfare system disorders related to illicit drug abuse and sexually transmitted disorders are other important concerns. While in care, the children are often far away from their usual primary care services and information about previous primary care is often lacking. We will review the literature on different health care models for child welfare in a systematic search strategy in relevant databases and complimented with grey literature from the national representatives of MOCHA. This

work will liaise with, and complement, the work of WP 2 on models of social care support for children with complex needs.

Task 6. To describe health care models and best practices for children in the child welfare system in European countries.

We will collect data from national guidelines, government websites and information from the national representatives of MOCHA for all countries in EU, Norway and Iceland on health care models for children in the child welfare system.

Deliverables (brief description and month of delivery)

7.1. Report on national policies for primary care for migrant children in Europe **Month 15**

7.2. Report on differences in outcomes and performance by SES, family type and migrants of different primary care models for children **Month 30**

Work package number	8	Start Date or Starting Event	1
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Work package title	Use of Electronic Records to Enable Safe and Efficient Models
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Participant number	1	4b	5	12	13		
Short name of participant	ICL	CN-IRPPS	Surrey	UI	EUC		
Person/months per participant:	52	4	4	4	8		

<p>Objectives The objectives of this work package are to:</p> <ul style="list-style-type: none"> • Identify the types and models of electronic record system (EHR) supporting child primary health care, and whether these are child health specific EHRs. • Identify any child health agreed standard data sets which are or have the potential to be included in primary care records, national summary records, data exchanges, or similar, as well as parent and personal child held health records. • Identify national or collaborative child health registries, cohort studies, or similar. • Compare the above findings with established coding and standards initiatives at a high level, including SNOMED, ICD-10, DSM5, NANDA and NIC nursing codes, TC251/ISO, and IHTSDO, particularly for areas of omission or conflict. • Identify examples of added value which can be obtained from integrated use of standard records and controlled secondary use of data. • Identify effective initiatives in Europe using mobile (mHealth) technologies including apps, social media, and other innovations directed to families. • Indicate facilitators and barriers to development and maintaining of optimum models of electronic record support to the delivery of primary health care for children, including interface with complex care.
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<p>Description of work (where appropriate, broken down into tasks), lead partner and role of Participants.</p> <p>In the modern era, models of care should not be islands of isolated activity. Electronic records, and other e-health tools, should be supportive tools but should not dominate practice. At the same time, the availability of such tools can enable new models and paradigms of care; indeed, in the future they can be anticipated to be a cornerstone of effective primary care service provision, and individual workers or facilities can operate above their skill level if supported by on line support. However, child health EHRs have had a mixed history in the face of pressures to conform to adult-dominated e-health strategies with less or no child health functionality.</p>

The Work Package will be led by Professor Rigby, Deputy Project Leader, who has over 40 years' experience in child health electronic records, with support from Professor Majeed, Professor of Primary Care and Public Health (both Imperial). Professor de Lusignan (Surrey) will provide links with modern standards work, the European Federation of Medical Informatics Primary Care Group which he chairs, and access to derived data sets. Dr. Pecoraro (CNR-IRPPS) will contribute expertise on secondary data analysis, while Dr. Hadjipanayis (EUC) will provide evidence from EAPRASnet (European Academy of Paediatrics Research in Ambulatory Settings network) surveys which he has instigated. Finally, Dr. Gunnlaugsson (Iceland) will contribute visioning of what can be achieved with an integrated national data set approach.

Most Tasks will be self-contained but be shared within the work package, and with progress being reported to all WP Leaders. However, the WP will hold a Workshop to cross-link emergent findings in Month 26.

Task 1 – Existing and Planned Future Electronic Records Architecture and Systems

The first task will be to ascertain the situation regarding EHRs, and references to child health (or lack of) in future national e-health plans, and also the existence of any other key child health records such as neonate parent held records. Other initiatives, such as telemedicine and telehealth, will also be noted where in significant use. The Country Agents and EPRASNet surveys will be important sources of this baseline information.

Task 2 – Mapping to Standards

These findings will then be studied in more detail to identify agreed data sets and functions, and the degree of commonality or variation, and any rationale including typologies or models of record support to practice. Finally these will be compared at a high topic level across standards such as SNOMED, ICD-10, DSM5, NANDA and NIC nursing codes, the work of TC251/ISO, the International Health Terminology Standards Development Organisation (IHTSDO), and (particularly for ongoing or complex care) to the work of CONTSsys, to identify common solutions, omissions, and possible conflicts.

Task 3 Registries and Added Value Functions

There exist in a number of countries various forms of child register, immunisation register, and the like. These will be identified, and their functions, data sets, and value to child health care identified, both in the context of their current national child primary health care model, and with a view to transferability of best practice. Links will be made to the PARENT and CHICOS EU Projects in particular.

Task 4 – Secondary use and other Added Value from EHR Systems

While electronic records are primarily created by and for doctors and other health professionals to support the care delivery process, increasingly it is recognised that significant new knowledge about care, treatment outcomes, and aetiology can be gained using Large Data and Big Data analyses methods, and there are different successful experiences in the use of EHR systems for secondary purposes, such as clinical research, epidemiology, pharmacovigilance, and comorbidity detection. Coding standards as identified in Task 2 are key to this if cross-system and cross-border aggregations and analyses are to be possible. Major current large scale or innovative examples relating to primary care child health will be sought from current systems in Europe, linking also back to the host primary care models and record support models for child primary care, so as to yield guidance for future best practice.

Task 5 – Whole System Approaches

The new potential of using whole system approaches to target preventive care and stratify other care, using integrated national standards will be explored based on the example of Iceland. This will be compared to other initiatives identified across Europe, from elsewhere in the literature, and from Professor Rigby's involvement with OECD work on Smarter Health and Welfare Systems (2013), to identify possible future models.

Task 6 – Supporting New Models of Care

This work package will also iterate with Work Package 1, identifying current models of care, and Work Package 9, giving guidance and evidence for future models. Informatics and e-health should support practice not determine it, but conversely these technologies can improve the targeting and efficiency of delivery and enable new models to be developed. This Task will therefore relate the Work Package's findings to the findings of WP 1 to link models of practice with innovation in electronic record systems. Conversely, in WP 9 the potential of e-health to enable leaner, more responsive, or better outcome models will be input as part of the formulation of WP 9 deliverables.

Deliverables (brief description and month of delivery)

8.1 Future Achievable Potential Models of Child Health Electronic Record Systems to Support Care Delivery **Month 30**

Work package number	9	Start Date or Starting Event	1
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Work package title	Validated Optimal Models of Children’s Prevention-Orientated Primary Health Care
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Participant number	7	1	9	10	14		
Short name of participant	TNO	ICL	UM	MUL	UTwente		
Person/months per participant:	31	8	2	4	8		

Objectives

The objectives of this work package are:

- Further development of optimal, sustainable and cost-efficient patient-centered and prevention oriented primary child health care models emerging from the analyses of the other WPs.
- Testing of primary child health care models against the needs of addressing specific preventable conditions in European countries and showcasing of existing innovative evaluated practices.
- Estimating the citizens’ perceived benefits of primary child health care models, including the existing ones.
- Analysis of views of stakeholders on the vital changes necessary and achievable in policies to improve the primary child health care systems.
- Analysis of the transferability of primary child health care models by means of assessing how best to engender an evidence-based approach to policy making and analysis of governance styles to patient-centered and prevention oriented primary child health care models.

Description of work (where appropriate, broken down into tasks), lead partner and role of Participants

This WP will develop optimal patient-centered and prevention oriented primary child health care models emerging from the analyses of WP 1 and the other WPs. Based on the outcomes of the other WPs optimal models of primary care for children will be chosen. The conditions for implementation of the alternative models, transferability and preferences of general public will be tested at macro, meso and micro level using quantitative and qualitative methods. The potential implementation and transferability of the alternative models on effectiveness, costs and equity of child health services will be postulated based on identified national principles for health systems and for policies relating to children, as well as policy cultures. The results will be promulgated for

discussion at high-level European, political and NGO events. This will enable active iteration and development of hypothesised models.

This WP is led by TNO. Maastricht University and Medical University of Lublin are responsible for the analyses at macro level, TNO at meso level and University of Twente at micro level. Imperial College London (leader of WP 1 and the Dissemination WP 10) will supervise the development of optimal primary child health care models.

Task 1 – Organise multidisciplinary workshops to further develop optimal models

Lead: Imperial College London.

A starting workshop with WP 1 and leaders of WPs 1-8 will clarify and formulate a set of optimum models that are representative for the child health care systems in the EU and have the highest prospects for sustainability and cost-efficiency. Ensuing workshops, primarily at conferences such as EUPHA and meetings of the European pediatric associations, will ensure iterative development. Special attention will be given to issues of implementation, and sustainability and cost-efficient preventive youth health care models. This will be a major input into the final Project Report of WP 10.

Task 2 – Verification of the implementation conditions of best practices

Lead: TNO. Medical University of Lublin and Maastricht University contribute.

Promising primary child health care models as selected in task 1 will be tested on typical issues in public health. A comparative case study between member states will be conducted of a choice of innovative best practices such as prevention of SIDS or mental health screening and promotion in children that are encountered in WPs 1-8. These best practices include good practices on which agreement is reached in generally accepted guidelines or standards. The influence of the models of primary child care on the implementation conditions of the cases will be studied using desk research and a survey among policy makers, professionals and other key figures at the macro and meso level. The framework for the analysis will be theories on diffusion and implementation^{11,12}.

Task 3 – Assembling the public preferences for primary care models at the micro-level

Lead: University of Twente. TNO contributes.

Public preferences for prevention oriented primary child health care models emerging from the analyses in the other WPs will be tested, based on the expected outcomes, access and patient-centeredness of care. The results will be used to support policy decision making by identifying the important attributes of a high quality primary health care system according to the public, based initially on a qualitative analysis of key differences between proposed patient-centered and prevention oriented primary child health care models emerging from the analyses in the other WPs (task 1).

Task 4 – Analysis of stakeholders' views at the meso level.

Lead: TNO. Medical University of Lublin and Maastricht University contribute.

This task will seek input of groups of stakeholders on scenarios on how to get to the optimal models as selected in task 1. Based on the influence of primary child care models on the implementation of the examples of best practices of task 2, the necessary changes and expected facilitating and inhibiting factors for implementing the new, optimal models will be included in the scenarios. The acceptance and feasibility of the optimal models

¹¹ Fleuren, M. A., Paulussen, T. G., Van Dommelen, P., & Van Buuren, S. (2014). Towards a measurement instrument for determinants of innovations. *International Journal for Quality in Health Care : Journal of the International Society for Quality in Health Care / ISQua*, doi:mzu060 [pii]

¹² Greenhalgh, T., Robert, G., Macfarlane, F., Bate, P., & Kyriakidou, O. (2004). Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Quarterly*, 82(4), 581-629

will be tested using online focus groups with stakeholders, e.g. policy makers, school health doctors, nurses etc. recruited through the country agents.

Task 5 – Analysis of evidence based policy approaches and governance styles at the macro level in the area of primary child health care models to inform transferability

Lead: Maastricht University. Medical University of Lublin contributes.

This task will start with mapping evidence-based policy making approaches and governance styles to primary child health care models. The transferability analysis will be supported by an assessment of the culture of evidence-based practice. It will focus on how and what kind of evidence is used in decision making processes and how it is implemented to inform policy and practice. It will provide an assessment on knowledge utilization and governance of primary child health care models.

The overall philosophy of the acceptability and preference analysis of WP 9 is based on the understanding of the cascade from optimal theory as study level, through innovation intention at the national policy level, innovation as implemented at the meso level, and innovation is realised at the micro level.

Deliverables (brief description and month of delivery)

- | | |
|--|----------|
| 9.1. An e-book showcasing conditions for implementation of examples of best practices in primary child health care in European countries. | Month 32 |
| 9.2. A report containing consensus statements on most optimal models with guidance on potential benefits and how these might be achieved. | Month 40 |

Work package number	10	Start Date or Starting Event	Month 1
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Work package title	Dissemination
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Participant number	1	2	3	9	10	13	
Short name of participant	ICL	UCD	UMCG	UM	MUL	EUC	
Person/months per participant:	26	2	2	2	2	2	

Objectives

The objectives of this work package are to:

- Ensure that stakeholders (policy makers, professionals, and children, young people and families) are fully aware of the project and its aims and how to engage with it from its inception.
- Ensure that methodologies and interim findings are exposed to critical review, and thus refinement and improvement.
- Ensure that the final results of the project, including deliverables but also wider messages, are promoted widely to all stakeholders and those in positions of influence to leverage maximum impact.

Description of work (where appropriate, broken down into tasks), lead partner and role of Participants

This work package will be the means of a very active engagement and dissemination programme. This will be *formative* (disseminating the project’s objectives and methods) as well as *summative* (disseminating the findings). This work package will work in synergy with each individual work package to facilitate each WP’s own dissemination of specific technical activities, innovations, and findings (with due recognition of the Project context and ownership). The Dissemination work package itself will focus primarily on leading the dissemination of the holistic and integrated activities and results, but will monitor the wider dissemination activities also..

To maximise the impact of our work, we aim to disseminate two principle sets of communications:

- 1) The Scientific messages which will relate to methods of designing, resourcing, populating, and appraising models of primary health care for children, and their

impacts. This will be through conference presentations, stakeholder workshops and peer reviewed journal publication

- 2) Secondly, the policy and adoption implication messages; which are a key end objective of the MOCHA project. However, in full recognition of both the national Member State competence for health systems, and the current groundswell against perceived directional instructions from the European level, these messages will be phrased and delivered in such a way that they are attractive to both national and local policy makers as sound evidence-based advice and **not** as policy directives.

To achieve these objectives, there will be a number of target populations for the dissemination activities, which will also seek to encourage feedback and further evidence. These will include academic, scientific and professional groups and individuals; policy makers (both political and professional) involved in deciding future health policies; and bodies representing parents, children and young people. Much of the dissemination will be at European level and in professional journals, but materials on the web site (with which other sites will be encouraged to link) will be important, as will targeted national dissemination as recommended by country agents and some publications in selected lay outlets.

To cover these objectives partners in the work package, and members of the Expert Panel supporting this work, include persons directly embedded in a number of key scientific and strategic European organisations including the World Health Organisation, Health Forum Bad Gastein, European Public Health Association, European Health Management Association, European Patients' Association, European paediatric networks (such as the European Academy of Paediatrics, European Paediatric Associations and European Confederation of Primary Care Paediatrics), Alliance for Childhood (with its network and regular European Parliament meetings) and Eurochild. Other key conferences, such as those of nursing associations at European level, will also be targeted, while the European Union for School and University Health and Medicine has offered collaboration.

The work package will work by initially commissioning the design and delivery of a project logo and design templates, and a common web portal, then linking with other WP leaders and other project partners to set the pattern of the initial formative dissemination programme. Thereafter, the work package will work closely with the Project Management WP 11, and WPs 1 and 9, and in liaison with all WP leaders, to ensure that all key interim and final results are disseminated appropriately at conferences, working meetings (such as European Parliament and NGO meetings), and in scientific journals – with a balance between dissemination of technical results by WPs and Task leaders, dissemination of higher level policy and choice issues to policy-making stakeholders, and dissemination of integrated project results by this WP. Every opportunity will be taken, within the project resources, to engage in workshops and presentations at professional and stakeholder high-level events to enrich and validate the emergent processes and findings. Conversely, calls for materials for strategic events will be monitored to ensure that there is an appropriate project presence whenever possible. Links will be encouraged between our portal and all the websites of our stakeholders and all organisations (European and national) that might be interested in the results of the project.

At the end of the project, WP Dissemination will coordinate extensive promulgation of the results, including creation of electronic and printed versions of the final report and recommendations, and the preparation of a lay accessible public version via the project portal and linkage to other key websites, as well as by direct dissemination. Secondly, a final large audience conference is planned to promote all the findings on better child

primary health models and the effective deployment. It is intended to seek sponsorship, and to charge a fee for attendees from outside the project, such as to cover most costs.

Deliverables (brief description and month of delivery)

10.1 Functioning web site, including contact details, News and Publications sections, and private working area. **Month 5**

Work package number	11	Start Date or Starting Event	1
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Work package title	Project Management
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Participant number	1						
Short name of participant	ICL						
Person/months per participant:	50						

Objectives
To manage the project effectively.

Description of work (where appropriate, broken down into tasks), lead partner and role of Participants

The Project Management WP will be central to ensuring the smooth running of the whole project. It will be run by the Project Leader and his Deputy, both of whom are experienced in big projects and in European Commission and other international projects. They will work closely with all the WP leaders, while the strong personnel links with WP 1 (Initial Scientific Coordination, and management of Country Agents throughout) and WP 11 (Dissemination), will ensure the strong cohesion of the project, its dissemination, and its impact. They will be supported by a full-time project officer, who will ensure continuous communication with all WP Leaders.

In months 1-3 WP 11 will liaise with each WP leader to ensure that business processes are established, and necessary staff recruited or others freed up as necessary in each partner, so that in Month 4 the project can commence its 36 month core scientific phase at full capacity from the onset.

There will be three main means of coordination of objectives, processes, and scientific integration:

First, there will be an Annual Meeting of all partners and personnel. This will be a one-day meeting involving all partners and country agents. For sake of efficiency, but also to enable good inter-personal linkage to develop, the meeting will be preceded by half-day meetings of the WP Leaders and of the External Advisory Board; it will be followed by opportunity for each Work Package to have its own working meeting, and for some inter-WP discussions. Thus most members will attend for two days.

Second, there will be a physical meeting of the WP Leaders each intervening six months. For all WP Leaders meetings the agenda will be pre-agreed, and will comprise general business items,

discussion of any emergent or possible risks or deviations, and scientific WP linkage topics as appropriate.

Third, there will be a monthly Work Package Leaders’ teleconference, with a notified agenda on the same basis, every month that has no physical meeting.

WP 11 will also manage the six-monthly meetings of the External Advisory Board. This has a strong expert and stakeholder membership, as shown (all are confirmed as shown):

Aneela Ahmed	Young person from Youth Subgroup of European Patients Forum
Dr. Prerna Banati	Chief – Programme and Planning, UNICEF Office of Research (Innocenti Centre), Florence
Vivian Barnekow	Lead of Child and Adolescent Health and Development Programme, WHO Regional Office for Europe
Jeni Bremner	Director, European Healthcare Management Association
Ragnheiður Ósk Erlendsdóttir	Senior Nurse, Primary Healthcare Centre, Iceland
Dr. Katrin Fjeldsted	President, Standing Committee of European Doctors (CPME) (<i>a general practitioner</i>)
Jana Hainsworth	Secretary General, Eurochild
Dr. Johan Hansen	Chair, Health Services Research Group, European Public Health Association (EUPHA)
Dr. Hans Kluge	Division of Health Systems, WHO Regional Office for Europe
Prof. Neal Halfon	UCLA, USA
Michiel Matthes	Secretary-General, Alliance for Childhood European Network Group
Johanna Pacevicius	Coordinator, Social Policy and Public Health Committee, Assembly of European Regions
Prof. Richard Parish, CBE	Professor of Health Development, University of Chester and international expert on prevention-orientated health policy
Lloyd Russell-Moyle	Vice President, European Youth Forum
<i>Agreed, nominee awaited</i>	European Primary Care Forum

The project administrator will overview administrative arrangements such as resource monitoring. He/she will also prepare agendas for all the meetings listed, and produce notes promptly noting agreements and actions. He/she will also provide an administrative link point with the Commission Desk Officer, and partner institutions’ administration, in support of the project leader.

The Project Leader and Deputy, supported by the administrator, will monitor progress toward each deliverable and milestone, pro-actively monitoring progress towards achievement. Working with the External Advisory Board, and in liaison with WPs 1 and 10, this WP will also hold ultimate responsibility for ensuring the quality assurance, content review, and final house style of all deliverables.

This work package will, in liaison with the Commission’s link officer, review the project’s progress across scientific objectives, and its use of resources against budget, at the midpoint of the project. It will also coordinate and hold final responsibility for the final project report, drawing from each work package and linking closely with the Dissemination Work Package 10.

Deliverables (brief description and month of delivery)

3.2 Management structure and procedures

Work Package 1 is the Project Management work package. It will be led by the Project Leader, supported by a project assistant and by the facilities of the host institution.

Each Work Package has been designed by its own team, and prior to that a successful working meeting was held for all the WP Leaders. Thus the project starts with the advantage of shared vision, shared commitment, and mutual support for the leadership and for the partner work streams. There was mutual support for the successful Stage 1 submission, and the composite set of Work Package plans for all work packages has been shared and endorsed by all involved. Thus the project starts with a strong team commitment and mutual understanding of other partners, and of commitment to the task of the proposal.

Within the project, the following will be the means of managing the project and ensuring speedy identification and resolution of any problems:

- Monthly work and progress returns to the project office.
- Monthly telephone conference between WP Leaders, including identification and discussion of any problems arising on progress, resources or other matters.
- Six monthly physical meeting of WP Leaders

For any issues arising within individual partners, the route to managing solutions will be firstly, within the institution to find a solution; secondly within the work package to seek to cross-cover any work problems; and thirdly at project level within the WP Leaders' meeting. In the last resort the Project Leader will have final decision. No partner will be allowed to exceed their budget without appropriate approval and resource transfer. If any partner seeks to (or does) undertake work not in the project plan, or not in accord with agreed procedures (especially with regard to ethics) that work will not be funded.

Additionally, the External Advisory Board of experts will meet six monthly, and be available remotely at other times, to give advice on any scientific or professional issues arising.

The list of milestones is shown here. Not only will it be monitored in the project office, but preparedness will be monitored two months and one month in advance of each.

It is felt that this close but tiered structure, built on the family nature of the project, but incorporating objective measures of progress and of resource consumption, will be appropriate for the project. The early milestones are selected to ensure project progress with foundational facilities and processes, the later ones relate to deliverables which are strategic to other actions and results. Monitoring in the project office, by an identified team member will ensure that an overview is constantly available.

Critical risks have been considered. The risks and controlling or mitigating actions, are shown in table 3.2b.

3.3 Consortium as a whole

The consortium as a whole has been assembled with the goal of matching the scientific objectives and necessary spread and expertise related to the core task in hand – identifying, evaluating and proposing better models of efficient and effective models of primary health care for children – including measurement techniques, stakeholder understanding, and e-health support in the 21st century. All members have been selected for their established and proven scientific strengths, matched also to a proven ability to work as a team. The great majority of partners know one another and collaboration is not new; newer members have been selected for their new skills liked also to the desire to work within a bigger team.

The project and consortium are led by an internationally experienced community paediatrician, and other paediatricians are involved, while there are also two professors of general practice involved – thus the two professional interests of medicine are well and equally represented. There are also other doctors, including public health specialists. Nursing is represented in a number of ways and specialisms.

The consortium also has experts in essential other disciplines, including UML modelling, statistics, quality measurement, e-health and policy analysis. All work package leaders are internationally known in the fields they lead; most are experienced in advising governments or contributing to international professional fora in their respective fields. The cohesion of the WP Leader team is shown by the fact that they have already met specifically to develop and confirm the design and preparation of this proposal, which they see as a very much needed piece of work for the benefit of future European society. The project plan includes regular scientific interaction between consortium members, enabling both scientific cohesion and project coordination.

At the same time, while firmly based on core health sciences and strong experience, the consortium also intentionally includes new concepts and early or mid-career younger scientists. Included in this are the topics of complex mental health issues of children (Dr. Stine Lundstrøm Kamionka, Southern Denmark); sociological and cultural context of policy making (Dr. Kinga Zdunek, Lublin, PL), and the effects of incentives and sanctions (Dr. Helen Wells, Keele, UK) – these young upcoming scientists have already proven themselves by noted publications and presentations at the international level and will add sharpness to the consortium as well as gaining from the opportunity and enriching European research capacity; all are female.

At the other end of the spectrum, the consortium includes two leading American experts (one funded within the project under the EU-US agreement for health research), and a research team from Australia – both these teams are world class, will add expertise and situation comparisons to the consortium, and in each case have collaborated previously with either the Project Leader or a WP Leader.

Other Countries

There are three other countries involved in the proposal – in research-small but impact-high ways.

Switzerland - Prof. Pierre-André Michaud, University of Lausanne, is an international expert on adolescent health, and heads a WHO Collaborating Centre on this subject at that university. He will contribute to the WP on this topic. Funding is planned to be under the bilateral agreement with Switzerland whereby the Swiss government will meet the cost. Thus this gains the project key international expertise in an important subject, and gains external resourcing.

Australia – Murdoch Children’s Research Centre, associated with University of Melbourne and the Royal Children’s Hospital, Melbourne, is an internationally renowned child health research centre. A number of experts – most already known to members of the MOCHA team – will contribute to MOCHA, primarily thought situation and analysis and policy analysis comparisons.

This will provide a benchmark for analysis of the European situation, and will aid stimulation of original and lateral thinking. There is an Australian National Health and Medical Research Council (NHMRC) programme recently agreed for collaboration with Horizon 2020, their European Union (EU) Collaborative Research Grants scheme, whereby if a Horizon 2020 project is approved by the European Commission including an Australian partner, the NHMRC will consider applications for them to fund the agreed Australian input for one institution. This call, PHC-23-2014, is specifically included in this scheme, and funding under it of Australian input would generate added value to the Horizon 2020 funding. Australia will only contribute on this self-funding basis.

United States of America – under an EU-US accord, American partners can be included in projects under the Societal Challenges health topics of Horizon 2020. Boston Children’s Hospital is the child health facility of Harvard Medical School, and within that Dr. Jay Berry is an expert on studying models for the delivery of complex care to children. He is already collaborating with Dr. Maria Brenner of UCD Dublin, MOCHA WP Leader, on this topic. Comparators between Europe and the USA, given the latter country’s plurality of approaches to primary care provision, will enrich the project at modest cost. It will also be likely to give chance to promote the results of MOCHA and European research into the United States – Dr. Brenner and Dr. Berry are already invited contributors to American national research meetings on the topic.

Prof. Neal Halfon of UCLA will contribute to the expert panel, primarily by remote input and has considerable expertise in child health systems and primary care model analysis, leading national cohort studies in North America and has collaborated with the Project lead over many years.

3.4 Resources to be committed

Table 3.4b: ‘Other direct cost’ items (travel, equipment, other goods and services, large research infrastructure)

The project only has one participant whose costs for ‘travel’, ‘equipment’, and ‘goods and services’ exceeds 15% of the personnel costs for that participant (according to the budget table in section 3 of the proposal administrative forms).

