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Grant Agreement number: 677024 — RD-ACTION — HP-JA-2014

Associated with doc[redacted]

EUROPEAN COMMISSION
Consumers, Health, Agriculture and Food Executive Agency
Director

GRANT AGREEMENT

NUMBER — 677024 — RD-ACTION

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

on the one part,

the **Consumers, Health, Agriculture and Food Executive Agency (CHAFEA)** ('the Agency'), under the power delegated by the European Commission ('the Commission'),

represented for the purposes of signature of this Agreement by Mr Luc BRIOL, Director, or his duly authorised representative,

and

on the other part,

1. 'the coordinator':

INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) (INSERM), 180036048, established in 101 Rue de Tolbiac, PARIS 75654, France, FR31180036048, represented for the purposes of signing the Agreement by Regional Delegate, Sylviane INOCENCIO

and the following other beneficiaries, if they sign their 'Accession Form' (see Annex 3 and Article 40):

2. **MEDIZINISCHE UNIVERSITAET WIEN (MUW)**, established in SPITALGASSE 23, WIEN 1090, Austria, ATU57469858,

3. **SERVICE PUBLIC FEDERAL SANTE PUBLIQUE, SECURITE DE LA CHAINE ALIMENTAIRE ET ENVIRONNEMENT (SPF)**, N/A, established in SQUARE VICTOR HORTA 40 BUR 1D 1G, BRUSSELS 1060, Belgium, N/A,

4. **INSTITUT SCIENTIFIQUE DE SANTE PUBLIQUE (WIV-ISP)**, 0254014195, established in Rue Juliette Wytsman 14, BRUXELLES 1050, Belgium, BE0254014195,

5. **BULGARIAN ASSOCIATION FOR PROMOTION OF EDUCATION AND SCIENCE (BAPES)** BG16, 115782273, established in BRATYA SVESHTAROVI STR 4, PLOVDIV 4017, Bulgaria,

6. **HRVATSKI SAVEZ ZA RIJETKE BOLESTI (HSRB)** HR1, 21002274, established in Ivanicgradska 38, Zagreb 10000, Croatia,

7. **FAKULTNI NEMOCNICE V MOTOLE (NKCVO)**, 00064203 , established in V UVALU 84, PRAHA 5 150 06 , Czech Republic, CZ00064203,

8. **TARTU ULIKOOL (UTARTU)**, 74001073, established in ULIKOOLI 18, TARTU 50090, Estonia, EE100030417,

9. **RINNEKOTI SAATIO (RINNEKOTI)** FI1, 02019768, established in RINNEKODINTIE 10, ESPOO 02980, Finland, FI02019768,

10. **ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS (APHP)**, 42132660400012, established in 3 Avenue Victoria, PARIS 75004, France, FR95267500452,

11. **EURORDIS - EUROPEAN ORGANISATION FOR RARE DISEASES ASSOCIATION (EURORDIS)** FR3, 413459066/129742P, established in RUE DIDOT 96, Paris 75014, France,

12. **MEDIZINISCHE HOCHSCHULE HANNOVER (MHH)**, Not applicable, established in Carl-Neuberg-Strasse 1, HANNOVER 30625, Germany, DE115650503,

13. **DEUTSCHES INSTITUT FUR MEDIZINISCHE DOKUMENTATION UND INFORMATION (DIMDI) (DIMDI)**, established in WAISENHAUSGASSE 36-38A, KOLN 50676, Germany, DE123052538,

14. **ORSZAGOS TISZTIFOORVOSI HIVATAL (OCMO)**, 329530, established in ALBERT FLORIAN UT 2-6., BUDAPEST 1097, Hungary, HU15329530,

15. **SEMMELWEIS EGYETEM (SE)** HU13, FI62576, established in ULLOI UTCA 26, BUDAPEST 1085, Hungary, HU15329808,

16. **HEALTH SERVICE EXECUTIVE HSE (HSE)**, established in LIMETREE AVENUE 2ND FLO OAK HOUSE, NAAS, Ireland, IE66093541,

17. **OSPEDALE PEDIATRICO BAMBINO GESU (OPBG)**, -, established in PIAZZA SANT ONOFRIO 4, ROMA 00165, Italy, VAT exemption,

18. **REGIONE DEL VENETO (VR-IIBRD)**, established in Palazzo Balbi - Dorsoduro 3901, VENEZIA 30123, Italy, IT02392630279,

19. **SLIMIBU PROFILAKSES UN KONTROLES CENTRS (SPKC)**, 90009756700, established in Duntes 22, Riga LV1005, Latvia, 90009756700,

20. **VIESOJI ISTAIGA VILNIAUS UNIVERSITETO LIGONINES SANTARISKIU KLINIKOS (VULSK)** LT3, 124364561, established in SANTARISKIU G 2, VILNIUS 08661, Lithuania, LT243645610,

21. **ACADEMISCH ZIEKENHUIS LEIDEN (LUMC)**, 27366422, established in ALBINUSDREEF 2, LEIDEN 2333 ZA, Netherlands, NL003566213B01,

22. **HELSEDIREKTORATE (HDIR)**, 983544622, established in UNIVERSITETSGATA 2, OSLO 0164, Norway, NO983544622 ,

23. **OSLO UNIVERSITETSSYKEHUS HF (NKSD)**, 993467049, established in KIRKEVEIEN 166 TARNBYGGET, OSLO 0450, Norway, NO993467049MVA,

24. **INSTYTUT POMNIK CENTRUM ZDROWIA DZIECKA (IPCZD)**, 0000092381/000557961, established in Aleja Dzieci Polskich 20, WARSZAWA 04730, Poland, PL9521143675,

25. **MINISTERIO DA SAUDE - REPUBLICA PORTUGUESA (DGS)**, Decreto-Lei n.° 212/2006, de 27 de Outubro , established in Av. João Crisóstomo, 9, LISBOA 1049-062 , Portugal,

26. **UNIVERSITATEA DE MEDICINA SI FARMACIE GRIGORE T.POPA IASI (UMF)**, CF4701100, established in STRADA UNIVERSITATII 16, IASI 700115, Romania,

27. **UNIVERZITA KOMENSKEHO V BRATISLAVE (CUMS)**, 00397865, established in SAFARIKOVO NAM 6, Bratislava 1 81499, Slovakia, SK2020845332,

28. **UNIVERZITETNI KLINICNI CENTER LJUBLJANA (UKCL)**, 5057272, established in ZALOSKA CESTA 002, LJUBLJANA 1000, Slovenia, SI52111776,

29. **CENTRO DE INVESTIGACION BIOMEDICA EN RED (CIBER)** ES7, established in CALLE MONFORTE DE LEMOS 5, MADRID 28029, Spain, ESG85296226,

30. **STOCKHOLMS LAENS LANDSTING (KS)**, 2321000016, established in Hantverkargatan 45, STOCKHOLM 104 22, Sweden, SE232100001601,

31. **UNIVERSITY OF NEWCASTLE UPON TYNE (UNEW)**, established in KINGS GATE, NEWCASTLE UPON TYNE NE1 7RU, United Kingdom, GB499672470,

32. **Department of Health (UK PHE)**, -, established in Quarry House, Quarry Hill, Leeds LS2 7UE, United Kingdom, 888815064,

33. **Ministere des Affaires Sociales et de la Sante (DGS FR)**, N/A, established in AVENUE Duquesne 14, PARIS CEDEX 75350, France, N/A,

34. **ISTITUTO SUPERIORE DI SANITA (ISS)**, 80211730587, established in Viale Regina Elena 299, ROMA 00161, Italy, IT03657731000,

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 the action 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

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 '***Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases — RD-ACTION***' (**'action'**), as described in Annex 1.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***36*** **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).

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 39, 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 10.

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 4,379,979.00** (four million three hundred and seventy nine thousand nine hundred and seventy nine EURO).

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses ***60% 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 **8,344,079.80** (eight million three hundred and forty four thousand seventy nine EURO and eighty eurocents).

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

(a) for **direct personnel costs**: as actually incurred costs (**actual costs**);

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

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

(d) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2.D ('**flat-rate costs**');

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 Agency — when the payment of the balance is made — in the following steps:

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

The reimbursement rate (see Article 5.2) is applied to the eligible costs (actual costs and flat-rate costs; see Article 6) declared by the beneficiaries (see Article 15) and approved by the Agency (see Article 16).