P4 - CNR	Cost (€)	Justification
Travel	15000	Participation in MOCHA meetings & events (two institutions in two locations within one partner).
Equipment	8500	Purchase of needed IT equipment to carry out project activities
Other goods and services	56457	Country Agent Assessment and implementing MOCHA surveys and analysis (two institutions in two locations within one partner) + Audit Certificate
Total	79957€	

P7 - TNO	Cost (€)	Justification
Travel	9500	Participation in MOCHA meetings & events (two institutions in two locations within one partner).
Equipment		
Other goods and services	12500	For open publications and preparing an e-book
Large Research Infrastructure	23487	TNO has opted for the LRI scheme in the Participants database of the EC. The LRI scheme has not yet been positively assessed by the Commission. This is in process and in conformity with the procedure which is communicated through the EC.
Total	45487	

P9 - UM	Cost (€)	Justification
Travel	15000	Participation in MOCHA meetings
Equipment		
Other goods and services	1500	Open Access Publications
Total	16500	

P10 – MUL	Cost (€)	Justification
Travel	20400	Travel & Subsistence for MOCHA meetings and conference attendance
Equipment	5250	Laptop and software
Other goods and services	3000	Dissemination and Publications
Total	28650	

P12 – UI	Cost (€)	Justification
Travel	5000	Travel & Subsistence for MOCHA meetings
Equipment	2000	Laptop
Other goods and services		
Total	7000	

P13 – EUC	Cost (€)	Justification
Travel	5500	Travel & Subsistence for MOCHA meetings
Equipment		
Other goods and services		
Total	5500	

P16 – Keele	Cost (€)	Justification
Travel	4643	Travel & Subsistence for MOCHA meetings
Equipment		
Other goods and services		
Total	4643	

P18 – CHUV	Cost (€)	Justification
Travel	5000	Travel & Subsistence for MOCHA meetings
Equipment		
Other goods and services		
Total	5000	

P19 – MCRI	Cost (€)	Justification

Travel	20000	Overseas travel for MCRI staff to participation in MOCHA activities
Equipment		
Other goods and services	5000	Dissemination and Publication Costs
Total	25000	

Section 4 – Members of the Consortium

4.1 Participants

PI - ICL

Description of the institution (Profile)

Imperial College London is internationally renowned for research excellence and its translation to improved quality of life and the environment. It is among the top 10 academic institutions in the world (Times Higher Education, 2014) with an unparalleled record in the application of biomedical research to innovative drug discovery and healthcare benefit. The Faculty of Medicine is at the forefront of this endeavour, with five world leading departments working closely alongside the UK's first Academic Health Sciences Centre (AHSC) to translate research into health outcomes through the Biomedical Research Centre (BRC). Paediatrics and Child Health research majors around infectious disease, allergy and respiratory disease and child public health especially in the area of health services research and preventive care. The AHSC's vision is to improve quality of life of patients and populations by translating discoveries into medical advances, new therapies and techniques, and by promoting their application in the NHS and around the world, in as fast a timeframe as is possible. The work of the AHSC follows four key values; Excellence, Discovery, Innovation and Equity and the patient is central to the pursuit of its goals:

- To utilise the research strengths of the College combined with the critical mass of the Trust to enhance healthcare for patients and populations
- To create powerful new interdisciplinary synergies spanning the College, AHSC and the AHSN to transform healthcare through translational science, bio-engineering and informatics
- To educate and train the future generation of multidisciplinary clinical scientists capable of utilising new technologies for enhanced healthcare
- To translate research into new policies for the benefit of patients nationally and internationally
- To create new wealth through innovation in healthcare, discovery science and population-based translation

Main Tasks undertaken in MOCHA

Imperial will be responsible for overall scientific management and coordination of all MOCHA scientific activities, as well as being responsible for overall consortium management duties.

Imperial will be leading Work-Packages 1, 8, 10 and 11.

As part of its responsibilities in WP10, Imperial will oversee development and implementation of a successful dissemination strategy, ensuring that all partners actively contribute towards effective dissemination activities.

Under WP11, Imperial will be charged with ensuring a strong and smooth collaboration between all project partners, keeping track of all project deliverables and respective deadlines, in order to address the Commission's requirements in terms of progress reporting.

CV of PI and main people involved (including gender):

Prof. Mitch Blair (male) - Mitch Blair is Reader in Paediatrics and Child Public Health and Undergraduate Course lead for Paediatrics and Child Health in the Division
 MOCHA Part B
 Nr. 634201

of Paediatrics since 2005. Dr Blair is a consultant paediatrician and specialist in child public health working from Northwick Park Hospital in Harrow. He has a

background in medical education, epidemiology and health services research. His primary research interests are in preventive child health programmes, child health indicators, and complementary medicine usage in children. He currently directs a multiprofessional group developing e learning for the Department of Health.

Prof. Michael Rigby (male) – is Visiting Professor. He has 45 years' experience in innovation in child health preventive services, commencing in 1970 with development of a computerised pre-school scheduling, screening and recording service for a population of 1.25 million, and he has 25 years' experience of EU projects, 15 of them in project management and work package leadership roles. He is Fellow of the British Computer Society, Chartered IT Professional, Fellow of the Royal Society of Medicine, Fellow of the Royal Statistical Society, Member of the European Public Health Association, and Member of the Society for Social Medicine.

He has a particular focus on child public health information and other public health projects in Europe. He was the creator and Project Coordinator of the Child Health Indicators of Life and Development (CHILD) project 2000 - 2002, within the European Union's Health Monitoring programme - this involved all 17 EU and EEA countries of that time. This led to his working with the European Regional Office of the World Health Organisation on the information aspects of its Child and Adolescent Health and Development Strategy 2005, and the development of the supporting Information and Health Needs tool for country use.

He was Deputy Leader (and for some months locum leader), and a Work Package Leader, for the Framework 7 project Research Inventory of Child Health in Europe (RICHE) (www.childhealthresearch.eu).

Denise Alexander (female) – Researcher (currently at the Department of International Health, Maastricht until approximately January 2015) on large European Union-funded projects – RICHE, TACTICS, PHASE, The Scientific Platform Project on Lifestyle Determinants of Obesity, Supported Socialisation for People with Serious Mental Illness. Produced literature reviews, report writing, editing for final reports.

Analysis and interpretation of report results and synthesis of evidence.

Devised the taxonomy to inform database for large European Research project (RICHE), management of database content in conjunction with IT Web hosting company.

Freelance research work on a number of small projects

Prof. Azeem Majeed (male) – Prof. Azeem Majeed is a Professor of Primary Care and Head of the Department of Primary Care & Public Health at Imperial College London. He qualified at the University of Wales College of Medicine in Cardiff, Wales and is accredited in both General Practice and Public Health Medicine. He began his academic career at St. George's Hospital Medical School as a Lecturer in Epidemiology & Public Health Medicine, and was later promoted to Senior Lecturer in Primary Care. He then moved to a Senior Lecturer post at University College London, where he had a joint appointment between the School of Public Policy and the Department of Primary Care & Population Sciences. In 2000, he gained a five-year primary care senior scientist award, which allowed him to spend more time on research. He was promoted to Professor by University College London in 2002. He took up the post of Professor of Primary Care and Head of the Department of Primary Care & Public Health at Imperial College London in 2004.

His main research interests are in:

- chronic disease management, particularly diabetes & cardiovascular disorders

- health policy and the organisation and delivery of health care
- the use of information for policy, planning and research
- developing innovative methodologies for primary care and public health research using clinical and administrative databases
- the use of new technology to improve health care

List of up to 5 relevant publications/ or products/services/software, other

achievements:

- Blair M, Hall D From health surveillance to health promotion: the changing focus in preventive children's services. Arch Dis Child 91(9):730-735 Sep 2006
- Cowling TE, Harris MJ, Watt HC, Gibbons DC, Majeed A. Access to general practice and visits to accident and emergency departments in England: cross-sectional analysis of a national patient survey. Br J Gen Pract. 2014 Jul;64(624):e434-9.
- Blair M, Debell D. Reconceptualising health services for school-age children in the 21st century. Arch Dis Child. 2010.
- Ottova, Veronika; Alexander, Denise; Rigby, Michael; Staines, Anthony and 31 others. Research Inventory of Child Health: A Report on Roadmaps for the Future of Child Health Research in Europe; Research Inventory of Child Health in Europe (RICHE) Project, Hamburg and Dublin, 2013, 119pp.
- Alexander D, Rigby M, Sjöström M, Frazzica RG, Hillger C, Neumann G, Kirch W (Editors). Challenges and Findings in Measuring the Behavioural Determinants of Obesity in Children in Europe; Huber, Bern, 2010, ISBN 978-3-456-84864-8, 250pp.

List of up to 5 relevant previous projects or activities, connected to the subject of the proposal:

- Collaboration for Leadership in Applied Health Research and Care – North West London – project exploring the interface between primary and secondary care for children with Sickle cell disease, Allergy and Unscheduled care for under fives.
- Research Inventory of Child Health in Europe (RICHE) 2010–2013 (D.G. Research 7th. Framework) – Deputy WP Project Leader
- Public Health Actions for a Safer Europe (PHASE) 2007-2009 (D.G. Sanco Health Programme) – Task Group Leader, Inter-Personal Violence to Children
- Behavioural Determinants of Obesity in Children in Europe 2006-2007 (Scientific Platform of the Working Party on Lifestyle and Specific Sub- populations, D.G. Sanco) – Instigator and Leader of Child programme of work.
- Child Health Indicators of Life and Development (CHILD) project 2000–2002 (D.G. Sanco Community Health Monitoring Programme) – Instigator and Project Manager

Partner 2 – UCD

Description of the institution (Profile)

University College Dublin is one of Europe's leading research-intensive universities. At UCD undergraduate education, master's and PhD training, research, innovation and community engagement form a dynamic spectrum of activity. UCD is Ireland's largest and most diverse university with over 30,000 students, drawn from approximately 124 countries. It actively promotes university life as a journey of intellectual and personal discovery through its highly innovative and flexible UCD Horizons undergraduate curriculum and is the most popular destination for Irish school-leavers. UCD is Ireland's leader in graduate education with approximately 7,000 graduate students, and almost 2,000 PhD students. Over 50% of UCD undergraduate's progress to graduate studies. UCD is home to over 6,000 international students and delivers degrees to over 5,000 students on overseas campuses. In addition, the University places great emphasis on the internationalisation of the Irish student experience – preparing all UCD students for future employment and life that crosses borders, boundaries and cultures. The School of Nursing, Midwifery and Health Systems teaches and many aspects of nursing, including Children's Nursing. Dr. Brenner and Prof. Larkin are actively engaged in partnership work with health service providers, in Ireland and internationally, and the School is active in the Erasmus exchange programme with schools of nursing across Europe.

Main tasks undertaken in MOCHA:

Dr. M Brenner: Work package leader for The Primary/Social Care/Secondary Care Interfaces – Work Package 2.

Task leader within this work package for Enduring Complex Conditions.

UCD Team: Prof P Larkin

CV of PI and main people involved (including gender):

Dr. Maria Brenner (female)

Prof Philip Larkin (male)

CVs attached.

List of up to 5 relevant publications/ or products/services/software, other achievements;

Noyes J., **Brenner M.**, Fox P. & Guerin A. (2014) Reconceptualising children's complex discharge with health systems theory: novel integrative review with embedded expert consultation and theory development. *Journal of Advanced Nursing*, 70(5), 975-996.

Brenner M., Hilliard C., Peel G., Crispino G., Geraghty R. & O'Callaghan G. (2014) Management of pediatric skin-graft donor sites: a randomized controlled trial of three wound care products. *The Journal of Burn Care & Research* (in press).

Brenner M. (2013) Complex care practices: exploring multiple variables using a factorial survey. *Children's Research Network of Ireland and Northern Ireland Annual Conference*, 10th December 2013.

Hilliard C., **Brenner M.**, Wall T., Bennett T., Coughlan B. Regan G. Hayden S. & Drennan J. (2012) Supporting care delivery to children and families in PICU and TCU: a Delphi study of children's nurses' research priorities. *Conference Proceedings – Paediatric Intensive Care Society Annual Scientific Meeting*. 26th September 2012.

Larkin P. (2012) Communicating with Children and their Families during sensitive and challenging times. In Lambert V. *Communication skills for Child Health Nurses*. Oxford University Press

List of up to 5 relevant previous projects / activities (connected to the MOCHA proposal);

Year Awarded	Awarding Body	Study Title	Role
2014	LauraLynn Ireland's Children's Hospice	<i>Evaluating LauraLynn@Home: a pilot hospice at home programme</i>	PI
2014	Resilience Ireland	<i>Evaluation of the Role of the Case Manager for Children and Young Adults with Complex Care Needs in Ireland</i>	PI
2012	Lucille Packard Foundation	<i>Hospital Discharge Planning for Children (Boston Children's Hospital/Harvard)</i>	Collaborator
2012	UCD Seed Funding	<i>Exploring the Constituents of an Effective Transition of a Child with Complex Technological Healthcare Needs from Hospital to Home</i>	PI
	Health Research Board	<i>Feasibility Analysis of Key Performance Indicators for Emergency Departments in Ireland.</i>	Co- applicant

Description of significant Infrastructure/ Facilities to be used/ Major Items of Equipment (relevant to proposed work);

The contribution from UCD will predominantly be desk-based research. No major items of equipment will be required, apart from IT support for two post-docs, one to support the work package and one that will be working specifically exploring the social care

interface.

² A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

Partner 3 –UMCG

Description of the institution (Profile)

The University Medical Center Groningen (UMCG) has a long research tradition with several ongoing large cohort studies (e.g. lifelines) both in general populations as well as in clinical samples. Its core mission is to support and improve healthy ageing with a multidisciplinary approach. It participates in many EU funded projects. The department of Health Sciences/ Community Health conducts many large-scale R&D projects that comprise both social and epidemiological methods. The research usually occurs in close collaboration with partners working in both community settings, e.g. public health services, and clinical services, and with both national and international partners. The department has a structural cooperation with Central European partners, e.g. in Slovakia, Bulgaria and Poland and with various partners in the Baltic region and North America. The program is collaborating with private partners, and with practicing professionals.

Main tasks undertaken in MOCHA:

The UMCG leads Work Package (WP) 3, which explores the organization and service characteristics of various models of school health services and adolescent health services in Europe, the outcomes of these models for children and adolescents and its suitability in different contexts. Moreover, it participates in WP1 and 2. It leads the task of patient and family experiences regarding paediatric primary care (WP1) and the primary/secondary/social care interface (WP2). For this, the innovative patient-centred approach of DIPEX International will be used with six European countries using the Oxford qualitative research methodology about patient experiences. Furthermore, the UMCG will act as country agent for the Netherlands.

CV of PI and main people involved (including gender):

Dr Danielle Jansen (Female) – CV is attached

<p>List of up to 5 relevant publications/ or products/services/software, other achievements;</p> <ol style="list-style-type: none"> 1. Reijneveld SA, Wiegiersma PA, Ormel J, Verhulst FC, Vollebergh WA & Jansen DEMC. Adolescents' Use of Care for Behavioral and Emotional Problems: Types, Trends, and Determinants. <i>PLoS One</i>. 2014 Apr 3;9(4):e93526. 2. Jansen DEMC, Wiegiersma P, Ormel J, Verhulst FC, Vollebergh WA & Reijneveld SA. Need for mental health care in adolescents and its determinants: the TRAILS study. <i>European Journal of Public Health</i>. 2013 Apr; 23(2): 236-41. 3. Spijkers W, Jansen DEMC, Reijneveld SA. Effectiveness of Primary Care Triple P on child psychosocial problems in preventive child healthcare: a randomized controlled trial. <i>BMC Med</i>. 2013 Nov 11;11:240. doi: 10.1186/1741-7015-11-240. 4. Jansen DEMC, Veenstra R, Ormel J, Verhulst FC, Reijneveld SA. Early risk factors for being a bully, victim, or bully/victim in late elementary and early secondary education. The longitudinal TRAILS study. <i>BMC Public Health</i>. 2011 Jun 6;11:440. 5. Oeseburg B, Jansen DEMC, Groothoff JW, Dijkstra GJ and Reijneveld SA. Emotional and behavioural problems in adolescents with intellectual disability with and without chronic diseases. <i>Journal of Intellectual Disability Research</i>. 2010 54: 1; 81-89.
<p>Relevant projects</p> <ol style="list-style-type: none"> 1. Spijkers E, Jansen DEMC & Reijneveld SA. The effectiveness of the Triple P programme to support parenting in Dutch preventive child healthcare: a randomised controlled trial (2008-2012). 2. Nanninga M, Jansen DEMC, Knorth EJ & Reijneveld SA. Entrance to care. Determinants and patterns of health care utilization of children with behavioural, emotional and social problems (2011-2015). 3. Van den Heuvel M, Flapper B, Jansen DEMC, Verkade HJ & Reijneveld SA. Mental health problems in pediatric practice (2011-2015). 4. Jansen DEMC, Holwerda A & Reijneveld SA. Multiproblem families: a program study (2012-2013) 5. Jansen DEMC, Spijkers W & Reijneveld SA. Effectivity of support for multiproblem families. (2014-2019)
<p>Description of significant Infrastructure/ Facilities to be used/ Major Items of Equipment (relevant to proposed work); No significant infrastructure will be required</p>

Partner 4 – CNR

Description of the institution (Profile)

The network of CNR research institutes, which are distributed all over the national territory of Italy, is multidisciplinary: it has competences in the field of health and biology, of computer science, of environment and climate, of chemistry and physics, of behavioural, economic and social sciences. The CNR-Institute of Neuroscience (CNR-IN) performs and promotes research activities in pursuit of excellence and strategic relevance within the national and international ambit facing all the principal topics in the study of the nervous system and cognitive sciences. The Padova section of the CNR-IN has a long-standing experience in carrying out research at national and international level. Researchers' areas of specific expertise include: methodology of research, harmonization of longitudinal studies, statistical modelling; performance of systematic reviews and meta-analysis, development of national health indicators, such as DFLE and DALY, and pharmacokinetics of Alzheimer. Researchers have also a well-recognized experience in designing clinical trials.

Under the CNR-IN umbrella, the Institute for Research on Population and Social Studies (IRPPS-CNR) will also play a crucial part across the project, based on its expertise in the design and development of health care information systems. The Institute conducts relevant research in such fields as the study of the relationship between population trends and social and economic development, applied to several domain among which health economic and health studies in a statistical-mathematical and socio-medical perspective, as well as on the study of social dynamics and policies regarding welfare systems.

Main Tasks undertaken in MOCHA

The Padova section of the CNR has the lead of the WP 4 “Identification and application of innovative measures of quality and outcome”. The main task will be focused on the investigation of the cross-national differences in the effect of the preventive child health programmes based on the path analysis technique. It is also involved in WP 1 to contribute in the harmonization process of the data collected by the country agents, to perform a systematic review of the existing primary care research and a meta-analysis to combine results of individual studies. It is also involved in WP 6 to contribute in the analysis of the economics of the models from

the statistical modelling perspective.

The Padova section of the CNR has a long standing experience in carrying out projects, both at National and European level, either as a principal investigator or as a coordinator or as a WP lead. The main team is constituted by biostatisticians with outstanding experience in conducting observational and experimental study.

Within the FP5, it was both the project leader of the CLESA project (Cross-national determinants of quality of life and health services for the elderly) and the scientific coordinator of the WP “Cross-national comparison of predictors of hospitalisation, institutionalisation, and mortality”. It was a collaborative project including five European and an Israeli longitudinal studies of ageing. The main tasks of the WP were the ex-post harmonization of selected domains and the development of a statistical technique to compare the predictors of mortality across the six countries involved in the project using the harmonized variables.

Within the PHP (DG-SANCO), the Padova section of the CNR was a member of the Injury Data Base (IDB) Population Task Force and was often invited by the EC to present methodological aspect of data collection and was in charge to assist the EC to produce statistics on injury using the IDB data.

Moreover, within the Public Health Action for a Safer Europe (PHASE) - Interpersonal Violence, it was the scientific coordinator of the WP on “Interpersonal violence”. The specific objectives were to map interpersonal violence (with a focus on child maltreatment, youth violence, intimate partner violence and elder abuse) in Europe in terms of size and impact of the problem, information deficiencies and methodological problems. The main task of the WP was to perform a systematic review of the literature-addressing the issue of Interpersonal violence among child, youth, women and elderly-and the consequent meta-analysis and to produce the deliverables that consisted in the elaboration of four fact sheets on Interpersonal violence in EU+ on epidemiological measures of violence and currently available public health information on interpersonal violence, identifying gaps and recommend improvements.

The Padova section of the CNR is also actively involved with the World Health Organization (WHO), being member of the WHO project “Study on Global Aging and Adult Health (SAGE)” project team and a member of the advisory board of the project ““WHO Study on global aging and adult health (SAGE): Harmonizing health outcomes and determinants across longitudinal studies on aging”.

The CNR-IRPPS, for its part, will support MOCHA through the following activities:

- Modelling of health-care business processes using UML language and BPMN notation to describe scenarios in terms of actors involved, activities performed and information exchanged;
- Developing data models to integrate information collected in different heterogeneous sources;
- Use of health care record for secondary purposes to develop clinical indicators for quality assessment, taking into account structure, process and outcomes of health care services.

CV of PI and main people involved (including gender):

- **Dr. Nadia Minicuci (female)** —Researcher at the National Research Council, Institute of Neuroscience, Padova, Italy Ph.D. in Statistics, University of California, Santa Barbara, Department of Statistics and Applied Probability (USA) in 1993.
- Master in Mathematical Statistics, University of California, Santa Barbara, Department of Statistics and Applied Probability (USA) in 1990.
- Degree of Doctor of Statistics and Economics, University of Padova, Department of Statistics (Italy) in 1985.
- **Dr. Daniela Luzi (female)** – Researcher at IRPPS. Her research interests have privileged the analysis of the impact of ICTs on information management and communication processes in health care. Within this context, research topics such as the analysis of clinical trial protocol under a semantic and structural perspectives as well as modeling of the process, have been deal with in scientific papers and publications. She has participated in several EU projects and was responsible for national projects where information systems were designed and developed.
- **Dr.FabrizioPecoraro (male)** – Has a degree in Computer Engineering in Rome and is a Philosophy Docotrate in Bioengineering.

During his doctorate studentship period, he also held the position of assistant researcher at the University of Strathclyde in Glasgow, Scotland. Since 2007 he works as a researcher at the Italian National Research Council, where his research activities have mainly focused on business process analysis, development of conceptual models based on standard clinical data such as HL7 and CDISC, design and development of information systems.

List of up to 5 relevant publications/ or products/services/software, other achievements:

1. Sociodemographic and socioeconomic patterns of chronic non- communicable disease among the older adult population in Ghana. (Minicuci N, Biritwum RB, Mensah G, Yawson AE, Naidoo N, Chatterji S, Kowal P). *Glob Health Action. Apr 15;7:21292*
2. Hypertension among older adults in low- and middle-income countries: prevalence, awareness and control (Lloyd-Sherlock P, Beard J, Minicuci N, Ebrahim S, Chatterji S). *Int J Epidemiol. Feb;43(1):116-28.*
3. **Fabrizio Pecoraro, Daniela Luzi, Fabrizio L. Ricci. A Clinical Data Warehouse Architecture based on the Electronic Healthcare Record Infrastructure. *Proceedings of 7th International Conference on Health Informatics (HEALTHINF), Angers, France, March 3-6, 2014. ISBN: 978-989-758-010-9.***
4. Oscar Tamburis, Fabrizio L. Ricci, Fabrizio Pecoraro. A Mathematical Model to Plan the Adoption of EHR Systems.*In: John Wang. Encyclopedia of Business Analytics and Optimization, 2014, 14-29. Editore IGI-Global, Hershey, USA. ISBN [print]: 978-1466652026. ISBN [online]: 978-1466652033. DOI: 10.4018/978-1-4666-5202-6.ch002.*
5. Fabrizio Pecoraro, Daniela Luzi, Fabrizio L. Ricci. Secondary uses of EHR systems: a feasibility study.*Proceedings of 4th IEEE International Conference on e-Health and Bioengineering (EHB), Iasi, Romania, November 21-23, 2013. (Improving Quality of Life through Research and Innovation). ISBN: 978-1-4799-2372-4. DOI: 10.1109/EHB.2013.6707295.*

List of up to 5 relevant previous projects or activities, connected to the subject of the proposal:

1. Platform for sharing best practices for management of rare diseases (RA-RE-Best practices) (FP7-HEALTH-2012-Innovation-1)
2. H@H (Health at home): Smart communities for the wellbeing of the citizens (funded by the Italian Ministry of Research)
3. Evaluation of the cost-effectiveness of a program of universal audiological neonatal screening (funded by the Italian Ministry of Health)
4. Model for a pneumologic non hospital assistance for patients with Chronic Respiratory Insufficiency (funded by the Italian Ministry of Health)

5. MEDIS: (Medical Device Information System): Monitoring and exchange of information on clinical investigation on medical devices (funded by the Italian Ministry of Health)

Description of significant Infrastructure/ Facilities to be used/ Major Items of Equipment (relevant to proposed work);

No significant infrastructure will be required

Partner 5 – University of Surrey

One of the UK's leading professional, scientific and technological universities in the UK, the University of Surrey ranked 39th in the prestigious Top 100 List of the world's most international universities, part of the Times Higher Education (THE) World University rankings for 2013-14. Actively involved in successive research collaborations with industrial and research partners across Europe since the Fourth Framework Programme, the University of Surrey received funding for 160 projects in the Seventh Framework Programme, including 26 Marie Curie fellowships.

The Department of Health Care Management and Policy (DHCMP) at the University of Surrey has been involved in quality improvement interventions over the last 15 years, primarily for long term conditions in the UK and internationally. Our interests are how to measure quality and health outcomes from routine data, quality improvement and technology trials, and integrating the use of the computer into the clinical consultation.

As a group, we have over 200 full length peer review scientific research publications; in addition to over 100 other peer review journal articles, letters or editorials and in excess of this number of conference abstracts. We have direct links with an excellent group of international collaborators; and links through the primary care informatics working groups of IMIA and EFMI (the International and European informatics organisations).

CV of PI and main people involved (including gender):

Prof Simon de Lusignan – (male) is a Professor of Primary Care & Clinical Informatics and Chair in Health Care Management, who has over 15 years' experience of conducting research using routine data; including a range of descriptive, interventional and evaluative studies to measure quality and health outcomes. A well experienced researcher with over 250 publications, with the majority about the use of routine data to measure quality and health outcomes. Experienced principal investigator and team leader, who has raised project funding value £>5million. He is also a practicing GP and Director of the RCGP Research and Surveillance Centre. Prof de Lusignan will lead the team at Surrey.

List of up to 5 relevant publications/ or products/services/software, other achievements;

Key publications:

- Pebody R, Green H, Andrews N, Zhao H, Boddington N, Bawa Z, Durnall H, Singh N, Sunderland A, Letley L, Ellis J, Elliot A, Donati M, Smith G, de Lusignan S, Zambon M. Uptake and impact of a new live attenuated influenza vaccine programme in England: early results of a pilot in primary school-age children, 2013/14 influenza season. *Euro Surveill.* 2014 Jun 5;19(22). pii: 20823
- Woodman J, Allister J, Rafi I, de Lusignan S, Belsey J, Petersen I, et al. Simple approaches to improve recording of concerns about child maltreatment in primary care records: developing a quality improvement intervention. *Br J Gen Pract* 2012;62(600):e478-e86(9).
- Rafiq M, McGovern A, Jones S, Harris K, Tomson C, Gallagher H, de Lusignan S. Falls in the elderly were predicted opportunistically using a decision tree and systematically using a database-driven screening tool. *J Clin Epidemiol.* 2014 Apr 28. pii: S0895-4356(14)00094-8. doi: 10.1016/j.jclinepi.2014.03.008.
- Liyanage H, de Lusignan S. Ontologies to capture adverse events following immunisation (AEFI) from real world health data. *Stud Health Technol Inform.* 2014;197:15-9.
- Hassan Sadek, N., Sadek, A. R., Tahir, A., Khunti, K., Desombre, T., de Lusignan, S. (2012). Evaluating tools to support a new practical classification of diabetes: excellent control may represent misdiagnosis and omission from disease registers is associated with worse control. *International journal of clinical practice*, 66(9), 874-882.

List of up to 5 relevant previous projects / activities (connected to the MOCHA proposal);

DHCMP is a work package leader on the ADVANCE Consortium, a unique collaboration between key players in sector, including European Centre for Disease Prevention and Control (ECDC), European Medicines Agency (EMA), national public health and regulatory bodies, vaccine manufacturers, SMEs, and academic institutions. The framework will help health professionals, regulatory agencies, public health institutions and the general public make informed decisions on immunisation.

The DHCMP worked with the Royal College of General Practitioners and the Institute for Child Health on the Multisite Audit project, recording concerns about child maltreatment in primary care databases. The project aimed to help identify children at risk of maltreatment who need early intervention but do not meet the criteria for receiving children's social care. The process aimed to improve local coordination of care, and matched the aims of the 2009 National Institute for Health

and Clinical Excellence (NICE) guidance on when to suspect child maltreatment.

The DHCMP has collaborated with Imperial College on the LOLIPOP study, working on the derivation and validation of a risk model for prediction of cardiovascular disease events in UK Indian Asians.

Prof. Graham Cookson (Male)

Graham Cookson is Professor of Economic and Public Policy in the Faculty of Business, Economics and Law at the University of Surrey, UK. Before taking up his chair at the University of Surrey he spent seven years in the Department of Management at King’s College London. As an undergraduate he read Philosophy, Politics and Economics at Somerville College, Oxford University and after working for an internet company returned to study for a M.Sc. and Ph.D. in econometrics at Imperial College London.

As an applied micro-economist and econometrician, his research focuses on the economics and management of the public services and public policy, especially the measurement and determinants of productivity, the efficiency-effectiveness trade-off and their relationship with skill mix. While most of his work has been in health care, he has also worked in education, local government, policing, transport, foreign direct investment and legal aid. He has received funding from numerous sources including major grant awarding bodies such as the Economic and Social Research Council and the National Institute for Health Research. In 2013 he was awarded £1 million via the prestigious Leverhulme Trust Research Leadership Award to establish a research group to study “*Delivering ‘better for less’: improving productivity in the public services.*” His research has been covered by leading global media outlets including, inter alia, the BBC, the *Financial Times*, *The Guardian*, *The Independent*, *The Times*, *The Daily Telegraph*, and the *New Statesman*. At present he has over 20 published research outputs and a further half dozen under review.

Relevant Publications

Cookson, G., Jones, S. and McIntosh, B. (2013) Cancelled Procedures: Inequality, Inequity and the National Health Service Reforms, *Health Economics*, 22 (7): 870-876
 Cookson, G. (2013) The cost of the legal aid reforms in family law, *Journal of Social Welfare and Family Law*, 35 (1): 21-41
 McIntosh, B., Jones, S. and Cookson, G. (2012) Cancelled Surgeries and Perverse Incentives in the English National Health Service, *Journal of Health Services Research & Policy*, 17 (2): 79-86
 Blanc-Brude, F., Cookson, G., Piesse, J. and Strange, R. (Forthcoming) The FDI Location Decision, *International Business Review*
 Cookson, G., McIntosh, B. and Griffiths, P. (Forthcoming) The Healthcare Workforce and the Efficiency-Quality trade-off, *Advances in Healthcare Management*

Description of significant Infrastructure/ Facilities to be used/ Major Items of Equipment (relevant to proposed work);

The DHCMP obtained approval for the NHS Information Governance Toolkit for Hosted Secondary Use Team/ Project, Version 11. As part of this, all members of the team have received Information Governance training. The University of Surrey is registered with the Data Protection Register and is compliant with the Data Protection Act and other legislations.

Where required, patient data is pseudonymised using a non-reversible algorithm and all data is uploaded to the Research Group's private SQL server, located within secured premises, and only accessible to authorised members of the team. There are strict policies in place regulating the storage and access of all patient data, which can be found here: <http://clininf.eu/about/information-governance.html>. Our data analysis servers are optimized for routine healthcare data processing to provide faster deliveries for our projects.

Partner 6 – KI

Description of the institution (Profile)

The administrative hub of WP 7 will be the Clinical Epidemiology Unit of the Department of Medicine at Karolinska Institutet, Stockholm, Sweden, where Anders Hjern is a professor of social epidemiology in children and youth. <http://ki.se/en/meds/clinical-epidemiology-unit>. Situated at the Eugeniahemmet at the Karolinska University Hospital campus in Solna, the research at the Clinical Epidemiology Unit (KEP) is focused on translational epidemiologic studies in which register-data are often combined with information from questionnaires and hospital charts. The Clinical Epidemiology Unit (KEP) has extensive experience in the development of and working with quality registers based on health records to evaluate health care and is the home of the quality register for maternal health care in Sweden. The work of WP7 will be made in close collaboration with the Centre for Health Equity Studies, a research institute created jointly by Karolinska Institutet and Stockholm University, where Anders Hjern is a senior research fellow and Arzu Arat a research assistant. At Centre for Health Equity Studies, CHES, researchers from sociology, psychology and public health sciences work together on issues of health and inequality. <http://www.chess.su.se/>. CHES participated in the production of several reports for the WHO Commission on Social Determinants of Health and has an extensive international network in health inequity and inequality research. Currently CHES one of the European centers in the DRIVERS project (Addressing the strategic Determinants to Reduce health Inequity Via Early childhood, Realising fair employment and Social protection), funded by the 7th Framework Programme (2012-2015). <http://www.chess.su.se/research/projects/drivers-1.102046> CHES has an extensive collaboration with the Department of Social Work at the Stockholm University, with which it shares the same building. CHES also collaborates with the Child Health services in the Stockholm county in several ongoing research projects.

Main tasks undertaken in MOCHA:

WP 7 will work with issues related to providing equitable primary health care for

children and with health care for marginalised groups of children, in particular children in foster and institutionalized care and migrant children. The work in WP 7 will collect and synthesize information on these topics, and also work with administrative data in comparative case studies of different health care models.

The Clinical Epidemiology Unit (KEP) at Karolinska Institutet has an international reputation for good use of administrative data to evaluate health services and will provide excellent support in case studies of primary health care based on administrative data. CHES is one of the leading research centers in Europe regarding health inequities and inequalities and will serve as an ideal platform for the collection of information and theories regarding inequities in primary care for children. The collaboration with Department of Social Work will provide necessary support to address issues regarding health care for children in the child welfare system.

CV of PI and main people involved (including gender):

Prof. Anders Hjern. (Male) – Anders Hjern is a medical doctor trained as a paediatrician at the Karolinska University Hospital in Stockholm. He is an epidemiologist at the National Board of Health and Welfare and an Affiliated Professor of Paediatric Epidemiology at the Nordic School of Public Health. His research interests include adoption, health of foster children, migrant health and child public health.

<p>List of up to 5 relevant publications/ or products/services/software, other achievements;</p> <p style="text-align: center;">Relevant publications</p> <ol style="list-style-type: none"> 1. Hjern A, Haglund B, Rasmussen F, Rosen M. Socio-economic differences in daycare arrangements and use of medical care and antibiotics in Swedish preschool children. <i>ActaPaediatr.</i> 2000 Oct;89(10):1250-6. 2. Hjern A, Haglund B, Persson G, Rosén M. Is there equity in access to health services for ethnic minorities in Sweden? <i>European Journal of Public Health</i>, 2001; 11:147-152. 3. Vinnerlung, B. Franzen, E. Hjern, A. Lindblad, F. Long term outcomes of foster care: Lessons from Swedish National Cohort Studies. In: Fernandez, E. & Barth, R. How does foster care work. International evidence on Outcomes. London & Philadelphia; Kingsley, 2010, p 208-221. 4. Wallby T, HjernA.. Child health care uptake among low income and immigrant families in a Swedish county. <i>ActaPaediatr.</i> 2011; 100:1495-503. 5. Wallby T, Modin B, Hjern A. Child health care utilisation in families with young or single mothers in a Swedish county. <i>J Child Health Care.</i> 2012, E-publ, 2012
<p style="text-align: center;">Relevant projects</p> <ol style="list-style-type: none"> 1. Swedish national representative in the EU funded project on Indicators for Child Health, project CHILD, 2001-2002. 2. Founding member of the International Network for Research on Inequalities in Child Health (INRICH) 2007- http://www.centrelearoback.ca/inrich/ 3. Swedish representative in the European network on Research on Health and Social Care for Migrants, HOME, funded by the European Union through COST, 2007-2010. http://www.cost.eu/domains_actions/isch/Actions/IS0603 4. Work package leader (WP indicators and measurement) in the EU funded project RICHE, 2010-13 http://www.childhealthresearch.eu/ 5. Member of scientific advisory committee of EU funded project in injury prevention, TACTICS, 2011-13 http://www.childsafetyeurope.org/tactics/project-partners.html
<p>Description of significant Infrastructure/ Facilities to be used/ Major Items of Equipment (relevant to proposed work); No significant infrastructure will be required</p>

Partner 7 - TNO

Description of the institution (Profile)

TNO (Nederlandse Organisatie voor toegepast-natuurwetenschappelijk Onderzoek TNO) is one of the major internationally oriented contract research and technology organisations in Europe. With a staff of approximately 3500 and an annual turnover of 580 million Euros, TNO is carrying out research in order to achieve impact on the following seven themes: Healthy Living, Industrial Innovation, Transport and Mobility, Energy, Built Environment, Information Society, and Defence, Safety and Security.

TNO functions as an intermediary between basic research organisations and industry. By translating scientific knowledge into practical applications, TNO contributes to strengthening the innovation capacity of businesses and government. TNO is involved in many international projects (about 30% of the market turnover), including EU-funded collaborations, be it research or service contracts, for the European Commission, the European Parliament or European agencies.

The Healthy Living theme is directed at prevention of unhealthy lifestyles and chronic disease and covers all age groups. TNO has ample experience in monitoring health and behaviour and systematically developing, evaluating and implementing interventions that are aimed at changing people's behaviour or changing the physical and social environment in which behaviour occurs.

Main Tasks undertaken in MOCHA

TNO involvement in WP 3. School Health Services and Adolescent Health Services and WP leader in WP 9. Optimal Models to meet Health and Prevention Needs, their Testing and Transferability. TNO to review models of School-based Preventive Health Care across the EU (WP 3), to develop and test optimal patient-centred and prevention oriented primary child health care models emerging from the analyses in the other WPs on the meso and micor level and to perform a stakeholder analysis (WP 9). In the department of Child Health the Dutch well-childcare is evaluated and improved. TNO has valuable experience on School-based Preventive Health Care, ~~Meso and Micro Models and stakeholder analysis in the Netherlands.~~

CV of PI and main people involved (including gender):

- Dr. Paul Kocken (Male)
- Dr. Symone Detmar (Female)
- Dr. Margot Fleuren (Female)

CV's [are attached](#)

List of up to 5 relevant publications/ or products/services/software, other

achievements:

1. Bezem J, Theunissen M, Buitendijk SE, Kocken PL. A novel triage approach of child preventive health assessment: an observational study of routine registry-data. Under review BMC Health Services Research
2. Kocken PL, Theunissen M, Schönbeck Y, Janssens CJW, Henneman L, Detmar S. Ethnicity, educational level, and attitudes contribute to parental intentions about genetic testing for child obesity. J Community Genet 2013;4:243-250. DOI 10.1007/s12687-013-0137-1
3. Magnée T, Burdorf A, Brug J, Kremers SPM, Oenema A, van Assema P, Ezendam NPM, van Genugten L, Hendriksen I, Hopman-Rock M, Jansen W, de Jong J, Kocken P, Kroeze W, Kwak L, Lechner L, de Nooijer J, van Poppel M, Robroek SJW, Schreurs H, van Sluijs E, Steenhuis IJM, van Stralen MM, Tak NI, te Velde S, Vermeer WM, Wammes B, van Wier MF, van Lenthe FJ. Equity-specific effects of 26 Dutch obesity-related lifestyle interventions. Am J Prev Med 2013;44:e57-e66.
4. Kocken PL, Eeuwijk J, Kesteren NMC van, Dusseldorp E, Buijs G, Dafesh Z, Snel J. Promoting the purchase of low-calorie foods from school vending machines: a cluster-randomized controlled study. J Sch Health 2012;82:115-122.
5. Kocken PL, Joosten - van Zwanenburg E, Hoop T de. Effects of migrant health education aimed at Turkish and Moroccan female migrants with psychosomatic complaints treated by Dutch general practitioners. A randomized controlled evaluation study. Patient Education and Counselling 2008;70:25-30

List of up to 5 relevant previous projects or activities, connected to the subject of the proposal:

1. Effects of the triage approach of child preventive health assessment on case finding and care (Grant ZonMw 15651.1002).
2. Use of questionnaires in Preventive Child Health Care to support the identification of health problems in children 5/6 years and 10/11 years of age (Grant ZonMw 20400.3003)
3. Benzies & Batchies: Evaluation of an interactive school-based program to prevent sexual harassment behavior in lower educated students (Grant ZonMw 12427.0002)
4. Evaluation of the skills for life curriculum intended for Dutch secondary school students (Grant ZonMw 6230.0045 and SKO HBO, Pro-4-43)
5. Evaluation of a school-based multicomponent programme to prevent overweight in primary school children (Grant ZonMw 120610007)

Partner 8 – KCL

Description of the institution (Profile)

The Division of Health and Social Care Research provides a strong focus for health and social care researchers from a range of scientific backgrounds across King’s College, drawing its membership from the Schools of Medicine, Nursing & Midwifery and Social Science & Public Policy. It enables collaborative working among clinicians, basic scientists, managers and policy makers in health and social care.

It has established and consolidates existing strong external links with local and national health and social care organisations and with the local NHS Acute and Primary Care Trusts.

At King’s College London we are able to draw on a unique blend of expertise from health and social sciences and public policy which, with strategic support, promote high-quality, cross-cutting research of considerable relevance to the health service.

CV of PI and main people involved (including gender):

Dr Ingrid Wolfe (female) -Dr. Ingrid Wolfe is qualified both in public health and paediatrics, having come to medicine after completing a BSc in Physiology and worked in a medical research institute for three years. She specialised first in paediatrics then trained in public health medicine while continuing to work as a general paediatrician. Those two strands of her work came together, and were enriched by developing an expertise in children’s health services, systems, and policy research in the UK and Europe. CV’s Attached

List of up to 5 relevant publications/ or products/services/software, other achievements:

Viner R, Hargreaves D, Coffey C, Patton G, Wolfe I. Deaths in young people 0-24 years in the UK compared with the EU15+ countries, 1970-2008: analysis of the WHO mortality database. The Lancet 2014; doi10.1016/S0140- 6736(14)60485-2

Wolfe I, Thompson M, Gill P, Tamburlini G, Blair M, van den Bruel A, Ehrlich J,

Pettoello-Mantovani M, Janson S, Karanikolos M, McKee M. Health services for children in western Europe. *The Lancet* 2013; 381: 1224-34.

Wolfe, I., McKee M. (eds) *Children and Young People's Health Services and Systems in Europe: Lessons without Borders*. Open University Press (2013).

Wolfe I, Cass H, Thompson M, et al. Improving child health services in the UK: insights from Europe. *BMJ* 2011; 342: 90- 04.

Crowley, R., Wolfe, I, Lock, K. & McKee, M. 2011. Improving the transition between paediatric and adult healthcare: a systematic review. *Archives of Disease in Childhood*, 96, 548-53.

List of up to 5 relevant previous projects or activities, connected to the subject of the proposal:

Chief Scientific Advisor for the European Paediatric Association - our main piece of work is with an EU- wide network of paediatric association Presidents describing country child health systems which the MOCHA work will build on.

Led a European collaboration under the aegis of the European Observatory of Health Systems and Policies on child health and health systems in Europe. This was published as a book in late 2013 (see above) and to a Eurohealth Observer issue on child health services published earlier this year. (Wolfe I McKee M *Strengthening Child Health and Health Services in Europe*.

Eurohealth Observer 2014; 20(1): 3-7)

Director for the Evelina London Child Health Programme, leading work to design, implement, and evaluate a new type of child health service model. Our programme is firmly grounded in a child population health perspective, building on my research in child and adolescent population health, health services and systems as a means to improve local and international child health.

Description of significant Infrastructure/ Facilities to be used/ Major Items of Equipment (relevant to proposed work);

No significant infrastructure will be required apart from computer, telephone and desk.

Partner 9 - UM

Description of the institution (Profile)

Maastricht University (UM) with its Department of International Health (DIH) is part of the Research School for Public Health and Primary Care (CAPHRI), Faculty of Health Medicine and Life Sciences (FHML). Maastricht University (UM) is the youngest university in the Netherlands, founded in 1976 and is situated in the very south of the country in a geographically central position in Western Europe. Maastricht University is the most international university in the Netherlands with one-third of its teaching staff and 45% of its students from abroad.

Research at the UM is thematically focused on international issues critical to the development of society, the three spearheads of Life Sciences, Innovation and Governance being central to apply scientific knowledge and create practical solutions to societal problems. Research is organized in multidisciplinary teams and trans-disciplinary research strands and in close cooperation with international institutes, business and industry. UM researchers have attracted international attention by taking the lead in several large European research projects. The orientation on

theory/practice transfer is well established, including a strong orientation on policy advice. The Strategic Programme 2012 – 2016 of Maastricht University has defined “Europe and a Globalising World”, “Quality of Life” and “Learning and Innovation” as the three main research topics. In line with the strategy, Maastricht University has a clear and strong European focus.

DIH is a young department founded in the year 2008 as the former Faculty of Health Sciences (now FHML) realized the need for a European orientation in health research. DIH and its accompanied research program “Comparative Health” have been established in order to reflect the European perspective on research that the University takes, and due to the recognition that in today’s world public health requires a multi- and trans-disciplinary approach and multilevel cooperation to face today’s challenges. DIH departs from the understanding that local, regional, and national health developments have to be placed into a wider European and global perspective, that mechanisms of good governance in public health and healthcare need to be intensively addressed and research findings from Maastricht University have to be translated into a European context. The mission statement is “we take interdisciplinary perspectives on health in the process of European Integration and Europeanization”. DIH has a unique profile. Its aim is to create societal impact on European public health issues in the multilevel system of the EU and WHO Europe structures.

Activities in research address:

- *Public Health in Europe* from a comparative perspective (describing the different health systems in Europe, analysing their performance, trying to find evidence for best practice solutions, supporting dissemination of good practice, studying transferability and policy learning); examples include the assessment of public health capacities, child injury prevention policy or the level of health literacy)
- *European Public Health* (“European” solutions to health problems involving several EU or WHO Member States or cross cutting issues like governance of public health and health care systems in the multilevel systems of the EU, as well as innovative topics such as leadership in Public Health, EU Structural Funds and investments in health)
- *Global Health Europe* (exploring the European perspective on health in a global context and promoting synergies between public health research and the policy spheres of foreign policy and development)

Main Tasks undertaken in MOCHA

In regard of the profile of the UM in general and of the DIH in particular, the institute has the capacity and experience to apply tools of (comparative) policy analysis and diffusion research to the area of primary child health. Insofar, DIH is an ideal place to take on the tasks of analyzing the political and constitutional context (WP1), ways of knowledge translation to support transferability (WP9) and contribute to dissemination of results within MOCHA.

- analyzing the political and constitutional context (WP1)
- ways of knowledge translation to support transferability (WP9)
- contribute to dissemination of results within MOCHA

CV of PI and main people involved (including gender):

PI Helmut Brand, Prof. Dr. med., Dr. h.c., MSc, DLSHTM– (Male)

Helmut Brand (male) is Jean Monnet Chair of European Public Health and head of the Department of International Health at Maastricht University, The Netherlands. He studied Medicine in Düsseldorf and Zürich and earned a Master in Community Medicine from London School of Hygiene and Tropical Medicine and London School of Economics. Prof. Brand is a specialist in Public Health Medicine.

After working in several health authorities and Ministries of Health in Germany he was director of the Public Health Institute of North Rhine Westphalia. Since then European Integration in Health is the main topic of his work. His research expertise covers comparative analysis of various components of health systems including health information systems, health reporting, ehealth, public health capacities and cross-border care.

He is past-president of the Association of Schools of Public Health in the European region (ASPHER), president of the European Health Forum Gastein (EHFG) and co-chair of the European Alliance for Personalised Medicine (EAPM). As policy advisor he serves among others on the European Advisory Committee on Health Research (EACHR) of WHO Europe and on the Expert Panel on “Investing in Health” for the European Commission.

Timo Clemens, MSc – (Male)

Timo Clemens (male) is a PhD candidate at the Department of International Health, Faculty of Health Medicine and Life Sciences at Maastricht University. He has obtained a Bachelor and Master degree in European Public Health from Maastricht University and training in nursing from the University Hospital in Aachen, Germany. His PhD research involves the influence of European Union policies on national health system in general and hospitals in particular. He has covered in his research on the domestic effects of E U policies areas like EU economic governance as response to the financial crisis, free movement of patient and professionals, information to patient provisions, EU’s financial programs in the areas of health and cross-border cooperation of hospitals. Moreover, his expertise includes different approaches to study policy transfers between member states and the EU and member states. He employs methods of qualitative policy analysis and comparative perspectives to his area of research interest.

Timo Clemens is the managing assistant to the Jean Monnet Chair in European Public Health Helmut Brand. The project involves various activities across Europe to integrate the European dimension into health education and discussions financed by DG Education and Culture. He is an active member of the Young Forum Gastein Network.

List of up to 5 relevant publications/ or products/services/software, other achievements:

Boccia S, Brand A, Brand H, Ricciardi G. The integration of genome-based information for common diseases into health policy and healthcare as a major challenge for Public Health Genomics: the example of the methylenetetrahydrofolate reductase gene in non-cancer diseases. *MutatRes.* 2009 Jul 10;667(1-2):27-34. doi: 10.1016/j.mrfmmm.2008.10.003. Epub 2008 Oct 21. Review. PubMed PMID: 19007797.

Clemens T, Michelsen K, Brand H. Supporting health systems in Europe: addedvalue of EU actions? *Health Econ Policy Law.* 2014 Jan;9(1):49-69. doi:

10.1017/S1744133113000273. Epub 2013 Aug 22. PubMed PMID: 23968231

McKee, M., Fulop, N., Bouvier, P., Hort, A., Brand, H., Rasmussen, F., Kohler L, Varasovszky Z., Rosdahl, N. (1996). Preventing sudden infant deaths--the slow diffusion of an idea. *Health Policy*, 37(2), 117-135.

Schröter M, Schröder-Bäck P, Brand H. Using the reference framework for good measles management in practice--a case study from North Rhine- Westphalia. *Cent Eur J Public Health*. 2009 Dec;17(4):187-90. PubMed PMID: 20377046.

Zimmermann I, Albota M, Kellerhof M, Brand H: Health policy goals in child and adolescent health reporting - evaluation with reference to an intermediate term evaluation. *Gesundheitswesen*. 1995 Mar;57(3):161-4.

List of up to 5 relevant previous projects or activities, connected to the subject of the proposal:

TACTICS

Development and evaluation of childhood accident report cards on EU regional level.
176.000 €(total budget :1.296.806 €), European Commission, DG Sanco, Associated Partner, 2011-2014

Euregio III

EUREGIO III supports to identify & share best actions for the effective use of structural funds for health & help reduce health inequalities among EU regions.
107.000 €(total budget: 1.556.413 €), European Commission, DG Sanco, Associated Partner, 2009-2011

Benchmarking regional Health Policies (BEN 1 & BEN 2)

Analysis and evaluation of regional health Policies regarding the tracers Measles Immunisation, Breast Cancer Screening and Diabetes.

484.114 € European Commission, DG Sanco, Principal Investigator, 2002-2004

BEN2 :Follow up study of BEN I.

1.066.027 € European Commission, DG Sanco, Principal Investigator, 2004 -2006

Evaluation of national and regional Health Reports and Health Reporting Systems in Europe (EVA-PHR)

Context analysis of Health reports and Health reporting systems on national and

regional level to identify promoting and hindering factors in the production of Health Reports.

315.594 € European Commission, DG Sanco, Principal Investigator, 2001-2003

Comparative European Public Health Evaluation Study (CEPHES)

Policy Analysis and Evaluation of Public Health Services in seven countries from eastern and western Europe.

832.448 € European Commission, COPERNICUS, Principal Investigator, 1994-1997

Description of significant Infrastructure/ Facilities to be used/ Major Items of Equipment (relevant to proposed work);

No significant infrastructure will be required

Description of the institution (Profile)

Medical University of Lublin (MUL) is recently one of the fastest developing research centers in Poland. It is experienced in international cooperation due to many research project undertaken during recent years. One of our advantage is high standard of research in the field of public health.

Public Health Department (PHD) focuses on teaching and research in the broad spectrum of public health. The main scientific initiatives are described below.