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 Agency.

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;

(b) financial contributions given by third parties to the beneficiary specifically to be used for costs that are eligible under the action.

The following are however **not** considered receipts:

(a) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(b) 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 in proportion to the final rate of reimbursement of the eligible actual costs approved by the Agency (as compared to the amount calculated 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 27), the Agency 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 27.2) 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 17) — the Agency rejects costs (see Article 26) or reduces the grant (see Article 27), it will calculate the '**revised final grant amount**' for the action.

This amount is calculated by the Agency 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 Agency for the action, limiting it to the maximum grant amount and making a reduction if there is a profit (see Article 5.3);
- in case of **reduction of the grant**: 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 27.2) from the maximum grant amount set out in Article 5.1.

In case of **rejection of costs and reduction of the grant,** the revised final grant amount for the action 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 15);

(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 **flat-rate costs**:

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

(ii) the costs (actual 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. other direct costs;

D. indirect costs;

'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 D 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).

They may also include **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.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract or seconded by a third party against payment 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.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{hourly rate

multiplied by

the number of actual hours worked on the action}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 13).

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 are:

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

minus

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

The '**hourly rate**' is the amount calculated as follows:

{actual annual personnel costs 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. Direct costs of subcontracting (including related duties, taxes and charges, such as non-deductible value added tax (VAT) paid by beneficiaries that are not public bodies acting as public authority) are eligible if the conditions in Article 10.1.1 are met.

C. Other direct costs

C.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges, such as non-deductible value added tax (VAT) paid by beneficiaries that are not public bodies acting as public authority) are eligible if they are in line with the beneficiary's usual practices on travel.

C.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 9.1.1 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 beneficiaries that are not public bodies acting as public authority) 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 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.

C.3 **Costs of other goods and services** (including related duties, taxes and charges, such as non-deductible value added tax (VAT) paid by beneficiaries that are not public bodies acting as public authority) are eligible, if they are purchased specifically for the action and in accordance with Article 9.1.1.

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

D. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 7% of the eligible direct costs (see Article 5.2 and Points A to C above).

Beneficiaries receiving an operating grant[1] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

6.3 Conditions for costs of affiliated entities to be eligible

not applicable

[1] 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.

6.4 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.3), 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 Agency;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 33);

(xi) in-kind contributions provided by third parties;

(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 Agency 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.

6.5 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 26).

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 27).

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 9);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 10);
- call upon affiliated entities to implement action tasks described in Annex 1 (see Article 11).

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

ARTICLE 9 — PURCHASE OF GOODS, WORKS OR SERVICES

9.1 Rules for purchasing goods, works or services

9.1.1 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 20).

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 17 and 18 also towards their contractors.

9.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[2] or 'contracting entities' within the meaning of Directive 2004/17/EC[3] must comply with the applicable national law on public procurement.

[2] 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).

9.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 9.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 26).

If a beneficiary breaches any of its obligations under Article 9.1.2, the grant may be reduced (see Article 27).

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

ARTICLE 10 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

10.1 Rules for subcontracting action tasks

10.1.1 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 20).

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 Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 39), 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 Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 17 and 18 also towards their subcontractors.

10.1.2 The beneficiaries must ensure that their obligations under Articles 20, 21, 22 and 30 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.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 26).

[3] 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).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 27).

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

ARTICLE 11 — IMPLEMENTATION OF ACTION TASKS BY AFFILIATED ENTITIES

Not applicable

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATIONFR

ARTICLE 12 — GENERAL OBLIGATION TO INFORM

12.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 25.2 — 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.

12.2 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 36) 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 Agency 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.

12.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27).

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

ARTICLE 13 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

13.1 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 12) or in the context of checks, reviews, audits or investigations (see Article 17).

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 17), 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 Agency may accept non-original documents if it considers that they offer a comparable level of assurance.

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

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

13.1.2 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 **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), 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 *Agency* 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.

13.2 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 26), and the grant may be reduced (see Article 27).