- **Area of activity:** In the last years the main research conducted in the PHD were concerning: the quality of life, satisfaction with life, health hazards, health education, prophylaxis of diseases of affluence, health-risk behaviors, cancer-related pain and prophylaxis of osteoporosis. Recently the new direction of research was initiated – the analysis of the impact of European Union on the national health policy. The research project on Europeanization of Polish healthcare policy used the qualitative methodology applied mainly on the grounds of the social sciences. So far, it has not been very popular in Poland, despite the fact that a significant increase in interest in qualitative research methodology has been noted. This research project is an example of effective cooperation between the two lines of research social science and the health sciences. Qualitative methods have much to offer to researchers analyzing the issues of health, health policy and issues related to the provision of health services. Due to the fact that they are typically used at the level of the social sciences, they may remain undiscovered among the group of researchers devoting fully to biomedical speculations.
- **Scientific staff:** Currently the PHD consists of 10 senior researchers and junior academics. Their work results with numerous articles, editorials and abstracts. In total 967 scientific works were published between 1990 and 2014 (22.719 IF). A present 5 doctoral projects are being conducted in the unit.
- **Organizational activities:** PHD was actively involved in co-organization and organization of many conferences. The latest achievement of PHD is coordinating the initiative of Lublin Health Promoting Days, the cyclical training and scientific conference. The Department develops the scientific interest of students and involves them in numerous initiatives under the supervision of senior assistants. The students are associated in scientific interests group.

- Collaboration: Since Poland become a member of EU the PHD was involved as a partner in The Enmed Project financed from 6th Framework Program which was conducted in partnership with the Semmelweis University (Hungary), University of Porto (Portugal) and Helsinki Polytechnic Stadia (Finland). Furthermore during the work on Europeanization project the cooperation with European Social Observatory (Brussels) was initiated. Currently the PHD has submitted an application for Medical Cluster which consists of the specialized in relevant area as scientific advisors who act as local and national experts in the relevant field.

Main Tasks undertaken in MOCHA

- Medical University of Lublin involvement in MOCHA will be placed on 3 levels:
 - Work Package 1. National Health Policy and Culture. In the scope of the WP A the responsibilities of MUL will refer to identification of models of paediatric primary care based on national health policy and culture.
 - Work Package 9. Transferability. In the scope of the WP 9, concerning the optimal models to meet health and prevention needs, their testing and transferability, within the responsibilities of MUL the analysis of the transferability of the patient centered and prevention oriented primary child healthcare models to European Countries is included.
 - Work Package 10. Dissemination. In the scope of this WP, MUL will be involved in critical review of the overall messages, to ensure that they are helpful and advisory and not directive
 - Country Agent for Poland. As a country agent MUL will provide the detail expertise referring to the national issues related to the child care.

CV of PI and main people involved (including gender):

Kinga Zdunek (Female), PhD, is a senior assistant in Public Health Department of Medical University of Lublin. In 2007 completed sociological studies at Maria Curie-Skłodowska University in Lublin, in 2013 submitted doctoral dissertation on Europeanization of Polish health policy. Political discourse analysis. Her flagship project devoted the analysis of impact of EU on national health policy aimed to characterize the logical underpinning theory of the European Union influence on the Polish health policy by showing the main theoretical properties of the process and the valid rules. The

methodological approach for the research project was developed based on Oxford methodology. During her professional career she was cooperating with high level institutions, both on national and international level, such as Polish Ministry of Health and European Social Observatory in Brussels. She is an author and co-author of 14 works (articles and editorials in English and Polish).

- Luiza Nowakowska (Female), MA, is a teaching and research assistant in Independent Medical Sociology Unit of Medical University of Lublin. In 2004 completed sociological studies at Maria Curie-Skłodowska University in Lublin, in 2011 started Doctoral Studies in Sociology. Doctoral dissertation is devoted to the problem of effective perinatal care in Poland. In particular, the issue of the role of home births in the Polish medical system has been examined. Main areas of interest: medical sociology, medicalization of everyday life, systems of care for mother and child.

List of up to 5 relevant publications/ or products/services/software, other achievements:

- Zdunek K., Kulik T.B., Pacian A., Europeizacja a polityk zdrowotna, [in:] Dosвід, realí í perspektivirozvitkusistemo- horonizdrov'â, Lviv 2013, LOBO "Medicina í pravo", pp. 9-15.
- Kulik T. B., Zdunek K., Pacian A., Polityk zdrowotna w kraja- chUniiEuropejskiej, [in:] Dobrostan i społeczeństwo, Babiarz M., Szpringer M. (red.), Lublin 2013, NeuroCentrum, pp. 157-164.
- Zdunek K., Kulik T.B., Janiszewska M., Bogusz R., Zdrowie a UniaEuropejska, UniaEuropejska a globalizacja, ZdrowiePubliczne, 121 (3), 2011, pp. 283-287.
- Zdunek K., Kulik T.B., Pacian A., Healthy ageing - global crisis or global challenge? [in:] Caring and working in ageing societies, Bell Ch., Clarke P. (red.), 2010, pp. 39-49.

List of up to 5 relevant previous projects or activities, connected to the subject of the proposal:

MedizinischeHochschule Hannover scholarship: Health behavior of the Polish community in Germany (2008-2009).

Description of significant Infrastructure/ Facilities to be used/ Major Items of Equipment (relevant to proposed work);

No significant infrastructure will be required

Partner 11 – HIH

Description of the institution (Profile)

Harstad University College (HiH) was established in 1983 and is a part of the higher public education system in Norway. HiH has approximately 1300 students and a staff around 120.

HiH offers a friendly and intimate atmosphere. It is easy to get to know other students as well as staff members, and the university college is characterized by a high level of student activity.

Our modern facilities accommodate most of the activities under one roof, centrally and beautifully located close to the city centre and the harbour.

CV of PI and main people involved (including gender):

- Prof. Anne Clancy (Female) , will be involved in the MOCHA project, as PI, bringing her expertise in nursing and public health nursing services.– Anne completed her doctoral studies at the Nordic School of Public Health in 2010. The title of her doctoral thesis in Public Health is: Perceptions of public health nursing practice –on borders and boundaries, visibility and voice. Anne is currently employed as an associate professor at the School of Nursing at Harstad University College. Her main fields of interest are ethics, public health and nursing and she has written several articles on public health nursing practice. Anne was a member of the National Ethical Committee for nurses in Norway during the period 2004-2011 and is a member of the Nordic Network for Health promotion. Anne is currently leader of the research group– Life and life force. CV attached

List of up to 5 relevant publications/ or products/services/software, other achievements:

Primary Health Care: Comparing Public Health Nursing Models in Ireland and Norway," in Nursing Research and Practice, vol. 2013, Article ID 426107, 9 pages, 2013. doi:10.1155/2013/426107. Anne Clancy, Patricia Leahy-Warren, Mary Rose Day and Helen Mulcahy

Contradictory discourses of health promotion and disease prevention in the

educational curriculum of Norwegian public health nursing: A critical discourse analysis. 2013 In The Scandinavian Journal of Public Health. Berit Misund Dahl, Therese Andrews, Anne Clancy.

Clancy, A., Gressnes, T., & Svensson, T.: "Public health Nursing and interprofessional collaboration- a questionnaire study" The Scandinavian Journal of Caring Sciences (2013)

Clancy, A., & Svensson, T.: "Perceptions of public health nursing consultations - tacit understanding of the importance of relationships" Primary Health Care Research and Development (2010).

Clancy, Anne, & Svensson, T: "Faced" with responsibility: Levinasian ethics and the challenges of responsibility in Norwegian public health nursing. Nursing Philosophy (2007), 8, pp. 158-166.

List of up to 5 relevant previous projects or activities, connected to the subject of the proposal:

- Changes and challenges in Norwegian public health nursing (2010).
- Stories on ethics (2012)
- Space and place in nursing (2012-2015)
- Young people and online gaming- a relational family focus (2012-2014)
- Health promotion focus in public health nursing

Description of significant Infrastructure/ Facilities to be used/ Major Items of Equipment (relevant to proposed work);

No significant infrastructure will be required

Partner 12 – UI

Description of the institution (Profile)

The University of Iceland is a public research university in Reykjavík, Iceland, and the country's oldest and largest institution of higher education. Founded in 1911, it has grown steadily from a small civil servants' school to a modern comprehensive university, providing instruction for about 14,000 students in twenty-five faculties. It is the second largest university in the country with over 3,000 students in four different Schools, i.e., Business (including Public Health/Psychology), Computer Science, Law, and Science and Engineering.

CV of PI and main people involved (including gender):

Dr. Geir Gunnlaugsson is a paediatrician and has since 2002 been involved in the development and use of Electronic Health records (EHR) for preventive child health services in Iceland. Today, all preventive child health services for children from 0-15 years of age have a specially designed EHR, one for children 0-5 years (SAGA), and another for school health services for children 6-15 years (Ískrá). These include all of the child population in the country. With his background firmly embedded in child public health work in Iceland and experience in the design and the use of EHR in preventive child health services, he will contribute to the work of Work Package 8

List of up to 5 relevant publications/ or products/services/software, other

achievements:

- 1) Gunnlaugsson G, Einarsdóttir J. ReynslafullorðinnaÍslendingaaflíkamlegumrefsingumogofbeldi í æsku [e. Experience of Icelandic adults of corporal punishment and abuse in childhood]. Icelandic Medical Journal 2013; 99:235-239.
- 2) Gunnlaugsson G. Design and use of electronic child health records in Iceland: tool for child health promotion. International Congress of Pediatrics 2013 (ICP): Bridging the Gaps in Child and Adolescent Health. 27th Congress of the International Pediatric Association, Melbourne Convention and Exhibition Centre, August 24-29, 2013, Melbourne, Australia.
- 3) Gunnlaugsson G (2012). Electronic Child Health Records: Case-Study from Iceland. Working Paper for the EU funded project RICHE – Research Inventory of Child Health in Europe. See: <http://www.childhealthresearch.eu/Members/ahjern/electronic-health-records-case-study-from-iceland/view>
- 4) Jonsdottir OH, Thorsdottir I, Hibberd PL, Fewtrell MS, Wells J, Palsson GI, Lucas

A, Gunnlaugsson G, Kleinman RE. Timing of the introduction of complementary foods in infancy: A randomized controlled trial. Pediatrics 2012;130:1038–1045.

- 5) Gunnlaugsson G, Kristjánsson ÁL, Einarsdóttir J, Sigúfisdóttir ID. Intrafamilial conflict and emotional well-being: A population based study among Icelandic adolescents. Child Abuse & Neglect 2011;35:372-381.

List of up to 5 relevant previous projects or activities, connected to the subject of the proposal:

2010-13 Research Inventory for Child Health in Europe (RICHE). EU funded project (FP7). Collaboration of 25 partners in 19 European countries. Actively involved in all aspects of the project with focus on WP2 on Child Health Indicators, and sole author of the paper Electronic Child Health Records: Case-Study from Iceland (2012; 36p). The project has finished, and the final report published: Research Inventory of Child Health: A Report on Roadmaps for the Future of Child Health Research in Europe. Final Report. A key recommendation is the establishment of a European Child Health Observatory. See RICHE website <http://www.childhealthresearch.eu/>

2003-04 Grøholt EK, Nordhagen R (NOMESCO Working Group: Children's health in the Nordic Countries – Barns helse i Norden. In Health Statistics in the Nordic Countries

2003 [Helsestatistik for de nordiskelande 2003]. Nielsen J (Ed.). Copenhagen: Nordisk MedicinalstatistiskKomité; 2005: p. 193-245. Special edition: Rapport 2005:6, Oslo: Folkehelseinstituttet; 2005, 47 p. See: <http://www.fhi.no/dav/54A59EE417.pdf>

2002-05 On behalf of the Icelandic Ministry of Health and Social Security, representative in a working group on the health of children and adolescents in the Arctic area (Future of Children and Youth of the Arctic Initiative: Health Programme). See: Wigle D, Gilman A, McAllister K, Gibbons T (for the Working Group). Analysis of Arctic Children and Youth Health Indicators. Produced for the Arctic Council Sustainable Development Group. Future of Children and Youth of the Arctic Initiative. Report of the Health Programme. Ritsjt. Thompson M. Ottawa: Health Canada; 2005, 113p. See: <http://www.sdwg.org/media.php?mid=13>

2001-04 Member of the European Task Force for Breastfeeding, under the leadership of the Institute for Preventive Nutrition, Karolinska institute, Stockholm, Sweden, and

IRCCS BurloGarofolo, Trieste, Italy. The final report, published in 2004, Protection, promotion and support of breastfeeding in Europe: a blueprint for action. European Commission. Luxembourg: Directorate Public Health and Risk Assessment; 34p. See: http://ec.europa.eu/health/ph_projects/2002/promotion/fp_promotion_2002_frep_18_en.pdf

2001-02 On behalf of the Directorate of Health, representative of Iceland in the EU funded project CHILD - Child Health Indicators for Life and Development. The group delivered a report in September 2002 and identified and defined 38 child health indicators to monitor the health of European children 0-17 years of age and their well-being in the Report to the European Commission. Rigby M, Köhler L. (Eds.). Luxembourg: Directorate Public Health and Risk Assessment; 2002, 98p. See: http://ec.europa.eu/health/ph_projects/2000/monitoring/fp_monitoring_2000_exs_08_en.pdf

Description of significant Infrastructure/ Facilities to be used/ Major Items of Equipment (relevant to proposed work);

The participant will, as found relevant, work together with staff at the Directorate of Health and the Primary Health Care Organization for the Capital Area to retrieve and analyze data in the Electronic Health Records for children in Iceland.

Partner 13 – EUC

Description of the institution (Profile)

European University Cyprus developed out of Cyprus College, which was founded in 1961 by Ioannis Gregoriou. Today EUC is a modern university, operating five Schools, namely, the School of Arts and Education Sciences, the School of Business Administration, the School of Humanities and Social Sciences, the School of Sciences, and the Medical School. All undergraduate and postgraduate programs offered by European University Cyprus are recognised nationally and internationally. The mission of the university is to educate our students for successful careers and life achievement, to understand and serve the needs of our society, and to create knowledge through research and innovation. With an emphasis on interdisciplinary approaches, EUC is one of the leading research institutions in Cyprus. During the last few years, the University has developed an intense action in a wide spectrum of ICT, Health, and Socioeconomic Sciences and Humanities through coordination or participation in national, international and European Union-funded research programs. EUC is the only organization in Cyprus that has become partner in the following three ESFRI (European Strategy Forum on Research Infrastructures) projects, funded under the FP7 Capacities Programme and aiming at optimizing the use and development of the best research infrastructures existing in Europe: European Social Survey, Digital Research Infrastructure for the Arts and Humanities (Preparing DARIAH) and Common Language Resources and Technology Infrastructure (CLARIN). Other sources of funding for research conducted by faculty members involve the Life-Long Learning 2007-2013 Programme, the Research Promotion Foundation, the United Nations, Governmental Bodies and others. The University also serves as the national representative for the prestigious International Social Survey Program (ISSP), the World Economic Forum, and as the official administrator in Cyprus of the World Bank publications.

CV of PI and main people involved (including gender):

Adamos Hadjipanayis (male) (PI) is the Secretary General of the European Academy of Paediatrics and member of the steering committee of EAPRASnet (European Academy of Paediatrics Research in Ambulatory Setting network). The

network has recruited primary care and general paediatricians from European and Mediterranean countries. The aim is to collect data originating from the primary paediatric care settings in Europe, by which data harmonization and optimization of the care given to children shall be achieved.

He is the founder of www.paidiatros.com. This is the most famous website in Greek for parents and paediatricians. It's a dedicated portal on children's healthcare and wellbeing. One of the most important tools of the website is the electronic health care of children which has been developed by a team of scientist lead by AdamosHadjipanayis. This tool is currently used by both parents and paediatricians. The profile of AdamosHadjipanayis matches perfectly the WP 8(The Role of Electronic Records and Data to Support Effective Models).

Dr. Christos Dimopoulos (male) is an Associate Professor of Computer Science & Engineering in European University Cyprus. He is currently the Director of the Decision Support and Systems Optimisation (DSSO) research laboratory and the technical leader of the ICT- Enhanced Education (ICTEE) laboratory. Dr.Dimopoulos has significant teaching and research experience in the field of Information Systems. In particular, he has been teaching requirements analysis and data-modelling courses in both undergraduate and postgraduate levels, while he has applied innovative interdisciplinary ideas to the modelling of Decision Support Systems. These skills will enhance the capacity of the project's network to identify and model the existing ('as-is') electronic records in children's primary health care and to develop improved models for the future ('to-be') design of these records.

A data modelling / analysis researcher from European University Cyprus will also participate in the implementation of the project. The researcher will assist the team in the analysis of the electronic data records and the data sets which are currently employed in children's primary health care.

List of up to 5 relevant publications/ or products/services/software, other achievements:

1. Web-based electronic health record - www.paidiatros.com
2. Telemedicor system. Remote diabetes' self-management system. -Fully automated, multi-level medical data access which allows many kinds of medical applications (online check ups, knowledge database, exchange of medical information, etc).

3. Dimopoulos, C., Cegarra, J., Gavriel, G., “Developing Interdisciplinary Specifications for the Design and Implementation of IT Scheduling Decision Support Systems: An SME Case Study”, in the 10th International Conference on Manufacturing Research (ICMR 2012), Electronic Proceedings, Birmingham, UK, 2012.

List of up to 5 relevant previous projects or activities, connected to the subject of the proposal:

1. EAPRASnet (European Academy of Paediatrics Research in Ambulatory Setting network) <http://epaediatrics.eu/eaprasnet11.ehtml>

2. COSI - Core set of indicators

The aim of COSI is to develop an indicator database after systematic literature review for existing indicators and public sources as knowledge base – ready. This core set describes the desirable performance of any medical provider in the field of primary child care under optimal conditions in Europe. Moreover will develop recommendation for the medical primary care of children in Europe and applied to the diverse settings as pilot and for European comparisons and eventually for benchmarking.

3. i-DESME

<http://www.idesme.com>

The project’s aim was to develop a framework process for the interdisciplinary design and implementation of production scheduling Decision Support Systems (DSS). The project activities involved the implementation of scientific studies for the analysis and modelling of the scheduling environment and its electronic infrastructure from the human, organizational and technological perspectives. These findings led to the development of a requirements specification document which described and modelled the functional and non-functional requirements of the new support system in an interdisciplinary manner.

Description of significant Infrastructure/ Facilities to be used/ Major Items of Equipment (relevant to proposed work);

European University Cyprus hosts extensive IT & Library infrastructures which allow the efficient implementation of the project’s objectives. In particular, the Department of Computer Science & Engineering provides access to more than 50 fully equipped PC positions for research purposes. In addition, the EUC Library provides a seating

capacity of 200 positions for study purposes and contains more than 75,000 volumes of highly specialized books covering all subject areas.

Description of the institution (Profile)

The department Health Technology and Services Research (HTSR) investigates the impact of medical technologies to improve personalized healthcare from the perspective of patients and the health system. One of the objectives is to elicit patient and stakeholder preferences to inform about medical technology use, benefit-risk and health technology assessment and to evaluate the adoption of medical technologies in the health system to improve the efficiency and quality of healthcare delivery. HTSR has a long tradition of patient preference research, as evidenced by numerous international collaborations.

One of the domains of research of the department HTSR is youth. The University of Twente is a main partner in the Academic Working place Youth Twente (AWJT) ‘Strengthening the care for vulnerable children’. Within this working place, youth health care, primary care partners and Centres for Youth and Family (CJG’s) collaborate in order to bring together practice, policy, education and research. The objective is, based on scientific evidence, to improve the chain of care between youth healthcare and other organisations involved in the care of children, and to implement effective interventions especially for the most vulnerable children.

The HTSR department has a long tradition of patient preference research, as evidenced by numerous international collaborations with Johns Hopkins School of Public Health, NUS school of Pharmacy, Hochschule Neubrandenburg in Germany and RTI health solutions in the USA.

Main Tasks undertaken in MOCHA

Firstly a qualitative analysis of key differences between proposed patient-centered and prevention oriented primary child health care models emerging from the analyses in the other WPs (task 1) will be conducted. The focus will be on differences that influence quality of care (outcomes, patient-centeredness, and access) from the perspective of the general public. In a workshop of a forthcoming European conference the priorities in attributes of primary child health care models will be deliberated with experts from different countries. The qualitative analysis and opinions on attributes are input for the Patients’/Public Preference Questionnaire that

will be developed using a recommended preference instrument. Data collection will take place in a limited number of EU countries, with a diversity of child health care models.

CV of PI and main people involved (including gender):

Janine van Til is an expert on the patient preference research and Karin Groothuis-Oudshoorn on the statistics of the methodology. Magda Boere-Boonekamp is the principal researcher in the youth health care domain. She has a broad network, regionally as well as nationally and internationally, in the field of (preventive) child healthcare and is a member of several related committees and working groups.

List of up to 5 relevant publications/ or products/services/software, other achievements:

vanTil JA, IJzerman MJ. Why Should Regulators Consider Using Patient Preferences in Benefit-risk Assessment? *Pharmacoeconomics*. 2013 Nov 28.

vanTil JA, Stiggelbout AM, IJzerman MJ. The effect of information on preferences stated in a choice-based conjoint analysis. *Patient EducCouns*. 2009 Feb;74(2):264–71.

Groothuis-Oudshoorn CGM, Fermont JM, van Til JA, IJzerman MJ. Public stated preferences and predicted uptake for genome-based colorectal cancer screening. *BMC Med Inform DecisMak*. 2014 Mar 19;14(1):18.

Wieske RC, Nijhuis MG, Carmiggelt BC, Wagenaar-Fischer MM, Boere-Boonekamp MM. Preventive youth health care in 11 European countries: an exploratory analysis. *Int J Public Health* 2012;57:637-41.

vanWijk RM, van Vlimmeren LA, Groothuis-Oudshoorn CG, Van der PloegCP,IJzerman MJ, Boere-Boonekamp MM. Helmet therapy in infants with positional skull deformation: randomised controlled trial. *BMJ*. 2014 May 1;348:g2741.

List of up to 5 relevant previous projects or activities, connected to the subject of the proposal:

2008 HEADS. Patient reported outcomes in helmet treatment: elicitation of parental and physician preferences and treatment satisfaction. Grant ZonMw – DO / HTA. Co-project leader: Janine van Til

2009 Academic Working Place Youth Twente: Strengthening the care for vulnerable children. UT and GGD Twente. Grant ZonMw – AWJ. Co-project leader Magda

Boere-Boonekamp

2009 Bachelor assignment R.C. Wieske on Preventive youth health care in 11 European countries. Publication in Int J Public Health 2012

2011 What is best when using drugs in chronic disease. Best-worse scaling to determine patient preferences in Parkinsons disease. Grant ZonMw – pharmacotherapy. Project leader: Janine van Til

2012 A roadmap for uncertainty analysis in MCDA. ZONMW – HTA methodology. Co-project leader: Janine van Til

2012 Regional consortium Pregnancy and childbirth, with project: Analysis of the coordination of care during pregnancy and perinatal period. Grant ZonMw. Project leader: Magda Boere-Boonekamp

2013 Patient preferences for diabetes care. ROCHE Germany. Co-project leader: Janine van Til

Description of significant Infrastructure/ Facilities to be used/ Major Items of Equipment (relevant to proposed work);

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Partner 15 – SDU

<p>Description of the institution (Profile)</p> <p>The University of Southern Denmark (Syddansk Universitet, SDU) was established in 1998 by the merger of The University of Odense (founded in 1966) with other institutions, and SDU has subsequently grown by further mergers to become Denmark's third largest comprehensive university. SDU has 5 faculties on 6 campuses distributed throughout Southern Denmark, including Copenhagen, and counts c. 4,000 employees and close to 27,000 registered students. SDU's commitment to research excellence and growth is reflected in a.o. the uniquely close integration of university research and the regional healthcare system, and the numerous successful partnerships with private companies. SDU is currently involved in the largest infrastructure project ever in Denmark, when the Health Sciences Faculty and Odense University Hospital are moving to the main campus, providing health sciences at SDU and the Region of Southern Denmark with sophisticated state-of-the-art modern research facilities.</p> <p>Main Tasks undertaken in MOCHA</p> <p>The SDU contributes Work Package (WP) 2 which aims to examine the primary physician/specialist interface, the interface between primary and secondary care for children with enduring health issues and the social care interface with families of children who have complex health needs. SDU will mainly contribute to this WP by focusing on children with the enduring mental health issues. This task will initially require the adaptation of a measurement tool such as the Facts Questionnaire which could serve to provide an illustration of the various approaches to care delivery for children with enduring complex health care needs at the acute community interface.</p>
<p>CV of PI and main people involved (including gender):</p> <ul style="list-style-type: none"> • MSc Stine Lundstroem Kamionka (Female)
<p>List of up to 5 relevant publications/ or products/services/software, other achievements:</p> <p>1. Kamionka SL, Buus N, Sodemann M, Clausen B, Noehr-Jensen P, Larsen KJ (2014) “Intersectoral pathways of vulnerable patient groups in Southern Denmark -</p>

preliminary results from an ongoing study”.

2. Winner of the 1st price poster presentation at the 14th International Conference for Integrated Care, Brussels 2014

List of up to 5 relevant previous projects or activities, connected to the subject of the proposal:

1. Centre of Suicide Prevention, Child and Adolescent Psychiatry Odense: Project “Enhanced treatment efforts towards suicidal behavior in the Region of Southern Denmark” (2010-2013)

2. Kamionka SL, Buus N, Sodemann M, Clausen B, Noehr-Jensen P, Larsen KJ (2014) “Intersectoral pathways of vulnerable patient groups in Southern Denmark - preliminary results from an ongoing study”.

3. Winner of the 1st price poster presentation at the 14th International Conference for Integrated Care, Brussels 2014

4. Broedsgaard E, Kamionka SL, (2009) “Organizational First Aid: Crisis Management at Odense University Hospital”. University of Southern Denmark, Institute of Marketing and Management

Description of significant Infrastructure/ Facilities to be used/ Major Items of Equipment (relevant to proposed work);

No significant infrastructure will be required

Partner 16 – Keele University

Keele was the first new United Kingdom University of the 20th Century, established with degree giving powers in 1949 as the University College of North Staffordshire. University status, as the University of Keele, followed in 1962. The University has three faculties: The Faculty of Health, The Faculty of Natural Sciences and The Faculty of Humanities and Social Sciences

The Faculty of Humanities and Social Sciences was created in 2004 and comprises: Keele Management School; the Schools of Law; Politics, International Relations and Philosophy; Public Policy & Professional Practice; and Sociology & Criminology; and the School of Humanities. The Faculty is also home to Research Institutes for the Humanities and Social Sciences. Research Institutes are charged with generating and supporting research, enterprise and knowledge transfer activities, hosting visiting academics; organising research seminars and conferences and for the training and supervision of research students.

Research in Criminology is conducted under the auspices of the Centre for Social Policy in the Research Institute for Social Sciences. The Centre includes social scientists working in all three faculties within the University. It brings together a number of research active groups covering research in the fields of Human Geography, Criminology, Education, Health Policy, Social Gerontology, Sociology and Social Work. Across these disciplines research focuses on community, mobilities and identities.

Main Tasks undertaken in MOCHA

Dr. Helen Wells' contribution to the current project stems from her expertise in understanding and interpreting the way in which sanctions and incentives are used to motivate compliance with rules, particular those applied to norm-bearing contexts.

CV of PI and main people involved (including gender):

Dr. Helen Wells (Female) - Dr. Helen Wells is Senior Lecturer in Criminology and an active researcher in the Centre for Social Policy. Her research interests are in the fields of

roads policing and traffic offending, within a broader topic of 'The Crimes of the Law Abiding'. This term refers to the offending of individuals who are nonetheless able to maintain a law-abiding self-identity and reflects an interest in the way in which otherwise respectable and compliant members of society select certain behaviours, and certain laws, as being exempt from any obligation to comply. She leads a group of researchers in the UK abroad looking at such topics as illegal downloading, non-problematic drug use, theft of time and goods in the workplace, fixed penalties for a range of low-level offences, and traffic offenders.

List of up to 5 relevant publications/ or products/services/software, other achievements:

1. Haines, A and Wells, H (2012) 'Persecution or protection? The public's response to two road-based surveillance systems' *Criminology and Criminal Justice*
2. Wells, H (2012) *The Fast and The Furious: Drivers, Speed Cameras and Control in a Risk Society* Aldershot: Ashgate
3. Wells H, Cropper S, Turner J. (2011) *Total Place and Alcohol Harm Reduction: Report on Service Recommendations for the Newcastle-under-Lyme Community Safety Partnership.*
4. Wells, H and Wills, D (2009) 'Individualism and Identity: Resistance to Speed Cameras in the UK' *Surveillance and Society* Vol.6, No.3
5. Wells, H (2008) 'The Techno-Fix Versus The Fair Cop: Procedural (In)Justice And Automated Speed Limit Enforcement'. *British Journal of Criminology* Vol.48, No.6

List of up to 5 relevant previous projects or activities, connected to the subject of the proposal:

1. 2002-2006 ESRC funded PhD on the response of drivers to enforcement by speed camera. Exploration of the experiences of those penalised and their understandings of the meaning of being problematised by the law.
2. I lead a group of researchers in the UK and abroad looking at 'The Crimes of the Law Abiding'. This refers to a range of behaviours which breach various laws and which thrust people who would otherwise consider themselves respectable, law-abiding citizens into contact and conflict with authority and see them receive sanctions for their behaviour. We are working towards a seminar series and a journal special edition and have presented

as a panel at conferences.

3. Supervision of an externally funded PhD focussing on the use of fixed penalties in a variety of contexts from road traffic, to parking, to littering, to smoking. Explores the rationales behind their use, their translation into policy and the experiences of those receiving them.

4. Supervision of an externally funded PhD student focussing on an evaluation of an educational intervention (in place of prosecution and fixed penalty) for drivers caught using their mobile phones while driving, or not wearing their seatbelt

Description of significant Infrastructure/ Facilities to be used/ Major Items of Equipment (relevant to proposed work);

No significant infrastructure will be required

Partner 17– CHB

Description of the institution (Profile)

Dr. Jay Berry, is located at Boston Children’s Hospital (BCH), which is built on a longstanding foundation of excellent paediatric clinical care, research, teaching, and community service. BCH is the paediatric teaching hospital of Harvard Medical School and is one of the largest and best regarded free-standing academic paediatric medical centers in the U.S., with ~390 beds, and 22,600 inpatient admissions, 22,400 surgeries, and 472,000 outpatient and emergency visits per year. It has nearly 1,000 active medical and dental staff and 775 residents and fellows. BCH is an international referral center for many children with medical complexity and a regional center for highly specialized care. BCH is viewed nationally as a leader in developing innovative models of care to serve children with medical complexity. BCH is the nation’s largest paediatric research facility, ranking first in federal research funding with ~\$225 million in research grants. Currently, 1,500 research faculties at BCH conduct biomedical research in 36 departments. A leading teaching facility, BCH hosts 32 clinical fellowship programs and 16 federally-funded training programs. The hospital places a high priority on training and nurturing clinical researchers. Dr. Berry is housed in the Division of General Paediatrics, in the Department of Medicine at BCH. The Division includes 7 clinical programs (both inpatient and outpatient), a health services research training program for postdoctoral fellows, and a total faculty of ~80 Harvard appointed physicians and scientists. Research faculty members in the Division are leading experts on a variety of topics, such as complex care, disability, hospital readmissions.

CV of PI and main people involved (including gender):

- Dr. Jay Berry (Male) – CV attached

List of up to 5 relevant publications/ or products/services/software, other achievements:

1. R. Characteristics of Hospitalizations for Patients Who Use a Structured Clinical Care Program for Children with Medical Complexity. J Pediatr. 2011 Aug;159(2):284-90.
2. Berry JG, Bloom S, Foley S, Palfrey J. Children with Chronic

Health Conditions: Another Case of Health Inequity. *Pediatrics*. 2010 Dec;126 Suppl 3:S111-9

3. Cohen E, Berry JG, Camacho X, Anderson G, Wodchis W, Guttman A. Patterns and Cost of Health Care Use of Children with Medical Complexity. *Pediatrics*. 2012 Dec;130(6):e1463-70

4. Berry JG, Goldmann D, Mandl K, Putney H, Antonelli R, Helm D, Weinick R. Health Information Management and Perceptions of the Quality of Care for Children with Tracheotomy: A Qualitative Study. *BMC Health Serv Res*. 2011 May 23;11:117

5. Berry JG, Hall D, Cohen A, Kuo D, Agrawal D, Kueser J, Feudtner C, Hall M, Neff J. Hospital utilization and characteristics of patients experiencing recurrent readmissions within children's hospitals. *JAMA*. 2011 Feb 16;305(7):682-90

List of up to 5 relevant previous projects or activities, connected to the subject of the proposal:

1. On-line Information and Network Center for Children with Medical Complexity. Funding source: Lucile Packard Foundation for Children's Health. Role: Co-investigator. Goals: To create a national registry of models of care for children with medical complexity practiced across U.S. children's hospitals to promote sharing of ideas on care delivery and quality improvement initiatives for these children.

2. Innovative Research Methods to Study Children with Multiple Chronic Conditions Funding source: Agency for Healthcare Research and Quality Role: principal investigator Goals: 1) To adapt for children a publicly available, comprehensive diagnosis classification scheme to describe identify and describe the clinical diagnoses of children with multiple chronic conditions (CMCC); and 2) to employ an innovative, machine learning method to systematically identify the most consequential interactions of coexisting chronic conditions in CMCC and to predict high resource utilization in these children.

3. Improving Healthcare Integration for Children with Tracheostomy Role: Principal Investigator Funding Source: National

Institute of Child Health and Human Development Goals: To improve healthcare integration and decrease re-hospitalizations for medically-complex children using an innovative information technology application (personally-controlled health record).

4. Hospital Discharge Planning for Children Role: Principal investigator Funding Source: Lucile Packard Foundation for Children's Health Goals: To develop national consensus for discharge planning of hospitalized children, including the integration of outpatient and hospital care for children with medical complexity.

5. Children's Hospital Applications Maximizing Patient Safety Role: Co-investigator Funding Source: Human Resource Service Administration Goals: To leverage an existing electronic health record to summarize and share key, clinically-relevant health information about medically-complex children for both hospital and community caregivers.

Description of significant Infrastructure/ Facilities to be used/ Major Items of Equipment (relevant to proposed work);

The core research offices of the Division of General Paediatrics at Boston Children's Hospital, where Dr. Berry conducts his research, are currently accommodated in 3,200 sqft of space. This space is fully equipped with desktop PCs, laptops, and statistical analysis software. Office equipment such as printers, facsimile machines, scanners, photocopiers, and mailroom services are available to this research project. Video- and tele-conferencing tools are readily-available for the research team to use. Dr. Berry also has access to infrastructure support from Research Computing (RC). RC is devoted to the specialized computing needs of the research community at BCH and has set-up the research computing infrastructure of the Division of General Paediatrics. RC offers the following services: data storage and backup for over 90 research labs (>20 terabytes); desktop support and backup services (RC technicians are certified by Apple, IBM, and Dell); server support and administration; purchase and maintenance of scientific analysis applications (e.g. SAS, STATA); computing lab and large format poster printing; and custom application development and developer support for research-specific functions. RC also provides services for conducting webinars across multiple sites as well as electronic transmission of large data files (e.g., large administrative databases and report documents).

Partner 18 – CHUV

Description of the institution (Profile)

The University Hospital of Lausanne is one of the five university hospitals in Switzerland. The Hospital is linked to the Faculty of Biology and Medicine of the University of Lausanne.

CV of PI and main people involved (including gender):

PA Michaud has been a full Professor in Adolescent Medicine at Lausanne Faculty of Biology & Medicine and Lausanne University hospital and is currently employed by the University Hospital.

PA Michaud is coordinating the Euteach program (www.euteach.com), which allows him to work with several European colleagues heavily involved in school and adolescent health. He has also access to the large library of the Faculty and can find technical support for literature reviews etc – CV attached

List of up to 5 relevant publications/ or products/services/software, other achievements:

1. MICHAUD PA, PATTON, G, CHANDRAMOULI, V. Adolescent Health. In : DetelsBeaglehole R, Lansang MA, Gulliford M. Oxford Textbook of Public Health, Fifth Edition, Oxford University Press, London, 2009 pp. 1452-1464 (new version in progress)
2. MICHAUD PA. Prevention and health promotion in schools and community settings: A commentary on the international perspective. J Adolesc Health. 2003;33:219-225

3. MICHAUD PA, STRONKSI S, FONSECA H, MACFARLANE A. The Development and pilot-testing of a training curriculum in adolescent medicine. *J Adolesc Health* 2004; 35:51-57
4. MICHAUD PA. Prevention and health promotion in schools and community settings: A commentary on the international perspective. *J Adolesc Health*. 2003;33:219-225
5. JEANNIN A, NARRING F, TSCHUMPER AM, INDERWILDI bONIVENTO L, ADOR V, BUTIKOFER A, SURIS JC, DISERENS C, ALSAKER F, MICHAUD PA. Self-reported needs and use of primary health care services by adolescents enrolled in post mandatory schools or vocational training programs in Switzerland. *Swiss Med Weekly* 2005;135:11-18 MAUERHOFER A, AKRE D MICHAUD PA, SURIS JC. Youth Friendly outpatient Care. *Arch Pediatr*. (2009) MAUERHOFER A, BERCHTOLD A, AKRE C, MICHAUD PA. Female adolescents' views on a youth

List of up to 5 relevant previous projects or activities, connected to the subject of the proposal:

1. Development of a training module on ethics as applied to adolescent health (UNFPA)
2. Consultant Assignment by UNFPA: evaluation of a youth friendly services programme in Turkey
3. Consultant Assignment for UNICEF: training of health professionals in Moldavia (adol.health)
4. Consultant Assignment for UNICEF: training of health professionals in Russia (adol. health)
5. Organization of European 2-days meeting on school health (WHO)

Third Parties involved in the project:

No third parties or subcontractors involved.

Description of significant Infrastructure/ Facilities to be used/ Major Items of Equipment (relevant to proposed work);

PA Michaud is coordinating the Euteach program (www.euteach.com), which allows him to work with several European colleagues heavily involved in school and adolescent health (such as those mentioned in the CV). He has also access to the large library of the Faculty and can find technical support for literature reviews etc.

Partner 19 – MCRI

Murdoch Childrens Research Institute (MCRI) is the preeminent child health research institute in Australia, and is recognised globally for its child health discoveries. Researchers at the Institute work side-by-side with doctors and nurses from our campus partners The Royal Children's Hospital and the University of Melbourne's Department of Paediatrics. As the largest child health research institute in Australia, it is well positioned to make major discoveries to improve child health. With over 70 large research teams, it has the critical mass needed in modern day research to solve problems more rapidly.

The mission is to obtain knowledge to improve the health of children, both here and around the world.

The vision is to be a major global contributor to the creation of knowledge that leads to improved child health.

The goal is to be one of the top five child health research institutes in the world.

The objective is to conduct globally competitive research that capitalises on our strengths across the disciplines of laboratory, clinical and public health research.

The aim is to drive enterprise, initiative and cross disciplinary interaction by taking advantage of the clinical opportunities and insights provided by co-location at The Royal Children's Hospital.

The Institute's research is structured around five research themes. The themes are made up of smaller research groups, and aim to build critical mass and bring together teams that have common interests and disciplines to find answers to child health problems. Themes are defined by their methodologies and by their globally competitive platforms. The themes consist of groups from clinical, laboratory and public health backgrounds.

Investigators Goldfeld, Hiscock and Freed are all based in the Population Health theme. The Theme aims to improve understanding of the complex interplay of social, environmental, and biological factors (including genetic and epigenetic factors - factors controlling gene activity) that influence child and adolescent health, and to translate this knowledge into effective prevention, early intervention and treatment strategies appropriate to diverse populations, particularly those affected by social disparities. In particular investigator Goldfeld leads a research group focussed on child health equity and policy and investigator Hiscock leads a group focused on community child health services research and also directs the Australian Paediatric Research Network which will provide much of the data to inform her work in MOCHA regarding the primary/specialist interface.

Aside from the expertise each of the investigators brings the MOCHA activities will require access to strong statistical support in order to utilise existing Australian datasets (WPI, 2 and 7), and therefore add value to the overall comparative work generated by MOCHA.

CVs of PI and main people involved (including gender):

Sharon Goldfeld (Female) - Consultant Paediatrician, Centre for Community Child Health, Royal Children's Hospital

Relevant Publications

Goldfeld S, Kvalsvig A, Incedon E, O'Connor M, Mensah F. Predictors of mental health competence in a population cohort of Australian children. *Journal of Epidemiology and Community Health* published online January 2014 doi: 10.1136/jech-2013-203007.

Woolfenden S, **Goldfeld S**, Raman S, Eapen V, Kemp L, Williams K. Inequity in child health: The importance of early childhood development. *Journal of Paediatrics and Child Health* 2013;49: E365-E369.

Wake M, Tobin S, Levickis P, Gold L, Ukoumunne OC, Zens N, **Goldfeld S**, Le H, Law J, Reilly S. Randomized trial of population-based home-delivered intervention for preschool language delay. *Pediatrics* 2013; 132(4): e895-904.

Goldfeld S, Quach J, Nicholls R, Reilly S, Ukoumunne O, Wake M. Four-year old outcomes of a universal infant-toddler shared reading intervention: The Let's Read trial. *Arch Pediatr Adolesc Med* 2012; 166(11): 1045-52

Goldfeld S, Oberklaid F. Maintaining an agenda for children and young people: The key role of data in linking policy, politics and outcomes. *Medical Journal of Australia* 2005, 183:1-3. (IF 3.1)

Relevant Projects

Australian Government Department of Education, Employment and Workplace Relations. **Goldfeld S**, Sayers M, Oberklaid F, Wake M. Australian Early Development Index Research Agenda. *A nationwide census of how young Australian children have developed as they start their first year of formal, full-time education*. \$1.5mil (AUD).

Ian Potter Foundation.(\$0.25mil) and Australian Research Council (\$0.6mil) **Goldfeld S**, Snow P, Eadie P, Munro J, Gold L, Oberklaid F, Connell J, Andersen-Dalheim B, Inniss G, Barnett T, Hopkins L, Investigating the impact of the Classroom Promotion of Oral Language (CPOL) Trial on children's language, literacy and mental health: *the effectiveness of an oral language intervention on the language and literacy development and mental health of children by Grade Three*.

Australian Research Alliance for children and Youth. **Goldfeld S**, Price A, Mensah F, Gold L, Hiscock H, Moore T. Right@home sustained nurse home visiting trial. \$3.3mil (AUD)

An Australian multi-state sustained nurse home visiting randomised controlled trial designed to promote family wellbeing and child development.

National Health and Medical Research Council Partnership Grant. \$0.67mil. Yelland J, Riggs E, Brown S, Casey S, Wallace E, **Goldfeld S**, East C, Furler J. *Bridging the Gap: addressing refugee inequalities through primary health care service reform*.

Prof. Gary Freed (Male) Professor of Population Health, School of Population Health, University of Melbourne

I am the Principal Investigator of one of the 7 Centers of Excellence in the US to develop, test and disseminate quality measures for pediatric care. Funded by the Agency for HealthCare Research and Quality, this 4 year, \$8 million grant resulted in the development and testing (for reliability and validity) of over 60 quality measures. The first 20 of these measures have been accepted into the National Quality Measure Clearinghouse of the federal government.

Associate Professor Harriet Hiscock (Female) Royal Children's Hospital (RCH), Melbourne. Paediatrician and senior research fellow, Centre for Community Child Health.

Clinical work: Director, Unsettled Babies Clinic, private paediatrics.

Relevant Publications

- 1. Hiscock H**, Cook F, Bayer J, Le HND, Mensah F, Cann W, Symon B, St James Roberts I. Preventing early infant sleep and crying problems and postnatal depression: A randomized trial. *Pediatrics* published online 6 Jan 2014 PMID: 24394682
 - 2. Hiscock H**, Bayer J, Lycett K, Ukoumunne O, Shaw D, Gold L, Gerner B, Loughman A, Wake M. Preventing mental health problems in children: the Families in Mind population-based cluster randomised controlled trial. *BMC Public Health* September Published online 8 June 2012.
 - 3. Hiscock H**, Roberts G, Efron D, Sewell J, Bryson H, Price A, Oberklaid F, South M, Wake M. Children Attending Paediatricians Study: a national prospective audit of outpatient practice from the Australian Paediatric Research Network. *Medical J Aust* 2011;194(8):392-7.
 - 4. Bayer JK, Hiscock H**, Scalzo K, Mathers M, McDonald M, Morris A, Birdseye J, & Wake M. Systematic review of preventive interventions for children's mental health: what would work in Australian contexts? *Aust N Z J Psychiatry* 2009;43(8):695-710.
 - 5. Hiscock H**, Bayer J, Price A, Ukoumunne OC, Rogers S, Wake M. Universal parenting programme to prevent early childhood behavioural problems: cluster randomised trial. *BMJ* 2008;336:318–21; doi:10.1136/bmj.39451.609676.AE.
- Large, community based trial of a universal parenting intervention delivered in primary care which aimed to prevent early child mental health problems and improve parenting behaviours.*

Relevant Projects

- *Children Attending Paediatrician Study* – 2008 and 2013 national audits of Australian paediatrician’s casemix (n=8,000 and 7,500 consultations, respectively), highlighting the mental health load (ADHD, autism, anxiety) and variation in paediatric practice for these common conditions.
- *Infant Sleep Study* – randomised controlled trial of a sleep intervention to improve infant sleep and maternal depression, delivered by Health Visitors. Demonstrated the ability to up skill a primary care health workforce to manage a common child health problem.
- Several surveys of paediatrician practice in various areas (food allergy, ADHD, chronic fatigue, infant colic etc) – all highlighting significant practice variation and the need for consistent, evidence-based practice in these areas.

List of up to 5 relevant publications/ or products/services/software, other achievements:

1. Goldfeld S, Kvalsvig A, Incledon E, O'Connor M, Mensah F. Predictors of mental health competence in a population cohort of Australian children. Journal of Epidemiology and Community Health published online January 2014 doi: 10.1136/jech-2013-203007.

2. Woolfenden S, Goldfeld S, Raman S, Eapen V, Kemp L, Williams K. Inequity in child health: The importance of early childhood development. Journal of Paediatrics and Child Health 2013;49: E365-E369.

1. Hiscock H, Cook F, Bayer J, Le HND, Mensah F, Cann W, Symon B, St James Roberts I. Preventing early infant sleep and crying problems and postnatal depression: A randomized trial. Pediatrics published online 6 Jan 2014 PMID: 24394682

2 Hiscock H, Bayer J, Lycett K, Ukoumunne O, Shaw D, Gold L, Gerner B, Loughman A, Wake M. Preventing mental health problems in children: the Families in Mind population-based cluster randomised controlled trial. BMC Public Health September Published online 8 June 2012. 3.Hiscock H, Roberts G, Efron D, Sewell J, Bryson H, Price A, Oberklaid F, South M, Wake M. Children Attending Paediatricians Study: a national prospective audit of outpatient practice from the Australian Paediatric Research Network. Medical J Aust 2011; 194(8):392-7.

4.Bayer JK, Hiscock H, Scalzo K, Mathers M, McDonald M, Morris A, Birdseye J, & Wake M. Systematic review of preventive interventions for children's mental health: what would work in Australian contexts? Aust N Z J Psychiatry 2009; 43(8):695-710.

5. Hiscock H, Bayer J, Price A, Ukoumunne OC, Rogers S, Wake M. Universal parenting programme to prevent early childhood behavioural problems: cluster randomised trial. BMJ 2008; 336:318-21; doi:10.1136/bmj.39451.609676.AE. Large, community based trial of a universal parenting intervention delivered in primary care which aimed to prevent early child mental health problems and improve parenting behaviours

List of up to 5 relevant previous projects or activities, connected to the subject of the proposal:

1. Children Attending Paediatrician Study – 2008 and 2013 national audits of Australian paediatrician’s casemix (n=8,000 and 7,500 consultations, respectively), high-lighting the mental health load (ADHD, autism, anxiety) and variation in paediatric practice for these common conditions.
2. Infant Sleep Study – randomised controlled trial of a sleep intervention to improve infant sleep and maternal depression, delivered by Health Visitors. Demonstrated the ability to up skill a primary care health workforce to manage a common child health problem.
3. Several surveys of paediatrician practice in various areas (food allergy, ADHD, chronic fatigue, infant colic etc) – all highlighting significant practice variation and the need for consistent, evidence-based practice in these areas.

Description of significant Infrastructure/ Facilities to be used/ Major Items of Equipment (relevant to proposed work);

No significant infrastructure will be required

4.2 Involvement of Third Parties

P1 - ICL

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	Y
<p><i>The Partner will be responsible for the service contract with an institution in each of 23 countries (those not covered by Partners for this function) to supply Country Agent information supplying functions (see proposal pages 20-21).</i></p> <p><i>The Partner will have a service contract with one independent member of the External Advisory Board.</i></p> <p><i>Est. Budget €1,035,000.00</i></p>	
Does the participant envisage that part of its work is performed by linked third parties ¹	N
<p><i>If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party</i></p>	
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	N
<p><i>If yes, please describe the third party and their contributions</i></p>	

P2 – UCD

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	Y
<p><i>Some of the work of country agent will be sub-contracted to the main national children's hospital for the services of a named individual research nurse.</i></p> <p><i>Est. Budget: €30,000.00</i></p>	
Does the participant envisage that part of its work is performed by linked third parties ³	N
<p><i>If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party</i></p>	
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	N
<p><i>If yes, please describe the third party and their contributions</i></p>	

P3 – UMCG

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	Y
<i>Obtaining patient experience of current service models is important. DIPEX International network will be commissioned to provide this analysis. Est. Budget: €250,600.00</i>	
Does the participant envisage that part of its work is performed by linked third parties ⁴	N
<i>If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party</i>	
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	N
<i>If yes, please describe the third party and their contributions</i>	

P5 – Surrey

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	Y
<i>In line with the WP 5 Description, and the Ethical Self-assessment, WP 5 will seek to collaborate with the custodians of large electronic data sets in Member States, to undertake coordinated harmonised analyses. At this stage it is not possible to identify individual institutions, as this depends on an earlier phase of the work, but a budgetary sum has been reserved. Est. Budget: €50.000,00</i>	
Does the participant envisage that part of its work is performed by linked third parties ⁴	N
<i>If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party</i>	
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	N
<i>If yes, please describe the third party and their contributions</i>	

P12 – UI

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	Y
<i>Setting up economic impact study and setting up database access through contractor Est. Budget: €6.000,00</i>	

Does the participant envisage that part of its work is performed by linked third parties ⁴	N
<i>If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party</i>	
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	N
<i>If yes, please describe the third party and their contributions</i>	

P14 – UTwente

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	Y
<i>Arranging 4 extra country surveys, through contractor Est. Budget: €20.000,00</i>	
Does the participant envisage that part of its work is performed by linked third parties ⁴	N
<i>If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party</i>	
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	N
<i>If yes, please describe the third party and their contributions</i>	

Participant Number/Short Name	Cost (€)	Justification
Large research infrastructure	23487	TNO has opted for the LRI scheme in the Participants database of the EC. The LRI scheme has not yet been positively assessed by the Commission. This is in process and in conformity with the procedure which is communicated through the EC.

Section 5: Ethics and Security

5.1 Ethics

MOCHA will not carry out any clinical trials, study individual patients or citizens' health records or health history, or access patient data. However, the proposers of the MOCHA project do see it as important to devise measures of outcome, and of quality, which can be applied by owners and practitioners of national operational models of primary care for children. They also see it as important to obtain public opinions and experiences of these services, as a key part of engagement with stakeholders.

The proposal therefore contains three separate arm's length and ethically contained components.

1. In WP 1, with a sub-component in WP 2, the project will commission the DIPEX International network (www.dipexinternational.org) to obtain views of patient experiences of health care in five Member States - Czech Republic, Germany, Spain, UK, and The Netherlands. The DIPEX network has an established methodology developed by Oxford University, applying UK research ethics policies and standards. DIPEX operates by approving specific research institutions which have been trained and assessed to apply the DIPEX principles and methods. The MOCHA project will commission DIPEX International to ascertain views on specific issues. DIPEX will be required to apply its general and country-specific ethics procedures. MOCHA staff and institutions will not in any way be involved in the conduct of this work, the recruitment of respondents, or the handling of raw data, which will happen within each country-specific approved institution. Prior to any commissioned DIPEX studies, each DIPEX centre will be required to produce proof of local ethical clearance - this will be made available to the Commission's desk officer for the project, as well as to the External Advisory Board.
2. Work Package 5 will seek to develop innovative outcome and quality measures of children's primary health care models, based on available large electronic data sets held in Member States. These should provide a valuable source of analyses based on Large Data principles, and possibly Big Data concepts. However, for practical and ethical reasons, neither MOCHA nor the Work Package partners will have access to these data (subject to the possible exception below). The methodology to be adopted, therefore, is that during the first year of operation of the project, an informed researcher in each EU Member State / EEA State (the project's identified 'Country Agent') will ascertain which sources of aggregated and anonymised data such as authorised depositories of primary care data, or data which can be analysed anonymously (such as immunisation registers) exist within their country such that can be used to analyse child primary health care model outcome or quality data, with a catalogue or logical construct of the data types held. They will also be asked to report on the access and authorisation criteria for researchers to access such data, and key contact persons in the form of database custodians or authorised research workers. This Europe-wide enquiry will be compiled into a Deliverable (Deliverable 5-2, Month 15). Then, in the light of that report, and as seems appropriate in order to further the objectives of the project of assessing comparative outcomes, and costs, of each type of child primary healthcare model, Work Package 5 will propose specific defined analyses which might be undertaken in a harmonised manner across those databases. The External Advisory Board will be asked to validate that analysis set, its scientific validity and relevance and its ethics, and the identified local researchers and local data custodians will be invited to participate in a collaborative analysis with each data set being accessed in its own State by its own approved and authorized scientists. Each na-

tional scientist will we required to produce a copy of their ethical and data custodian authorisation before the process is confirmed - copies of these authorisations will be made available to the Commission's desk officer for the project as well as to the Expert Panel. However, if specific data custodians ask the University of Surrey as WP leader, and with its in-house secure data analysis facilities under the direct supervision of the WP Leader as a medical professor, and subject to agreed transfer within Europe of analysed data, then the analyses may be undertaken in Surrey – in which case the local data custodian will be asked to approve the final analytic report from that data.