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

ARTICLE 14 — SUBMISSION OF DELIVERABLES

14.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1 (if any), in accordance with the timing and conditions set out in it.

14.2 Consequences of non-compliance

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

ARTICLE 15 — REPORTING — PAYMENT REQUESTS

15.1 Obligation to submit reports

The coordinator must submit to the Agency (see Article 36) 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 36).

15.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month 12
- *RP2: from month 13 to month 24*
- *RP3: from month 25 to month 36*

15.3 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;

(iii) a **summary** for publication by the Agency;

(iv) *the answers to the '**questionnaire**', covering issues related to the action implementation and its impact, if required in Annex 1;*

(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 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 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 Agency.

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 13) that will be produced upon request (see Article 12) or in the context of checks, reviews, audits and investigations (see Article 17), 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 10) 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**.

(v) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary, if:

- the (cumulative) amount of payments it requests as reimbursement of actual costs (and for which no certificate has yet been submitted) is EUR 325 000 or more and
- the maximum grant amount indicated, for that beneficiary, in the estimated budget (see Annex 2) as reimbursement of actual costs is EUR 750 000 or more.

15.4 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 dissemination;

(ii) the conclusions on the action and

(iii) *the 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:

- the cumulative amount of payments it requests as reimbursement of actual costs (and for which no certificate has been submitted) is EUR 325 000 or more and
- the maximum grant amount indicated, for that beneficiary, in the estimated budget (see Annex 2) as reimbursement of actual costs is EUR 750 000 or more.

15.5 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.

15.6 Language of reports

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

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

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 31) 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 Agency, the Agreement may be terminated (see Article 34).

ARTICLE 16 — PAYMENTS AND PAYMENT ARRANGEMENTS

16.1 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 15), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 15).

16.2 Pre-financing payment — Amount

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 **1,313,993.70** (one million three hundred and thirteen thousand nine hundred and ninety three EURO and seventy eurocents).

The Agency will — except if Article 32 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 42) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

16.3 Interim payments — Amount — Calculation

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

The Agency will pay to the coordinator the amount due as interim payment within 60 days from receiving the periodic report (see Article 15.3), except if Articles 31 or 32 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 Agency in the following steps:

Step 1 – Application of the reimbursement rate

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

16.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to the eligible costs (actual costs and flat-rate costs; see Article 6) declared by the beneficiaries (see Article 15) and approved by the Agency (see above) for the concerned reporting period.

16.3.2 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}}.

16.4 Payment of the balance — Amount — Calculation

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 28).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 60 days from receiving the final report (see Article 15.4), except if Articles 31 or 32 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 Agency 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}}.

If the balance is positive, it will be paid to the coordinator.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by a beneficiary to the Agency, the Commission or another 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).

If the balance is negative, it will be recovered.

16.5 Notification of amounts due

When making payments, the Agency 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 27 and 28.

16.6 Currency for payments

The Agency will make all payments in euro.

16.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the Agency 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 90% of the beneficiaries have acceded to the Agreement (see Article 40) and

(b) to beneficiaries that have acceded to the Agreement (see Article 40).

16.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: TRESOR PUBLIC
Address of branch: 94, R DE REAUMUR PARIS, France
Full name of the account holder: ACS INSERM PARIS VI ST ANTOINE
Full account number (including bank codes):
IBAN code: FR7610071750000000100523686

16.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the Agency 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.

16.10 Date of payment

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

16.11 Consequences of non-compliance

16.11.1 If the Agency 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 31 and 32) 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.

16.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 27) and the Agreement or the participation of the coordinator may be terminated (see Article 34).

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

ARTICLE 17 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

17.1 Checks, reviews and audits by the Agency and the Commission

17.1.1 Right to carry out checks

The Agency or 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 Agency or the Commission may be assisted by external persons or bodies.

The Agency or the Commission may also request additional information in accordance with Article 12. The Agency or 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.

17.1.2 Right to carry out reviews

The Agency or 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) and compliance with the obligations under the Agreement.

Reviews may be started **up to *five* 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 9, 10, 11), the beneficiary concerned must inform the third party.

The Agency or 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 Agency or 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 Agency or 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.