3. To obtain the views of the public as stakeholders of the optimal models coming out of the project through Work Package 9, University of Twente, Netherlands, as a WP partner will undertake a set of harmonised public opinion surveys in selected countries. This will be an opinion survey – participants will be selected as citizens, not as patients or related to individual treatment of themselves or their children. The questions will be about hypothetical future models of provision. University of Twente is experienced in such public opinion gathering work related to health issues, and will be in accordance with university, national and European protocols. The work will be conducted under international rules and legislation, as well as European standards of research ethics, as it is expressed in the applicable legislation and regulations:

- The Declaration of Helsinki (informed consent for participation of human subjects in medical and scientific research).
- The European Directive 95/46/EC (amendment 2003) and Regulation (CE) No 45/2001 of the European Parliament and of the Council of 18 December 2001, on privacy protection of individuals.
- Published Opinions of the European Group on Ethics in Science and New technologies, in particular those relating to:
 - ICT (Protection of privacy and protection against personal intrusion);
 - Ethics of responsibility (Right to information security);
 - Article 15 (Freedom of expression and research and data protection);
- The Chapter of Fundamental Rights of the EU;
- The conduct of the project will anticipate on emerging standards of data and privacy protection (such as required by the planned General Data Protection Regulation (GDPR)). Specifically, measures as data protection by design and by default will be applied, e.g. Privacy Enhancing Technologies, such as oneway encryption of data and separation of identifying information from other data on individual persons.

The research conducted in the Netherlands and the other participating countries to be agreed within the project and endorsed by the External Advisory Board will furthermore comply with prevailing national legislations and regulations applicable to the particular research activity. The consortium agreement will contain a statement to ensure compliance with those rules and adherence by all the partners, in particular those partners responsible for the public opinion surveys in their country.

It is anticipated the participants will be asked to fill out a questionnaire consisting of two

parts. In the first part preferences of respondents with regard to attributes of different child health care models are to be elicited using a recommended preference instrument (method still to be decided: e.g., direct scaling method, discrete choice experiment. In the second part socio-demographics and other characteristics will be asked: gender, age, marital status, employment status, educational level, solely for reasons of sample stratification and anonymous statistical analysis.

The prospective participants will be asked for consent before participating in the research. They will be informed about the study goals, and how it will involve them, what is further expected from them, risks and benefits, confidentiality and data protection, voluntarism of participation and the right to withdraw from the study. The researchers responsible for conducting the research in the participating countries will be experienced in conducting research.

Data collected during the project are treated with confidentiality according to state-of-the art standards and using Privacy Enhancing Technologies (PETs) where possible. Electronic data will be stored on secure servers in project shares that are only accessible through authorized user accounts. Study staff at each location will only have access to data relevant to their project roles.

All sites maintain state-of-the art security of their data systems, which include firewalls and regularly updated virus protection and daily back-ups. Back-up files at the participating institutions are maintained at a separate location to prevent data loss due to fire, theft, or other incident.

Identifying information (e.g., IP-address, email address) are only, stored if absolutely necessary for proper conduct of the research. If so, the identifying information will be encrypted and stored separately from the research data, with even more restricted access. Use of personal portals facilitate the application of PETs, such as advanced one-way encryption, that on one hand guarantee quality maintenance of the research and at the other hand make storage of identifying information redundant.

MOCHA Ethics – Question 4

1. During the first year of operation of the project, an informed researcher in each EU Member State / EEA State (the project's identified 'Country Agent') will ascertain which sources of aggregated and anonymised data such as authorised depositories of primary care data, or data which can be analysed anonymously (such as immunisation registers) exist such that can be used to analyse health model outcome data, with a catalogue or logical construct of the data types held. They will also be asked to report on the access and authorisation criteria for researchers to access such data, and key contact persons in the form of database custodians or authorised research workers. This Europe-wide enquiry will be compiled into a Deliverable (Deliverable 5-2, Month 15). Then, in the light of that report, and as seems appropriate in order to further the objectives of the project of assessing comparative outcomes, and costs, of each type of child primary healthcare model, Work Package E will propose specific defined analyses which might be undertaken in a harmonised manner across those databases. The External Advisory Board will be asked to validate that analysis set, its scientific validity and relevance and its ethics, and the identified local researchers will be invited to participate in a collaborative analysis with each data set being accessed in its own State by its own approved and authorised scientists. Each national scientist will we

required to produce a copy of their ethical and data custodian authorisation before the process is confirmed - copies of these authorisations will be made available to the Commission's desk officer for the project as well as to the Expert Panel.

2. During the last year of the project public opinion will be obtained concerning views on alternative possible models. This will be an opinion survey – participants will be selected as citizens, not as patients or related to individual treatment of themselves or their children. The questions will be about hypothetical future models of provision. The work will be undertaken by University of Twente, Netherlands, which is experienced in such public opinion gathering work related to health issues, and will be in accordance with university, national and European protocols. The work will be conducted under international rules and legislation, as well as European standards of research ethics, as it is expressed in the applicable legislation and regulations:
 - The Declaration of Helsinki (informed consent for participation of human subjects in medical and scientific research).
 - The European Directive 95/46/EC (amendment 2003) and Regulation (CE) No 45/2001 of the European Parliament and of the Council of 18 December 2001, on privacy protection of individuals.
 - Published Opinions of the European Group on Ethics in Science and New technologies, in particular those relating to:
 - ICT (Protection of privacy and protection against personal intrusion);
 - Ethics of responsibility (Right to information security);
 - Article 15 (Freedom of expression and research and data protection);
 - The Chapter of Fundamental Rights of the EU;
 - The conduct of the project will anticipate on emerging standards of data and privacy protection (such as required by the planned General Data Protection Regulation (GDPR)). Specifically, measures as data protection by design and by default will be applied, e.g. Privacy Enhancing Technologies, such as oneway encryption of data and separation of identifying information from other data on individual persons.
 - The research conducted in the Netherlands and the other participating countries to be agreed within the project and endorsed by the External Advisory Board will furthermore comply with prevailing national legislations and regulations applicable to the particular research activity. The consortium agreement will contain a statement to ensure compliance with those rules and adherence by all the partners, in particular those partners responsible for the public opinion surveys in their country.
 - It is anticipated the participants will be asked to fill out a questionnaire consisting of two parts. In the first part preferences of respondents with regard to attributes of different child

health care models are to be elicited using a recommended preference instrument (method still to be decided: e.g., direct scaling method, discrete choice experiment. In the second part socio-demographics and other characteristics will be asked: gender, age, marital status, employment status, educational level, solely for reasons of sample stratification and anonymous statistical analysis.

- The prospective participants will be asked for consent before participating in the research. They will be informed about the study goals, and how it will involve them, what is further expected from them, risks and benefits, confidentiality and data protection, voluntarism of participation and the right to withdraw from the study. The researchers responsible for conducting the research in the participating countries will be experienced in conducting research.
- Data collected during the project are treated with confidentiality according to state-of-the-art standards and using Privacy Enhancing Technologies (PETs) where possible. Electronic data will be stored on secure servers in project shares that are only accessible through authorized user accounts. Study staff at each location will only have access to data relevant to their project roles.
- All sites maintain state-of-the-art security of their data systems, which include firewalls and regularly updated virus protection and daily back-ups. Back-up files at the participating institutions are maintained at a separate location to prevent data loss due to fire, theft, or other incident.
- Identifying information (e.g., IP-address, email address) are only stored if absolutely necessary for proper conduct of the research. If so, the identifying information will be encrypted and stored separately from the research data, with even more restricted access. Use of personal portals facilitate the application of PETs, such as advanced one-way encryption, that on one hand guarantee quality maintenance of the research and at the other hand make storage of identifying information redundant.

5.2 Security

The proposal has no specified security issues.

ESTIMATED BUDGET FOR THE ACTION (page 1 of 2)

Estimated eligible ¹ costs (per budget category)										EU contribution			Additional information			
A. Direct personnel costs		B. Direct costs of subcontracting	[C. Direct costs of fin. support]	D. Other direct costs	E. Indirect costs ²	F. Special unit costs	Total costs	Reimbursement rate %	Maximum EU contribution ³	Maximum grant amount ⁴	Information for indirect costs	Information for auditors	Other information:			
A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons [A.6 Personnel for providing access to research infrastructure]		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary		D.1 Travel D.2 Equipment D.3 Other goods and services D.4 Costs of large research infrastructure		F.1 "Costs for clinical studies" **					Estimated costs of in-kind contributions not used on premises	Declaration of costs under Point D.4	Estimated costs of beneficiaries/linked third parties not receiving EU funding			
Form of costs ⁶	Actual	Unit ⁷	Unit ⁸		Actual	Actual	Actual	Flat-rate ⁹	Unit ¹¹							
	(a)	Total (b)	No hours	Total (c)	(d)	(e)	(f)	25%	Total (h1)	(i)= (a)+(b)+(c)+ (d)+(e)+(f)+ +[(h1)+(h2)]- (m)	(j)	(k)	(l)	(m)	Yes/No	
1. ICL	1329699.00	0.00			1035000.00	0.00	130164.00	364965.75		2859828.75	100.00	2859828.75	2859828.75	0.00	No	
2. UCD	557909.00	0.00			30000.00	0.00	42059.00	149992.00		779960.00	100.00	779960.00	779960.00	0.00	No	
3. UMCG	321325.00	0.00			250600.00	0.00	25000.00	86581.25		683506.25	100.00	683506.25	683506.00	0.00	No	
4. CNR	336792.00	0.00			0.00	0.00	79957.00	104187.25		520936.25	100.00	520936.25	519904.75	0.00	No	
5. SURREY	515655.00	0.00			50000.00	0.00	11000.00	131663.75		708318.75	100.00	708318.75	708318.00	0.00	No	
6. KI	241613.00	0.00			0.00	0.00	15060.00	64168.25		320841.25	100.00	320841.25	320841.00	0.00	No	
7. TNO	208487.00	0.00			0.00	0.00	45487.00	63493.50		317467.50	100.00	317467.50	317467.50	0.00	Yes	
8. KCL	96458.00	0.00			0.00	0.00	4500.00	25239.50		126197.50	100.00	126197.50	126197.50	0.00	No	
9. UM	22640.00	0.00			0.00	0.00	16500.00	9785.00		48925.00	100.00	48925.00	48925.00	0.00	No	
10. MUL	60528.00	0.00			0.00	0.00	28650.00	22294.50		111472.50	100.00	111472.50	111472.50	0.00	No	
11. HIH	56932.00	0.00			0.00	0.00	5000.00	15483.00		77415.00	100.00	77415.00	77415.00	0.00	No	
12. UI	27380.00	0.00			6000.00	0.00	7000.00	8595.00		48975.00	100.00	48975.00	48975.00	0.00	No	
13. EUC	24500.00	0.00			0.00	0.00	5500.00	7500.00		37500.00	100.00	37500.00	37500.00	0.00	No	
14. UTwente	30000.00	0.00			20000.00	0.00	4000.00	8500.00		62500.00	100.00	62500.00	62500.00	0.00	No	
15. SDU	21420.00	0.00			0.00	0.00	0.00	5355.00		26775.00	100.00	26775.00	26775.00	0.00	No	
16. KEELE	22879.00	0.00			0.00	0.00	4643.00	6880.50		34402.50	100.00	34402.50	34402.50	0.00	No	
17. CHB	40000.00	0.00			0.00	0.00	5795.00	11448.75		57243.75	100.00	57243.75	57243.75	0.00	No	
18. CHUV ¹³										27500.00					27500.00	
19. MCRI ¹³										112500.00					112500.00	
Total consortium	3996217.00	0.00			1391600.00	0.00	460315.00	1114133.00		6962265.00		6822265.00	6821232.25	0.00		140000.00

ESTIMATED BUDGET FOR THE ACTION (page 2 of 2)

- (1) See Article 6 for the eligibility conditions
- (2) The indirect costs covered by the operating grant (received under any EU or Euratom funding programme; see Article 6.5.(b)) are ineligible under the GA. Therefore, a beneficiary that receives an operating grant during the action's duration cannot declare indirect costs for the year(s)/reporting period(s) covered by the operating grant (see Article 6.2.E).
- (3) This is the theoretical amount of EU contribution that the system calculates automatically (by multiplying all the budgeted costs by the reimbursement rate). This theoretical amount is capped by the 'maximum grant amount' (that the Commission/Agency decided to grant for the action) (see Article 5.1).
- (4) The 'maximum grant amount' is the maximum grant amount decided by the Commission/Agency. It normally corresponds to the requested grant, but may be lower.
- (5) Depending on its type, this specific cost category will or will not cover indirect costs. Specific unit costs that include indirect costs are: costs for energy efficiency measures in buildings, access costs for providing trans-national access to research infrastructure and costs for clinical studies.
- (6) See Article 5 for the forms of costs
- (7) Unit : hours worked on the action; costs per unit (hourly rate) : calculated according to beneficiary's usual accounting practice
- (8) See Annex 2a 'Additional information on the estimated budget' for the details (costs per hour (hourly rate)).
- (9) Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs
- (10) See Annex 2a 'Additional information on the estimated budget' for the details (units, costs per unit).
- (11) See Annex 2a 'Additional information on the estimated budget' for the details (units, costs per unit, estimated number of units, etc)
- (12) Only specific unit costs that do not include indirect costs
- (13) See Article 9 for beneficiaries not receiving EU funding
- (14) Only for linked third parties that receive EU funding

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

UNIVERSITY COLLEGE DUBLIN, NATIONAL UNIVERSITY OF IRELAND, DUBLIN (UCD), established in BELFIELD, DUBLIN 4, Ireland, IE6517386K, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('2')

in Grant Agreement No 634201 ('the Agreement')

between IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE **and** *the European Union ('the EU', represented by the European Commission ('the Commission'))*,

for the action entitled 'Models of Child Health Appraised (MOCHA)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

ACADEMISCH ZIEKENHUIS GRONINGEN (UMCG), established in HANZEPLEIN 1, GRONINGEN 9713 GZ, Netherlands, NL800866393B01, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('3')

in Grant Agreement No 634201 ('the Agreement')

between IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE **and** *the European Union ('the EU', represented by the European Commission ('the Commission'))*,

for the action entitled 'Models of Child Health Appraised (MOCHA)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

CONSIGLIO NAZIONALE DELLE RICERCHE (CNR), CF80054330586, established in PIAZZALE ALDO MORO 7, ROMA 00185, Italy, IT02118311006, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('4')

in Grant Agreement No 634201 ('the Agreement')

between IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE **and** *the European Union ('the EU', represented by the European Commission ('the Commission'))*,

for the action entitled 'Models of Child Health Appraised (MOCHA)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

UNIVERSITY OF SURREY (SURREY) GB22, RC000671, established in Stag Hill, GUILDFORD GU2 7XH, United Kingdom, GB688953065, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('5')

in Grant Agreement No 634201 ('the Agreement')

between IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE **and** *the European Union ('the EU', represented by the European Commission ('the Commission'))*,

for the action entitled 'Models of Child Health Appraised (MOCHA)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

KAROLINSKA INSTITUTET (KI), 2021002973, established in Nobels Vag 5, STOCKHOLM 17177, Sweden, SE202100297301, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('6')

in Grant Agreement No 634201 ('the Agreement')

between IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE **and** *the European Union ('the EU', represented by the European Commission ('the Commission'))*,

for the action entitled 'Models of Child Health Appraised (MOCHA)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

NEDERLANDSE ORGANISATIE VOOR TOEGEPAST NATUURWETENSCHAPPELIJK ONDERZOEK - TNO (TNO), 27376655, established in SCHOEMAKERSTRAAT 97, DELFT 2628 VK, Netherlands, NL002875718B01, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('7')

in Grant Agreement No 634201 ('the Agreement')

between IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE **and** *the European Union ('the EU', represented by the European Commission ('the Commission'))*,

for the action entitled 'Models of Child Health Appraised (MOCHA)'.
and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

KING'S COLLEGE LONDON (KCL), RC000297, established in Strand, LONDON WC2R 2LS, United Kingdom, GB627403551, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('8')

in Grant Agreement No 634201 ('the Agreement')

between IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE **and** *the European Union ('the EU', represented by the European Commission ('the Commission'))*,

for the action entitled 'Models of Child Health Appraised (MOCHA)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

UNIVERSITEIT MAASTRICHT (UM), WHW ARTIKEL 1.8 LID, established in Minderbroedersberg 4-6, MAASTRICHT 6200 MD, Netherlands, NL003475268B01, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('9')

in Grant Agreement No 634201 ('the Agreement')

between IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE **and** *the European Union ('the EU', represented by the European Commission ('the Commission'))*,

for the action entitled 'Models of Child Health Appraised (MOCHA)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

UNIWERSYTET MEDYCZNY W LUBLINIE (MUL), 000288716, established in AL RACLAWICKIE 1, LUBLIN 20 059, Poland, PL7120106911, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('10')

in Grant Agreement No 634201 ('the Agreement')

between IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE **and** *the European Union ('the EU', represented by the European Commission ('the Commission'))*,

for the action entitled 'Models of Child Health Appraised (MOCHA)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

HOGSKOLEN I HARSTAD (HIH), 971512512, established in HAVNEGATA 5, HARSTAD 9480, Norway, NO971512512MVA, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('11')

in Grant Agreement No 634201 ('the Agreement')

between IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE **and** *the European Union ('the EU', represented by the European Commission ('the Commission'))*,

for the action entitled 'Models of Child Health Appraised (MOCHA)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

HASKOLI ISLANDS (UI), 600169-2039, established in Sudurgata, REYKJAVIK IS 101, Iceland, IS19133, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('12')

in Grant Agreement No 634201 ('the Agreement')

between IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE **and** *the European Union ('the EU', represented by the European Commission ('the Commission'))*,

for the action entitled 'Models of Child Health Appraised (MOCHA)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

AS CYPRUS COLLEGE LIMITED (EUC) EPE, HE83353, established in DIOGENES STREET 6 ENGOMI, NICOSIA 22006, Cyprus, CY10083353J, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('13')

in Grant Agreement No 634201 ('the Agreement')

between IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE **and** *the European Union ('the EU', represented by the European Commission ('the Commission'))*,

for the action entitled 'Models of Child Health Appraised (MOCHA)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

UNIVERSITEIT TWENTE (UTwente), 387, established in DRIENERLOLAAN 5, ENSCHEDE 7522 NB, Netherlands, NL002946725B01, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('14')

in Grant Agreement No 634201 ('the Agreement')

between IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE **and** *the European Union ('the EU', represented by the European Commission ('the Commission'))*,

for the action entitled 'Models of Child Health Appraised (MOCHA)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

SYDDANSK UNIVERSITET (SDU), 29283958, established in CAMPUSVEJ 55, ODENSE M 5230, Denmark, DK29283958, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('15')

in Grant Agreement No 634201 ('the Agreement')

between IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE **and** *the European Union ('the EU', represented by the European Commission ('the Commission'))*,

for the action entitled 'Models of Child Health Appraised (MOCHA)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

UNIVERSITY OF KEELE (KEELE) GB22, RC000655, established in KEELE UNIVERSITY FINANCE DPT, KEELE ST5 5BG, United Kingdom, GB279783684, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('16')

in Grant Agreement No 634201 ('the Agreement')

between IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE **and** *the European Union ('the EU', represented by the European Commission ('the Commission'))*,

for the action entitled 'Models of Child Health Appraised (MOCHA)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

CHILDREN'S HOSPITAL CORPORATION (CHB) US8, EIN042774441, established in LONGWOOD AVENUE 300, BOSTON 02115, United States, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('17')

in Grant Agreement No 634201 ('the Agreement')

between IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE **and** *the European Union ('the EU', represented by the European Commission ('the Commission'))*,

for the action entitled 'Models of Child Health Appraised (MOCHA)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

HOSPICES CANTONNAUX CHUV (CHUV), established in Rue du Bugnon 21, LAUSANNE 1005, Switzerland, CH369716, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('18')

in Grant Agreement No 634201 ('the Agreement')

between IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE **and** *the European Union ('the EU', represented by the European Commission ('the Commission'))*,

for the action entitled 'Models of Child Health Appraised (MOCHA)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

MURDOCH CHILDRENS RESEARCH INSTITUTE (MCRI) AU3, 006566972, established in FLEMINGTON ROAD RCH, PARKVILLE 3052, Australia, AU21006566972, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('19')

in Grant Agreement No 634201 ('the Agreement')

between IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE **and** *the European Union ('the EU', represented by the European Commission ('the Commission'))*,

for the action entitled 'Models of Child Health Appraised (MOCHA)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

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ANNEX 5

MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.
- For fields in [grey in square brackets]: enter the appropriate data

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H2020 Model Grant Agreements: H2020 General MGA — Multi: September 2014

Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the **'Terms of Reference (ToR)'** under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[insert legal name of the auditor] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the Financial Statement(s)¹ drawn up by the [Beneficiary] [Linked Third Party] for the Horizon 2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'), and

to issue a Certificate on the Financial Statements' ('CFS') referred to in Article 20.4 of the Agreement based on the compulsory reporting template stipulated by the Commission.

The Agreement has been concluded under the Horizon 2020 Research and Innovation Framework Programme (H2020) between the Beneficiary and [OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]

¹ By which costs under the Agreement are declared (see template 'Model Financial Statements' in Annex 4 to the Grant Agreement).

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The *[Commission]* *[Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union]**[Euratom]**[Agency]* is not a party to this engagement.

1.1 Subject of the engagement

The coordinator must submit to the *[Commission]**[Agency]* the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for each beneficiary and for each linked third party that requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 20.4 of the Agreement). The CFS must cover all reporting periods of the beneficiary or linked third party indicated above.

The Beneficiary must submit to the coordinator the CFS for itself and for its linked third party(ies), if the CFS must be included in the final report according to Article 20.4 of the Agreement..

The CFS is composed of two separate documents:

- The Terms of Reference ('the ToR') to be signed by the *[Beneficiary]* *[Linked Third Party]* and the Auditor;
- The Auditor's Independent Report of Factual Findings ('the Report') to be issued on the Auditor's letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon procedures ('the Procedures') to be performed by the Auditor, and the standard factual findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the final report according to Article 20.4 of the Agreement, the request for payment of the balance relating to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the *[Commission]*,*[Agency]*, the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 22 of the Agreement.

1.2 Responsibilities

The *[Beneficiary]* *[Linked Third Party]*:

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- must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according to the *[Beneficiary's] [Linked Third Party's]* accounting and book-keeping system and the underlying accounts and records;
- must send the Financial Statement(s) to the Auditor;
- is responsible and liable for the accuracy of the Financial Statement(s);
- is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the Procedures. It must provide the Auditor with a written representation letter supporting these statements. The written representation letter must state the period covered by the statements and must be dated;
- accepts that the Auditor cannot carry out the Procedures unless it is given full access to the *[Beneficiary's] [Linked Third Party's]* staff and accounting as well as any other relevant records and documentation.

The Auditor:

- *[Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations].*
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].*
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation].*

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with this ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement, the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

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The Auditor must comply with these Terms of Reference and with²:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the [Commission][Agency] requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary [and the Linked Third Party], and must specify - if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7).

Under Article 22 of the Agreement, the [Commission] [Agency], the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from [the European Union] [Euratom] budget. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the [Commission] [Agency], the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by [dd Month yyyy].

² Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

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1.6 Other terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor]

[legal name of the [Beneficiary][Linked Third Party]]

[name & function of authorised representative][name & function of authorised representative]

[dd Month yyyy]

[dd Month yyyy]

Signature of the Auditor

Signature of the [Beneficiary][Linked Third Party]

H2020 Model Grant Agreements: H2020 General MGA — Multi: September 2014

**Independent Report of Factual Findings on costs declared under Horizon 2020 Research and
Innovation Framework Programme**

(To be printed on the Auditor's letterhead)

To

[name of contact person(s)], [Position]

[*Beneficiary's*] [*Linked Third Party's* name]

[Address]

[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with [OPTION 1: *insert name of the beneficiary*] ('the Beneficiary') [OPTION 2: *insert name of the linked third party*] ('the Linked Third Party'), third party linked to the Beneficiary [*insert name of the beneficiary*] ('the Beneficiary'),

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

H2020 Model Grant Agreements: H2020 General MGA — Multi: September 2014

have carried out the procedures agreed with you regarding the costs declared in the Financial Statement(s)³ of the [Beneficiary] [Linked Third Party] concerning the grant agreement

[insert grant agreement reference: number, title of the action and acronym] ('the Agreement'),

with a total cost declared of

[total amount] EUR,

and a total of actual costs and 'direct personnel costs declared as unit costs calculated in accordance with the [Beneficiary's] [Linked Third Party's] usual cost accounting practices' declared of

[sum of total actual costs and total direct personnel costs declared as unit costs calculated in accordance with the [Beneficiary's] [Linked Third Party's] usual cost accounting practices] EUR

and **hereby provide our Independent Report of Factual Findings ('the Report')** using the compulsory report format agreed with you.

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') examined.

The Procedures were carried out solely to assist the [Commission] [Agency] in evaluating whether the [Beneficiary's] [Linked Third Party's] costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The [Commission] [Agency] draws its own conclusions from the Report and any additional information it may require.

³ By which the Beneficiary declares costs under the Agreement (see template 'Model Financial Statement' in Annex 4 to the Agreement).

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The scope of the Procedures was defined by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence. Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, the Auditor does not give a statement of assurance on the Financial Statements.

Had the Auditor carried out additional procedures or an audit of the [Beneficiary's] [Linked Third Party's] Financial Statements in accordance with International Standards on Auditing or International Standards on Review Engagements, other matters might have come to its attention and would have been included in the Report.

Not applicable Findings

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

Explanation (to be removed from the Report):

If a Finding was not applicable, it must be marked as 'N.A.' ('Not applicable') in the corresponding row on the right-hand column of the table and means that the Finding did not have to be corroborated by the Auditor and the related Procedure(s) did not have to be carried out.

The reasons of the non-application of a certain Finding must be obvious i.e.

- i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable;*
- ii) if the condition set to apply certain Procedure(s) are not met the related Finding(s) and those Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the Procedure and Finding related to 'beneficiaries with accounts established in euro' are not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.*

List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.

....

Exceptions

Apart from the exceptions listed below, the [Beneficiary] [Linked Third Party] provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

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Explanation (to be removed from the Report):

- If the Auditor was not able to successfully complete a procedure requested, it must be marked as 'E' ('Exception') in the corresponding row on the right-hand column of the table. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the Procedure must be indicated below.
- If the Auditor cannot corroborate a standard finding after having carried out the corresponding procedure, it must also be marked as 'E' ('Exception') and, where possible, the reasons why the Finding was not fulfilled and its possible impact must be explained here below.

List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.

....

Example (to be removed from the Report):

1. The Beneficiary was unable to substantiate the Finding number 1 on ... because
2. Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate unit costs was different from the one approved by the Commission. The differences were as follows: ...
3. After carrying out the agreed procedures to confirm the Finding number 31, the Auditor found a difference of _____ EUR. The difference can be explained by ...

Further Remarks

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

Example (to be removed from the Report):

1. Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because ...
2. In order to be able to confirm the Finding number 15 we carried out the following additional procedures:

Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the [Beneficiary] [Linked Third Party] and the [Commission] [Agency], and only to be submitted to the [Commission] [Agency] in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the [Beneficiary] [Linked Third Party] or by the [Commission] [Agency] for any other purpose, nor may it

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be distributed to any other parties. The [Commission] [Agency] may only disclose the Report to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the [Commission] [Agency] by the [Beneficiary] [Linked Third Party] for the Agreement. Therefore, it does not extend to any other of the [Beneficiary's] [Linked Third Party's] Financial Statement(s).

There was no conflict of interest⁴ between the Auditor and the Beneficiary [and Linked Third Party] in establishing this Report. The total fee paid to the Auditor for providing the Report was EUR [] (including EUR [] of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance.

[legal name of the Auditor]

[name and function of an authorised representative]

[dd Month yyyy]

Signature of the Auditor

⁴ A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:

- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Agreed-upon procedures to be performed and standard factual findings to be confirmed by the Auditor

The European Commission reserves the right to i) provide the auditor with additional guidance regarding the procedures to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the procedures, by notifying the Beneficiary in writing. The procedures carried out by the auditor to confirm the standard factual finding are listed in the table below.

If this certificate relates to a Linked Third Party, any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

The 'result' column has three different options: 'C', 'E' and 'N.A.':

- 'C' stands for 'confirmed' and means that the auditor can confirm the 'standard factual finding' and, therefore, there is no exception to be reported.
- 'E' stands for 'exception' and means that the Auditor carried out the procedures but cannot confirm the 'standard factual finding', or that the Auditor was not able to carry out a specific procedure (e.g. because it was impossible to reconcile key information or data were unavailable),
- 'N.A.' stands for 'not applicable' and means that the Finding did not have to be examined by the Auditor and the related Procedure(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable; ii) if the condition set to apply certain Procedure(s) are not met then the related Finding(s) and Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than the euro' the Procedure related to 'beneficiaries with accounts established in euro' is not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A	ACTUAL PERSONNEL COSTS AND UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE		

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Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<p>The Auditor draws a sample of persons whose costs were declared in the Financial Statement(s) to carry out the procedures indicated in the consecutive points of this section A.</p> <p><i>(The sample should be selected randomly so that it is representative. Full coverage is required if there are fewer than 10 people (including employees, natural persons working under a direct contract and personnel seconded by a third party), otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest)</i></p> <p>The Auditor sampled [] people out of the total of [] people.</p>		
A.1	<p>PERSONNEL COSTS</p> <p><u>For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs)</u></p> <p>To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary:</p> <ul style="list-style-type: none"> ○ a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract; ○ the payslips of the employees included in the sample; ○ reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system; ○ information concerning the employment status and employment conditions of personnel included in the sample, in particular their employment contracts or equivalent; 	<p>1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary's sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary's usual practices.</p> <p>2) Personnel costs were recorded in the Beneficiary's accounts/payroll system.</p> <p>3) Costs were adequately supported and reconciled with the accounts and payroll</p>	

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Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<ul style="list-style-type: none"> ○ the Beneficiary's usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay); ○ applicable national law on taxes, labour and social security and ○ any other document that supports the personnel costs declared. <p>The Auditor also verified the eligibility of all components of the retribution (see Article 6 GA) and recalculated the personnel costs for employees included in the sample.</p>	<p>records.</p> <p>4) Personnel costs did not contain any ineligible elements.</p> <p>5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.</p>	
	<p><i>Further procedures if 'additional remuneration' is paid</i></p> <p>To confirm standard factual findings 6-9 listed in the next column, the Auditor:</p> <ul style="list-style-type: none"> ○ reviewed relevant documents provided by the Beneficiary (legal form, legal/statutory obligations, the Beneficiary's usual policy on additional remuneration, criteria used for its calculation...); ○ recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, etc.) to arrive at the applicable FTE/year and pro-rata rate (see data collected in the course of carrying out the procedures under A.2 'Productive hours' and A.4 'Time recording system'). 	<p>6) The Beneficiary paying "additional remuneration" was a non-profit legal entity.</p> <p>7) The amount of additional remuneration paid corresponded to the Beneficiary's usual remuneration practices and was consistently paid whenever the same kind of work or expertise was required.</p>	

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Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<p><i>IF ANY PART OF THE REMUNERATION PAID TO THE EMPLOYEE IS NOT MANDATORY ACCORDING TO THE NATIONAL LAW OR THE EMPLOYMENT CONTRACT ("ADDITIONAL REMUNERATION") AND IS ELIGIBLE UNDER THE PROVISIONS OF ARTICLE 6.2.A.1, THIS CAN BE CHARGED AS ELIGIBLE COST TO THE ACTION UP TO THE FOLLOWING AMOUNT:</i></p> <p><i>(A) IF THE PERSON WORKS FULL TIME AND EXCLUSIVELY ON THE ACTION DURING THE FULL YEAR: UP TO EUR 8 000/YEAR;</i></p> <p><i>(B) IF THE PERSON WORKS EXCLUSIVELY ON THE ACTION BUT NOT FULL-TIME OR NOT FOR THE FULL YEAR: UP TO THE CORRESPONDING PRO-RATA AMOUNT OF EUR 8 000, OR</i></p> <p><i>(C) IF THE PERSON DOES NOT WORK EXCLUSIVELY ON THE ACTION: UP TO A PRO-RATA AMOUNT CALCULATED IN ACCORDANCE TO ARTICLE 6.2.A.1.</i></p>	<p>8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used.</p>	
		<p>9) The amount of additional remuneration included in the personnel costs charged to the action was capped at EUR 8,000 per FTE/year (up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).</p>	
	<p><i>Additional procedures in case “unit costs calculated by the Beneficiary in accordance with its usual cost accounting practices” is applied:</i></p> <p>Apart from carrying out the procedures indicated above to confirm standard factual findings 1-5 and, if applicable, also 6-9, the Auditor carried out following procedures to confirm standard factual findings 10-13 listed in the next column:</p>	<p>10) The personnel costs included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. This methodology was consistently used in all H2020 actions.</p>	

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Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<ul style="list-style-type: none"> ○ obtained a description of the Beneficiary's usual cost accounting practice to calculate unit costs; ○ reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; ○ verified the employees included in the sample were charged under the correct category (in accordance with the criteria used by the Beneficiary to establish personnel categories) by reviewing the contract/HR-record or analytical accounting records; ○ verified that there is no difference between the total amount of personnel costs used in calculating the cost per unit and the total amount of personnel costs recorded in the statutory accounts; ○ verified whether actual personnel costs were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and supported by documents. 	11) The employees were charged under the correct category.	
		12) Total personnel costs used in calculating the unit costs were consistent with the expenses recorded in the statutory accounts.	
		13) Any estimated or budgeted element used by the Beneficiary in its unit-cost calculation were relevant for calculating personnel costs and corresponded to objective and verifiable information.	
	<p><u>For natural persons included in the sample and working with the Beneficiary under a direct contract other than an employment contract, such as consultants (no subcontractors).</u></p> <p>To confirm standard factual findings 14-18 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary:</p> <ul style="list-style-type: none"> ○ the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary; 	14) The natural persons reported to the Beneficiary (worked under the Beneficiary's instructions).	
		15) They worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	

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Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<ul style="list-style-type: none"> ○ the employment conditions of staff in the same category to compare costs and; ○ any other document that supports the costs declared and its registration (e.g. invoices, accounting records, etc.). 	16) The results of work carried out belong to the Beneficiary.	
		17) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		18) The costs were supported by audit evidence and registered in the accounts.	
	<p><u>For personnel seconded by a third party and included in the sample (not subcontractors)</u></p> <p>To confirm standard factual findings 19-22 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary:</p> <ul style="list-style-type: none"> ○ their secondment contract(s) notably regarding costs, duration, work description, place of work and ownership of the results; ○ if there is reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution against payment): any documentation that supports the costs declared (e.g. contract, invoice, bank payment, and proof of registration in its accounting/payroll, etc.) and reconciliation of the Financial Statement(s) with the accounting system (project accounting and general ledger) as well as any proof that the amount invoiced by the third party did not include any profit; 	19) Seconded personnel reported to the Beneficiary and worked on the Beneficiary’s premises (unless otherwise agreed with the Beneficiary).	
		20) The results of work carried out belong to the Beneficiary.	
		<p><i>If personnel is seconded against payment:</i></p> <p>21) The costs declared were supported with documentation and recorded in the</p>	

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Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<ul style="list-style-type: none"> ○ if there is no reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution free of charge): a proof of the actual cost borne by the Third Party for the resource made available free of charge to the Beneficiary such as a statement of costs incurred by the Third Party and proof of the registration in the Third Party's accounting/payroll; ○ any other document that supports the costs declared (e.g. invoices, etc.). 	<p>Beneficiary's accounts. The third party did not include any profit.</p> <p><i>If personnel is seconded free of charge:</i></p> <p>22) The costs declared did not exceed the third party's cost as recorded in the accounts of the third party and were supported with documentation.</p>	
A.2	<p>PRODUCTIVE HOURS</p> <p>To confirm standard factual findings 23-28 listed in the next column, the Auditor reviewed relevant documents, especially national legislation, labour agreements and contracts and time records of the persons included in the sample, to verify that:</p> <ul style="list-style-type: none"> ○ the annual productive hours applied were calculated in accordance with one of the methods described below, ○ the full-time equivalent (FTEs) ratios for employees not working full-time were correctly calculated. 	<p>23) The Beneficiary applied method [<i>choose one option and delete the others</i>]</p> <p>[A: 1720 hours]</p> <p>[B: the 'total number of hours worked']</p> <p>[C: 'annual productive hours' used correspond to usual accounting practices]</p>	

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Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<p>If the Beneficiary applied method B, the auditor verified that the correctness in which the total number of hours worked was calculated and that the contracts specified the annual workable hours.</p> <p>If the Beneficiary applied method C, the auditor verified that the ‘annual productive hours’ applied when calculating the hourly rate were equivalent to at least 90 % of the ‘standard annual workable hours’. The Auditor can only do this if the calculation of the standard annual workable hours can be supported by records, such as national legislation, labour agreements, and contracts.</p> <p><i>BENEFICIARY’S PRODUCTIVE HOURS’ FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS:</i></p> <p><i>A. 1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)</i></p> <p><i>B. THE TOTAL NUMBER OF HOURS WORKED BY THE PERSON FOR THE BENEFICIARY IN THE YEAR (THIS METHOD IS ALSO REFERRED TO AS ‘TOTAL NUMBER OF HOURS WORKED’ IN THE NEXT COLUMN). THE CALCULATION OF THE TOTAL NUMBER OF HOURS WORKED WAS DONE AS FOLLOWS: ANNUAL WORKABLE HOURS OF THE PERSON ACCORDING TO THE EMPLOYMENT CONTRACT, APPLICABLE LABOUR AGREEMENT OR NATIONAL LAW PLUS OVERTIME WORKED MINUS ABSENCES (SUCH AS SICK LEAVE OR SPECIAL LEAVE).</i></p>	<p>24) Productive hours were calculated annually.</p> <p>25) For employees not working full-time the full-time equivalent (FTE) ratio was correctly applied.</p> <p><i>If the Beneficiary applied method B.</i></p> <p>26) The calculation of the number of ‘annual workable hours’, overtime and absences was verifiable based on the documents provided by the Beneficiary.</p> <p><i>If the Beneficiary applied method C.</i></p> <p>27) The calculation of the number of ‘standard annual workable hours’ was verifiable based on the documents provided by the Beneficiary.</p>	

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Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<p><i>C. THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL ANNUAL PRODUCTIVE HOURS' IN THE NEXT COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS.</i></p> <p><i>'ANNUAL WORKABLE HOURS' MEANS THE PERIOD DURING WHICH THE PERSONNEL MUST BE WORKING, AT THE EMPLOYER'S DISPOSAL AND CARRYING OUT HIS/HER ACTIVITY OR DUTIES UNDER THE EMPLOYMENT CONTRACT, APPLICABLE COLLECTIVE LABOUR AGREEMENT OR NATIONAL WORKING TIME LEGISLATION.</i></p>	<p>28) The 'annual productive hours' used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the 'annual workable hours'.</p>	
<p>A.3</p>	<p>HOURLY PERSONNEL RATES</p> <p><u>l) For unit costs calculated in accordance to the Beneficiary's usual cost accounting practice (unit costs):</u></p> <p>If the Beneficiary has a "Certificate on Methodology to calculate unit costs " (CoMUC) approved by the Commission, the Beneficiary provides the Auditor with a description of the approved methodology and the Commission's letter of acceptance. The Auditor verified that the Beneficiary has indeed used the methodology approved. If so, no further verification is necessary.</p> <p>If the Beneficiary does not have a "Certificate on Methodology" (CoMUC) approved by the</p>	<p>29) The Beneficiary applied [choose one option and delete the other]:</p> <p>[Option I: "Unit costs (hourly rates) were calculated in accordance with the Beneficiary's usual cost accounting practices"]</p> <p>[Option II: Individual hourly rates were applied]</p>	

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Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<p>Commission, or if the methodology approved was not applied, then the Auditor:</p> <ul style="list-style-type: none"> ○ reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; ○ recalculated the unit costs (hourly rates) of staff included in the sample following the results of the procedures carried out in A.1 and A.2. <p><u>II) For individual hourly rates:</u></p> <p>The Auditor:</p> <ul style="list-style-type: none"> ○ reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; ○ recalculated the hourly rates of staff included in the sample following the results of the procedures carried out in A.1 and A.2. <p><u>“UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES”:</u></p> <p><i>IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF THE CATEGORY TO WHICH THE EMPLOYEE BELONGS VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF FTE AND THE ANNUAL TOTAL PRODUCTIVE HOURS OF THE SAME CATEGORY CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH PROCEDURE A.2.</i></p> <p><u>HOURLY RATE FOR INDIVIDUAL ACTUAL PERSONAL COSTS:</u></p> <p><i>IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH</i></p>	<p><i>For option I concerning unit costs and if the Beneficiary applies the methodology approved by the Commission (CoMUC):</i></p> <p>30) The Beneficiary used the Commission-approved methodology to calculate hourly rates. It corresponded to the organisation's usual cost accounting practices and was applied consistently for all activities irrespective of the source of funding.</p> <p><i>For option I concerning unit costs and if the Beneficiary applies a methodology not approved by the Commission:</i></p> <p>31) The unit costs re-calculated by the Auditor were the same as the rates applied by the Beneficiary.</p> <p><i>For option II concerning individual hourly rates:</i></p>	

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Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<i>PROCEDURE A.1 BY THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2.</i>	32) The individual rates re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	
A.4	<p>TIME RECORDING SYSTEM</p> <p>To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in the sample that declare time as worked for the action on the basis of time records:</p> <ul style="list-style-type: none"> ○ description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system); ○ its actual implementation; ○ time records were signed at least monthly by the employees (on paper or electronically) and authorised by the project manager or another manager; ○ the hours declared were worked within the project period; ○ there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below) ; 	<p>33) All persons recorded their time dedicated to the action on a daily/ weekly/ monthly basis using a paper/computer-based system. <i>(delete the answers that are not applicable)</i></p> <p>34) Their time-records were authorised at least monthly by the project manager or other superior.</p> <p>35) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.</p>	

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Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<p>○ the hours charged to the action matched those in the time recording system.</p> <p><i>ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).</i></p>	<p>36) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.</p>	
	<p><u>If the persons are working exclusively for the action and without time records</u></p> <p>For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.</p>	<p>37) The exclusive dedication is supported by a declaration signed by the Beneficiary's and by any other evidence gathered.</p>	
B	COSTS OF SUBCONTRACTING		
B.1	<p>The Auditor obtained the detail/breakdown of subcontracting costs and sampled _____ cost items selected randomly <i>(full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest).</i></p> <p>To confirm standard factual findings 38-42 listed in the next column, the Auditor reviewed the</p>	<p>38) The use of claimed subcontracting costs was foreseen in Annex 1 and costs were declared in the Financial Statements under the subcontracting category.</p>	

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Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<p>following for the items included in the sample:</p> <ul style="list-style-type: none"> ○ the use of subcontractors was foreseen in Annex 1; ○ subcontracting costs were declared in the subcontracting category of the Financial Statement; ○ supporting documents on the selection and award procedure were followed; ○ the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment). <p>In particular,</p> <ul style="list-style-type: none"> i. if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement. ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement.. <p>For the items included in the sample the Auditor also verified that:</p> <ul style="list-style-type: none"> ○ the subcontracts were not awarded to other Beneficiaries in the consortium; 	<p>39) There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money.</p> <p><i>(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption “Exceptions” of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)</i></p> <p>40) The subcontracts were not awarded to other Beneficiaries of the consortium.</p>	

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Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	<ul style="list-style-type: none"> ○ there were signed agreements between the Beneficiary and the subcontractor; ○ there was evidence that the services were provided by subcontractor; 	41) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.	
		42) There was evidence that the services were provided by the subcontractors.	
C	COSTS OF PROVIDING FINANCIAL SUPPORT TO THIRD PARTIES		
C.1	<p>The Auditor obtained the detail/breakdown of the costs of providing financial support to third parties and sampled [redacted] cost items selected randomly (full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest).</p> <p>The Auditor verified that the following minimum conditions were met:</p> <ul style="list-style-type: none"> a) the maximum amount of financial support for each third party did not exceed EUR 60 000, unless explicitly mentioned in Annex 1; b) the financial support to third parties was agreed in Annex 1 of the Agreement and the other provisions on financial support to third parties included in Annex 1 were 	43) All minimum conditions were met	

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Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	respected.		

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D	OTHER ACTUAL DIRECT COSTS		
D.1	<p>COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES</p> <p>The Auditor sampled [] cost items selected randomly <i>(full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest).</i></p> <p>The Auditor inspected the sample and verified that:</p> <ul style="list-style-type: none"> ○ travel and subsistence costs were consistent with the Beneficiary's usual policy for travel. In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy; ○ travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference; ○ no ineligible costs or excessive or reckless expenditure was declared. 	44) Costs were incurred, approved and reimbursed in line with the Beneficiary's usual policy for travels.	
		45) There was a link between the trip and the action.	
		46) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting.	
		47) No ineligible costs or excessive or reckless expenditure was declared.	
D.2	<p>DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS</p> <p>The Auditor sampled [] cost items selected randomly <i>(full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest).</i></p> <p>For “equipment, infrastructure or other assets” [from now on called “asset(s)”] selected in the</p>	48) Procurement rules, principles and guides were followed.	
		49) There was a link between the grant agreement and the asset charged to the action.	

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	<p>sample the Auditor verified that:</p> <ul style="list-style-type: none"> ○ the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures; ○ they were correctly allocated to the action (with supporting documents such as delivery note invoice or any other proof demonstrating the link to the action) ○ they were entered in the accounting system; ○ the extent to which the assets were used for the action (as a percentage) was supported by reliable documentation (e.g. usage overview table); <p>The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary's country and with the Beneficiary's usual accounting policy (e.g. depreciation calculated on the acquisition value).</p> <p>The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.5 GA).</p>	50) The asset charged to the action was traceable to the accounting records and the underlying documents.	
		51) The depreciation method used to charge the asset to the action was in line with the applicable rules of the Beneficiary's country and the Beneficiary's usual accounting policy.	
		52) The amount charged corresponded to the actual usage for the action.	
		53) No ineligible costs or excessive or reckless expenditure were declared.	
D.3	<p>COSTS OF OTHER GOODS AND SERVICES</p> <p>The Auditor sampled [redacted] cost items selected randomly (<i>full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest</i>).</p> <p>For the purchase of goods, works or services included in the sample the Auditor verified that:</p> <ul style="list-style-type: none"> ○ the contracts did not cover tasks described in Annex 1; 	54) Contracts for works or services did not cover tasks described in Annex 1.	
		55) Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment.	

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<ul style="list-style-type: none"> ○ they were correctly identified, allocated to the proper action, entered in the accounting system (traceable to underlying documents such as purchase orders, invoices and accounting); ○ the goods were not placed in the inventory of durable equipment; ○ the costs charged to the action were accounted in line with the Beneficiary's usual accounting practices; ○ no ineligible costs or excessive or reckless expenditure were declared (see Article 6 GA). <p>In addition, the Auditor verified that these goods and services were acquired in conformity with the Beneficiary's internal guidelines and procedures, in particular:</p> <ul style="list-style-type: none"> ○ if Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement. ○ if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement. <p>For the items included in the sample the Auditor also verified that:</p> <ul style="list-style-type: none"> ○ the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment); <p><i>SUCH GOODS AND SERVICES INCLUDE, FOR INSTANCE, CONSUMABLES AND SUPPLIES, DISSEMINATION (INCLUDING OPEN ACCESS), PROTECTION OF RESULTS, SPECIFIC EVALUATION OF THE ACTION IF IT IS REQUIRED BY THE</i></p>	<p>56) The costs were charged in line with the Beneficiary's accounting policy and were adequately supported.</p>	
	<p>57) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups.</p>	
	<p>58) Procurement rules, principles and guides were followed. There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The purchases were made in accordance with the principle of best value for money.</p> <p><i>(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the</i></p>	

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	<p><i>AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.</i></p>	<p><i>caption “Exceptions” of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)</i></p>	
<p>D.4</p>	<p>AGGREGATED CAPITALISED AND OPERATING COSTS OF RESEARCH INFRASTRUCTURE</p> <p>The Auditor ensured the existence of a positive ex-ante assessment (issued by the EC Services) of the cost accounting methodology of the Beneficiary allowing it to apply the guidelines on direct costing for large research infrastructures in Horizon 2020.</p> <p><i>In the cases that a positive ex-ante assessment has been issued (see the standard factual findings 59-60 on the next column),</i></p> <p>The Auditor ensured that the beneficiary has applied consistently the methodology that is explained and approved in the positive ex ante assessment;</p> <p><i>In the cases that a positive ex-ante assessment has NOT been issued (see the standard factual findings 61 on the next column),</i></p> <p>The Auditor verified that no costs of Large Research Infrastructure have been charged as direct costs in any costs category;</p>	<p>59) The costs declared as direct costs for Large Research Infrastructures (in the appropriate line of the Financial Statement) comply with the methodology described in the positive ex-ante assessment report.</p>	
		<p>60) Any difference between the methodology applied and the one positively assessed was extensively described and adjusted accordingly.</p>	
		<p>61) The direct costs declared were free from any indirect costs items related to the Large Research Infrastructure.</p>	

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	<p><i>In the cases that a draft ex-ante assessment report has been issued with recommendation for further changes (see the standard factual findings 61 on the next column),</i></p> <ul style="list-style-type: none"> The Auditor followed the same procedure as above (when a positive ex-ante assessment has NOT yet been issued) and paid particular attention (testing reinforced) to the cost items for which the draft ex-ante assessment either rejected the inclusion as direct costs for Large Research Infrastructures or issued recommendations. 		
E	USE OF EXCHANGE RATES		
E.1	<p><u>a) For Beneficiaries with accounts established in a currency other than euros</u></p> <p>The Auditor sampled [redacted] cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement (full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest):</p> <p><i>COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO AT THE AVERAGE OF THE DAILY EXCHANGE RATES PUBLISHED IN THE C SERIES OF OFFICIAL JOURNAL OF THE EUROPEAN UNION (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.</i></p> <p><i>IF NO DAILY EURO EXCHANGE RATE IS PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN UNION FOR THE CURRENCY IN QUESTION, CONVERSION SHALL BE MADE AT THE AVERAGE OF THE MONTHLY ACCOUNTING RATES ESTABLISHED BY THE COMMISSION AND PUBLISHED ON ITS WEBSITE (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm),</i></p>	62) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final figures.	

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	<p><i>DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.</i></p>		
	<p><u>b) For Beneficiaries with accounts established in euros</u></p> <p>The Auditor sampled [redacted] cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement (full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest):</p> <p><i>COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY’S USUAL ACCOUNTING PRACTICES.</i></p>	<p>63) The Beneficiary applied its usual accounting practices.</p>	

[legal name of the audit firm]

[name and function of an authorised representative]

[dd Month yyyy]

<Signature of the Auditor>

ANNEX 6

MODEL FOR THE CERTIFICATE ON THE METHODOLOGY

- For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.
- For fields in [grey in square brackets]: enter the appropriate data.

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Terms of reference for an audit engagement for a methodology certificate in connection with one or more grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the **‘Terms of Reference (ToR)’** under which

[OPTION 1: [insert name of the beneficiary] (‘the Beneficiary’)] [OPTION 2: [insert name of the linked third party] (‘the Linked Third Party’), third party linked to the Beneficiary [insert name of the beneficiary] (‘the Beneficiary’)]

agrees to engage

[insert legal name of the auditor] (‘the Auditor’)

to produce an independent report of factual findings (‘the Report’) concerning the *[Beneficiary’s]* *[Linked Third Party’s]* usual accounting practices for calculating and claiming direct personnel costs declared as unit costs (‘the Methodology’) in connection with grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme.

The procedures to be carried out for the assessment of the methodology will be based on the grant agreement(s) detailed below:

[title and number of the grant agreement(s)] (‘the Agreement(s)’)

The Agreement(s) has(have) been concluded between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission (‘the Commission’)] [OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission (‘the Commission’)] [OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] (‘the Agency’), under the powers delegated by the European Commission (‘the Commission’)].*

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The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union] [Euratom] [Agency]* is not a party to this engagement.

1.1 Subject of the engagement

According to Article 18.1.2 of the Agreement, beneficiaries *[and linked third parties]* that declare direct personnel costs as unit costs calculated in accordance with their usual cost accounting practices may submit to the *[Commission] [Agency]*, for approval, a certificate on the methodology ('CoMUC') stating that there are adequate records and documentation to prove that their cost accounting practices used comply with the conditions set out in Point A of Article 6.2.

The subject of this engagement is the CoMUC which is composed of two separate documents:

- the Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;
- the Auditor's Independent Report of Factual Findings ('the Report') issued on the Auditor's letterhead, dated, stamped and signed by the Auditor which includes; the standard statements ('the Statements') evaluated and signed by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') performed by the Auditor and the standard factual findings ('the Findings') assessed by the Auditor. The Statements, Procedures and Findings are summarised in the table that forms part of the Report.

The information provided through the Statements, the Procedures and the Findings will enable the Commission to draw conclusions regarding the existence of the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practice and its suitability to ensure that direct personnel costs claimed on that basis comply with the provisions of the Agreement. The Commission draws its own conclusions from the Report and any additional information it may require.

1.2 Responsibilities

The parties to this agreement are the *[Beneficiary] [Linked Third Party]* and the Auditor.

The *[Beneficiary] [Linked Third Party]*:

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- is responsible for preparing financial statements for the Agreement(s) ('the Financial Statements') in compliance with those Agreements;
- is responsible for providing the Financial Statement(s) to the Auditor and enabling the Auditor to reconcile them with the [Beneficiary's] [Linked Third Party's] accounting and bookkeeping system and the underlying accounts and records. The Financial Statement(s) will be used as a basis for the procedures which the Auditor will carry out under this ToR;
- is responsible for its Methodology and liable for the accuracy of the Financial Statement(s);
- is responsible for endorsing or refuting the Statements indicated under the heading 'Statements to be made by the Beneficiary/ Linked Third Party' in the first column of the table that forms part of the Report;
- must provide the Auditor with a signed and dated representation letter;
- accepts that the ability of the Auditor to carry out the Procedures effectively depends upon the [Beneficiary] [Linked Third Party] providing full and free access to the [Beneficiary's] [Linked Third Party's] staff and to its accounting and other relevant records.

The Auditor:

- *[Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations].*
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].*
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation].*

The Auditor:

- must be independent from the Beneficiary [and the Linked Third Party], in particular, it must not have been involved in preparing the Beneficiary's [and Linked Third Party's] Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with these ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the [Beneficiary] [Linked Third Party].

The Commission sets out the Procedures to be carried out and the Findings to be endorsed by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with¹:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the Commission requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there was no conflict of interests in establishing this Report between the Auditor and the Beneficiary [*and the Linked Third Party*] that could have a bearing on the Report, and must specify – if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7 of the Agreement).

Under Article 22 of the Agreement, the Commission, [*the Agency*], the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are claimed from [*the European Union*] [*Euratom*] budget. This includes work related to this engagement. The Auditor must provide access to all working papers related to this assignment if the Commission, [*the Agency*], the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by [dd Month yyyy].

¹ Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

1.6 Other Terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor’s fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor]	[legal name of the [Beneficiary] [Linked Third Party]]
[name & title of authorised representative]	[name & title of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the [Beneficiary] [Linked Third Party]

Independent report of factual findings on the methodology concerning grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

(To be printed on letterhead paper of the auditor)

To

[name of contact person(s)], [Position]

[[Beneficiary's] [Linked Third Party's] name]

[Address]

[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with [OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')],

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

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have carried out the agreed-upon procedures ('the Procedures') and provide hereby our Independent Report of Factual Findings ('the Report'), concerning the [Beneficiary's] [Linked Third Party's] usual accounting practices for calculating and declaring direct personnel costs declared as unit costs ('the Methodology').

You requested certain procedures to be carried out in connection with the grant(s)

[title and number of the grant agreement(s)] ('the Agreement(s)').

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes: the standard statements ('the Statements') made by the [Beneficiary] [Linked Third Party], the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') confirmed by us.

The engagement involved carrying out the Procedures and assessing the Findings and the documentation requested appended to this Report, the results of which the Commission uses to draw conclusions regarding the acceptability of the Methodology applied by the [Beneficiary] [Linked Third Party].

The Report covers the methodology used from [dd Month yyyy]. In the event that the [Beneficiary] [Linked Third Party] changes this methodology, the Report will not be applicable to any Financial Statement² submitted thereafter.

The scope of the Procedures and the definition of the standard statements and findings were determined solely by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence.

Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not

² Financial Statement in this context refers solely to Annex 4 of the Agreement by which the Beneficiary declares costs under the Agreement.

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give a statement of assurance on the costs declared on the basis of the [Beneficiary's] [Linked Third Party's] Methodology. Had we carried out additional procedures or had we performed an audit or review in accordance with these standards, other matters might have come to its attention and would have been included in the Report.

Exceptions

Apart from the exceptions listed below, the [Beneficiary] [Linked Third Party] agreed with the standard Statements and provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and corroborate the standard Findings.

List here any exception and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, also indicate the corresponding amount.

.....

Explanation of possible exceptions in the form of examples (to be removed from the Report):

- i. the [Beneficiary] [Linked Third Party] did not agree with the standard Statement number ... because...;*
- ii. the Auditor could not carry out the procedure ... established because (e.g. due to the inability to reconcile key information or the unavailability or inconsistency of data);*
- iii. the Auditor could not confirm or corroborate the standard Finding number ... because*

Remarks

We would like to add the following remarks relevant for the proper understanding of the Methodology applied by the [Beneficiary] [Linked Third Party] or the results reported:

Example (to be removed from the Report):

Regarding the methodology applied to calculate hourly rates ...

Regarding standard Finding 15 it has to be noted that ...

The [Beneficiary] [Linked Third Party] explained the deviation from the benchmark statement XXIV concerning time recording for personnel with no exclusive dedication to the action in the following manner:

...

Annexes

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Please provide the following documents to the auditor and annex them to the report when submitting this CoMUC to the Commission:

1. Brief description of the methodology for calculating personnel costs, productive hours and hourly rates;
2. Brief description of the time recording system in place;
3. An example of the time records used by the [Beneficiary] [Linked Third Party];
4. Description of any budgeted or estimated elements applied, together with an explanation as to why they are relevant for calculating the personnel costs and how they are based on objective and verifiable information;
5. A summary sheet with the hourly rate for direct personnel declared by the [Beneficiary] [Linked Third Party] and recalculated by the Auditor for each staff member included in the sample (the names do not need to be reported);
6. A comparative table summarising for each person selected in the sample a) the time claimed by the [Beneficiary] [Linked Third Party] in the Financial Statement(s) and b) the time according to the time record verified by the Auditor;
7. A copy of the letter of representation provided to the Auditor.

Use of this Report

This Report has been drawn up solely for the purpose given under Point 1.1 Reasons for the engagement.

The Report:

- is confidential and is intended to be submitted to the Commission by the [Beneficiary] [Linked Third Party] in connection with Article 18.1.2 of the Agreement;
- may not be used by the [Beneficiary] [Linked Third Party] or by the Commission for any other purpose, nor distributed to any other parties;
- may be disclosed by the Commission only to authorised parties, in particular the European Anti-Fraud Office (OLAF) and the European Court of Auditors.
- relates only to the usual cost accounting practices specified above and does not constitute a report on the Financial Statements of the [Beneficiary] [Linked Third Party].

No conflict of interest³ exists between the Auditor and the Beneficiary [and the Linked Third Party] that could have a bearing on the Report. The total fee paid to the Auditor for producing the Report was EUR [] (including EUR [] of deductible VAT).

³ A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:

- was involved in the preparation of the Financial Statements;

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We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

Yours sincerely

[legal name of the Auditor]

[name and title of the authorised representative]

[dd Month yyyy]

Signature of the Auditor

-
- stands to benefit directly should the certificate be accepted;
 - has a close relationship with any person representing the beneficiary;
 - is a director, trustee or partner of the beneficiary; or
 - is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

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Statements to be made by the Beneficiary/Linked Third Party ('the Statements') and Procedures to be carried out by the Auditor ('the Procedures') and standard factual findings ('the Findings') to be confirmed by the Auditor

The Commission reserves the right to provide the auditor with guidance regarding the Statements to be made, the Procedures to be carried out or the Findings to be ascertained and the way in which to present them. The Commission reserves the right to vary the Statements, Procedures or Findings by written notification to the Beneficiary/Linked Third Party to adapt the procedures to changes in the grant agreement(s) or to any other circumstances.

If this methodology certificate relates to the Linked Third Party's usual accounting practices for calculating and claiming direct personnel costs declared as unit costs any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	Procedures to be carried out and Findings to be confirmed by the Auditor
<p>A. Use of the Methodology</p> <p>I. The cost accounting practice described below has been in use since [dd Month yyyy].</p> <p>II. The next planned alteration to the methodology used by the Beneficiary will be from [dd Month yyyy].</p>	<p>Procedure:</p> <p>✓ The Auditor checked these dates against the documentation the Beneficiary has provided.</p> <p>Factual finding:</p> <p>1. The dates provided by the Beneficiary were consistent with the documentation.</p>
<p>B. Description of the Methodology</p> <p>III. The methodology to calculate unit costs is being used in a consistent manner and is reflected in the relevant procedures.</p> <p><i>[Please describe the methodology your entity uses to calculate <u>personnel</u> costs, productive hours and hourly rates, present your description to the Auditor and annex it to this certificate]</i></p> <p><i>[If the statement of section "B. Description of the methodology" cannot be endorsed by the Beneficiary or there is no written methodology to calculate unit costs it should be listed here below and reported as exception by the Auditor in the main Report of</i></p>	<p>Procedure:</p> <p>✓ The Auditor reviewed the description, the relevant manuals and/or internal guidance documents describing the methodology.</p> <p>Factual finding:</p> <p>2. The brief description was consistent with the relevant manuals, internal guidance and/or other documentary evidence the Auditor has reviewed.</p> <p>3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.</p>

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<i>Factual Findings:</i> - ...]	
<p>C. Personnel costs</p> <p><u>General</u></p> <p>IV. The unit costs (hourly rates) are limited to salaries including during parental leave, social security contributions, taxes and other costs included in the remuneration required under national law and the employment contract or equivalent appointing act;</p> <p>V. Employees are hired directly by the Beneficiary in accordance with national law, and work under its sole supervision and responsibility;</p> <p>VI. The Beneficiary remunerates its employees in accordance with its usual practices. This means that personnel costs are charged in line with the Beneficiary's usual payroll policy (e.g. salary policy, overtime policy, variable pay) and no special conditions exist for employees assigned to tasks relating to the European Union or Euratom, unless explicitly provided for in the grant agreement(s);</p> <p>VII. The Beneficiary allocates its employees to the relevant group/category/cost centre for the purpose of the unit cost calculation in line with the usual cost accounting practice;</p> <p>VIII. Personnel costs are based on the payroll system and accounting system.</p> <p>IX. Any exceptional adjustments of actual personnel costs resulted from relevant budgeted or estimated elements and were based on objective and verifiable information. <i>[Please describe the 'budgeted or estimated elements' and their relevance to personnel costs, and explain how they were reasonable and based on objective and verifiable information, present your explanation to the Auditor and annex it to this certificate].</i></p> <p>X. Personnel costs claimed do not contain any of the following ineligible costs: costs related to return on capital; debt and debt service charges; provisions for future losses</p>	<p>Procedure:</p> <p><i>The Auditor draws a sample of employees to carry out the procedures indicated in this section C and the following sections D to F.</i></p> <p><i>[The Auditor has drawn a random sample of 10 full-time equivalents made up of employees assigned to the action(s). If fewer than 10 full-time equivalents are assigned to the action(s), the Auditor has selected a sample of 10 full-time equivalents consisting of all employees assigned to the action(s), complemented by other employees irrespective of their assignments.]. For this sample:</i></p> <ul style="list-style-type: none"> ✓ the Auditor reviewed all documents relating to personnel costs such as employment contracts, payslips, payroll policy (e.g. salary policy, overtime policy, variable pay policy), accounting and payroll records, applicable national tax, labour and social security law and any other documents corroborating the personnel costs claimed; ✓ in particular, the Auditor reviewed the employment contracts of the employees in the sample to verify that: <ul style="list-style-type: none"> i. they were employed directly by the Beneficiary in accordance with applicable national legislation; ii. they were working under the sole technical supervision and responsibility of the latter; iii. they were remunerated in accordance with the Beneficiary's usual practices; iv. they were allocated to the correct group/category/cost centre for the purposes of calculating the unit cost in line with the Beneficiary's usual cost accounting practices; ✓ the Auditor verified that any ineligible items or any costs claimed under other costs categories or costs covered by other types of grant or by other grants financed from the European Union budget have not been taken

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<p>or debts; interest owed; doubtful debts; currency exchange losses; bank costs charged by the Beneficiary's bank for transfers from the Commission/Agency; excessive or reckless expenditure; deductible VAT or costs incurred during suspension of the implementation of the action.</p> <p>XI. Personnel costs were not declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU budget and grants awarded by bodies other than the Commission/Agency for the purpose of implementing the EU budget).</p> <p><u>If additional remuneration as referred to in the grant agreement(s) is paid</u></p> <p>XII. The Beneficiary is a non-profit legal entity;</p> <p>XIII. The additional remuneration is part of the beneficiary's usual remuneration practices and paid consistently whenever the relevant work or expertise is required;</p> <p>XIV. The criteria used to calculate the additional remuneration are objective and generally applied regardless of the source of funding;</p> <p>XV. The additional remuneration included in the personnel costs used to calculate the hourly rates for the grant agreement(s) is capped at EUR 8 000 per full-time equivalent (reduced proportionately if the employee is not assigned exclusively to the action).</p> <p><i>[If certain statement(s) of section "C. Personnel costs" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor in the main Report of</i></p>	<p>into account when calculating the personnel costs;</p> <ul style="list-style-type: none"> ✓ the Auditor numerically reconciled the total amount of personnel costs used to calculate the unit cost with the total amount of personnel costs recorded in the statutory accounts and the payroll system. ✓ to the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, the Auditor carefully examined those elements and checked the information source to confirm that they correspond to objective and verifiable information; ✓ if additional remuneration has been claimed, the Auditor verified that the Beneficiary was a non-profit legal entity, that the amount was capped at EUR 8000 per full-time equivalent and that it was reduced proportionately for employees not assigned exclusively to the action(s). ✓ the Auditor recalculated the personnel costs for the employees in the sample. <p>Factual finding:</p> <ol style="list-style-type: none"> 4. All the components of the remuneration that have been claimed as personnel costs are supported by underlying documentation. 5. The employees in the sample were employed directly by the Beneficiary in accordance with applicable national law and were working under its sole supervision and responsibility. 6. Their employment contracts were in line with the Beneficiary's usual policy; 7. Personnel costs were duly documented and consisted solely of salaries, social security contributions (pension contributions, health insurance, unemployment fund contributions, etc.), taxes and other statutory costs included in the remuneration (holiday pay, thirteenth month's pay, etc.); 8. The totals used to calculate the personnel unit costs are consistent with those registered in the payroll and accounting records; 9. To the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, those elements were

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<p>Factual Findings:</p> <p>- ...]</p>	<p>relevant for calculating the personnel costs and correspond to objective and verifiable information. The budgeted or estimated elements used are: — (indicate the elements and their values).</p> <p>10. Personnel costs contained no ineligible elements;</p> <p>11. Specific conditions for eligibility were fulfilled when additional remuneration was paid: a) the Beneficiary is registered in the grant agreements as a non-profit legal entity; b) it was paid according to objective criteria generally applied regardless of the source of funding used and c) remuneration was capped at EUR 8000 per full-time equivalent (or up to up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).</p>
<p>D. Productive hours</p> <p>XVI. The number of productive hours per full-time employee applied is <i>[delete as appropriate]</i>:</p> <p>A. 1720 productive hours per year for a person working full-time (corresponding pro-rata for persons not working full time).</p> <p>B. the total number of hours worked in the year by a person for the Beneficiary</p> <p>C. the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the standard annual workable hours.</p> <p><u>If method B is applied</u></p> <p>XVII. The calculation of the total number of hours worked was done as follows: annual workable hours of the person according to the employment contract, applicable labour agreement or national law plus overtime worked minus absences (such as sick leave and special leave).</p> <p>XVIII. 'Annual workable hours' are hours</p>	<p>Procedure (same sample basis as for Section C: Personnel costs):</p> <ul style="list-style-type: none"> ✓ The Auditor verified that the number of productive hours applied is in accordance with method A, B or C. ✓ The Auditor checked that the number of productive hours per full-time employee is correct and that it is reduced proportionately for employees not exclusively assigned to the action(s). ✓ If method B is applied the Auditor verified i) the manner in which the total number of hours worked was done and ii) that the contract specified the annual workable hours by inspecting all the relevant documents, national legislation, labour agreements and contracts. ✓ If method C is applied the Auditor reviewed the manner in which the standard number of working hours per year has been calculated by inspecting all the relevant documents, national legislation, labour agreements and contracts and verified that the number of productive hours per year used for these calculations was at least 90% of the standard number of working hours per year.

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<p>during which the personnel must be working, at the employer’s disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.</p> <p>XIX. The contract (applicable collective labour agreement or national working time legislation) do specify the working time enabling to calculate the annual workable hours.</p> <p><u>If method C is applied</u></p> <p>XX. The standard number of productive hours per year is that of a full-time equivalent; for employees not assigned exclusively to the action(s) this number is reduced proportionately.</p> <p>XXI. The number of productive hours per year on which the hourly rate is based i) corresponds to the Beneficiary’s usual accounting practices; ii) is at least 90% of the standard number of workable (working) hours per year.</p> <p>XXII. Standard workable (working) hours are hours during which personnel are at the Beneficiary’s disposal performing the duties described in the relevant employment contract, collective labour agreement or national labour legislation. The number of standard annual workable (working) hours that the Beneficiary claims is supported by labour contracts, national legislation and other documentary evidence.</p> <p><i>[If certain statement(s) of section “D. Productive hours” cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:</i></p> <p>- ...]</p>	<p>Factual finding:</p> <p><u>General</u></p> <p>12. The Beneficiary applied a number of productive hours consistent with method A, B or C detailed in the left-hand column.</p> <p>13. The number of productive hours per year per full-time employee was accurate and was proportionately reduced for employees not working full-time or exclusively for the action.</p> <p><u>If method B is applied</u></p> <p>14. The number of ‘annual workable hours’, overtime and absences was verifiable based on the documents provided by the Beneficiary and the calculation of the total number of hours worked was accurate.</p> <p>15. The contract specified the working time enabling to calculate the annual workable hours.</p> <p><u>If method C is applied</u></p> <p>16. The calculation of the number of productive hours per year corresponded to the usual costs accounting practice of the Beneficiary.</p> <p>17. The calculation of the standard number of workable (working) hours per year was corroborated by the documents presented by the Beneficiary.</p> <p>18. The number of productive hours per year used for the calculation of the hourly rate was at least 90% of the number of workable (working) hours per year.</p>
<p>E. Hourly rates</p> <p>The hourly rates are correct because:</p> <p>XXIII. Hourly rates are correctly calculated since they result from dividing annual personnel</p>	<p>Procedure</p> <ul style="list-style-type: none"> ✓ The Auditor has obtained a list of all personnel rates calculated by the Beneficiary in accordance with the methodology used. ✓ The Auditor has obtained a list of all the relevant employees, based on which the

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<p>costs by the productive hours of a given year and group (e.g. staff category or department or cost centre depending on the methodology applied) and they are in line with the statements made in section C. and D. above.</p> <p><i>[If the statement of section 'E. Hourly rates' cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:</i></p> <p>- ...]</p>	<p>personnel rate(s) are calculated.</p> <p>For 10 full-time equivalent employees selected at random (same sample basis as Section C: Personnel costs):</p> <ul style="list-style-type: none"> ✓ The Auditor recalculated the hourly rates. ✓ The Auditor verified that the methodology applied corresponds to the usual accounting practices of the organisation and is applied consistently for all activities of the organisation on the basis of objective criteria irrespective of the source of funding. <p>Factual finding:</p> <p>19. No differences arose from the recalculation of the hourly rate for the employees included in the sample.</p>
<p>F. Time recording</p> <p>XXIV. Time recording is in place for all persons with no exclusive dedication to one Horizon 2020 action. At least all hours worked in connection with the grant agreement(s) are registered on a daily/weekly/monthly basis <i>[delete as appropriate]</i> using a paper/computer-based system <i>[delete as appropriate]</i>;</p> <p>XXV. For persons exclusively assigned to one Horizon 2020 activity the Beneficiary has either signed a declaration to that effect or has put arrangements in place to record their working time;</p> <p>XXVI. Records of time worked have been signed by the person concerned (on paper or electronically) and approved by the action manager or line manager at least monthly;</p> <p>XXVII. Measures are in place to prevent staff from:</p> <ul style="list-style-type: none"> i. recording the same hours twice, ii. recording working hours during absence periods (e.g. holidays, sick leave), iii. recording more than the number of productive hours per year used to calculate the hourly rates, and 	<p>Procedure</p> <ul style="list-style-type: none"> ✓ The Auditor reviewed the brief description, all relevant manuals and/or internal guidance describing the methodology used to record time. <p>The Auditor reviewed the time records of the random sample of 10 full-time equivalents referred to under Section C: Personnel costs, and verified in particular:</p> <ul style="list-style-type: none"> ✓ that time records were available for all persons with not exclusive assignment to the action; ✓ that time records were available for persons working exclusively for a Horizon 2020 action, or, alternatively, that a declaration signed by the Beneficiary was available for them certifying that they were working exclusively for a Horizon 2020 action; ✓ that time records were signed and approved in due time and that all minimum requirements were fulfilled; ✓ that the persons worked for the action in the periods claimed; ✓ that no more hours were claimed than the productive hours used to calculate the hourly

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<p>iv. recording hours worked outside the action period.</p> <p>XXVIII. No working time was recorded outside the action period;</p> <p>XXIX. No more hours were claimed than the productive hours used to calculate the hourly personnel rates.</p> <p><i>[Please provide a brief description of the <u>time recording system</u> in place together with the measures applied to ensure its reliability to the Auditor and annex it to the present certificate⁴].</i></p> <p><i>[If certain statement(s) of section “F. Time recording” cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:</i></p> <p>- ...]</p>	<p>personnel rates;</p> <ul style="list-style-type: none"> ✓ that internal controls were in place to prevent that time is recorded twice, during absences for holidays or sick leave; that more hours are claimed per person per year for Horizon 2020 actions than the number of productive hours per year used to calculate the hourly rates; that working time is recorded outside the action period; ✓ the Auditor cross-checked the information with human-resources records to verify consistency and to ensure that the internal controls have been effective. In addition, the Auditor has verified that no more hours were charged to Horizon 2020 actions per person per year than the number of productive hours per year used to calculate the hourly rates, and verified that no time worked outside the action period was charged to the action. <p>Factual finding:</p> <ol style="list-style-type: none"> 20. The brief description, manuals and/or internal guidance on time recording provided by the Beneficiary were consistent with management reports/records and other documents reviewed and were generally applied by the Beneficiary to produce the financial statements. 21. For the random sample time was recorded or, in the case of employees working exclusively for the action, either a signed declaration or time records were available; 22. For the random sample the time records were signed by the employee and the action manager/line manager, at least monthly. 23. Working time claimed for the action occurred in the periods claimed; 24. No more hours were claimed than the number productive hours used to calculate the hourly

⁴ The description of the time recording system must state among others information on the content of the time records, its coverage (full or action time-recording, for all personnel or only for personnel involved in H2020 actions), its degree of detail (whether there is a reference to the particular tasks accomplished), its form, periodicity of the time registration and authorisation (paper or a computer-based system; on a daily, weekly or monthly basis; signed and countersigned by whom), controls applied to prevent double-charging of time or ensure consistency with HR-records such as absences and travels as well as its information flow up to its use for the preparation of the Financial Statements.

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	<p>personnel rates;</p> <p>25. There is proof that the Beneficiary has checked that working time has not been claimed twice, that it is consistent with absence records and the number of productive hours per year, and that no working time has been claimed outside the action period.</p> <p>26. Working time claimed is consistent with that on record at the human-resources department.</p>

[official name of the [Beneficiary] [Linked Third Party]]

[official name of the Auditor]

[name and title of authorised representative]

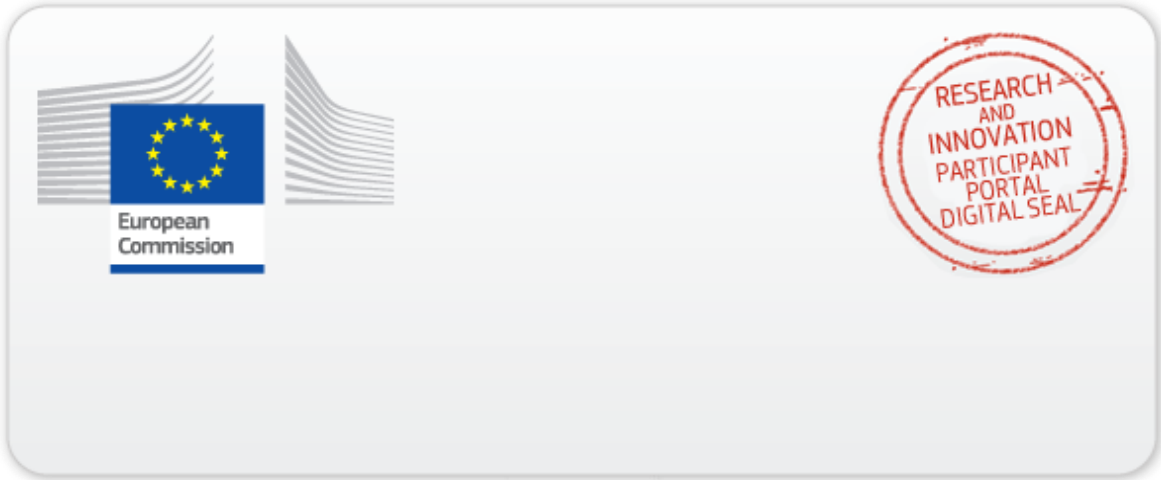
[name and title of authorised representative]

[dd Month yyyy]

[dd Month yyyy]

<Signature of the [Beneficiary] [Linked Third Party]>

<Signature of the Auditor>



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