17.1.3 Right to carry out audits

The Agency or 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 *five* 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 9, 10, 11), the beneficiary concerned must inform the third party.

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

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

Under Regulations No 883/2013[5] and No 2185/96[6] (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.

[5] 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 232, 18.09.2013, p. 1).

[6] 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).

17.3 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 966/2012[7], 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.

17.4 Checks, reviews, audits and investigations for international organisations

Not applicable

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

17.5.1 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 26), reduction of the grant (see Article 27), recovery of undue amounts (see Article 28) 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 39).

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.

17.5.2 Findings in other grants

The Agency or 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 *five* years after the payment of the balance** of this grant.

[7] 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).

The extension of findings may lead to the rejection of costs (see Article 26), reduction of the grant (see Article 27), recovery of undue amounts (see Article 28), suspension of payments (see Article 32), suspension of the action implementation (see Article 33) or termination (see Article 34).

17.5.3 Procedure

The Agency or 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.

17.5.3.1 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 Agency or 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 Agency or the Commission in justified cases.

The Agency or the Commission may then start a rejection procedure in accordance with the procedure set out in Article 26, either on the basis of the revised financial statements or the rate announced.

17.5.3.2 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 Agency or 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.

The Agency or the Commission may then start a reduction procedure in accordance with the procedure set out in Article 27, either on the basis of the alternative flat-rate or the flat-rate announced.

17.6 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 26).

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

ARTICLE 18 — EVALUATION OF THE IMPACT OF THE ACTION

18.1 Right to evaluate the impact of the action

The Agency or 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 Agency or 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.

18.2 Consequences of non-compliance

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

SECTION 3 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 19 — PRE-EXISTING RIGHTS AND OWNERSHIP OF THE RESULTS (INCLUDING INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS)

19.1 Pre-existing rights and access rights to pre-existing rights

Where industrial and intellectual property rights (including rights of third parties) exist prior to the Agreement, the beneficiaries must establish a list of these pre-existing industrial and intellectual property rights, specifying the owner and any persons that have a right of use.

The coordinator must — before starting the action — submit this list to the Agency.

The beneficiaries must give each other (and their affiliated entities) access to any pre-existing industrial and intellectual property rights needed for the implementation of the action and compliance with the obligations under the Agreement.

19.2 Ownership of results and rights of use

The results of the action (including the reports and other documents relating to it) are owned by the beneficiaries.

The beneficiaries must give the Agency and the Commission the right to use the results for their communication activities under Article 22.

19.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27).

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

ARTICLE 20 — CONFLICT OF INTERESTS

20.1 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 Agency 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 Agency may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

20.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27) and the Agreement or participation of the beneficiary may be terminated (see Article 34).

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

ARTICLE 21 — CONFIDENTIALITY

21.1 General obligation to maintain confidentiality

During implementation of the action and for **five years after the payment of the balance**, 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**').

They may use confidential information to implement the Agreement.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information becomes generally and publicly available, without breaching any confidentiality obligation;

(c) the disclosure of the confidential information is required by EU or national law.

21.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27).

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

ARTICLE 22 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

22.1 Communication activities by the beneficiaries

22.1.1 General obligation to promote the action and its results

The beneficiaries must promote the action and its results.

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

Unless the Agency requests or agrees otherwise, any communication activity related to the action (including at conferences, seminars, in information material, such as brochures, leaflets, posters, presentations, etc., in electronic form, via social media, etc.) and any infrastructure, equipment or major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

> *"This [insert appropriate description, e.g. report, publication, conference, infrastructure, equipment, insert type of result, etc.] is part of the project / joint action '677024 / RD-ACTION' which has received funding from the European Union's Health Programme (2014-2020)."*

When displayed in association 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 Agency.

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.

22.1.3 Disclaimer excluding Agency/Commission responsibility

Any communication activity related to the action must indicate the following disclaimer:

> *"The content of this [insert appropriate description, e.g. report, publication, conference, etc.] represents the views of the author only and is his/her sole responsibility; it can not be considered to reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains."*

22.2 Communication activities by the Agency

22.2.1 Right to use the beneficiaries' materials, documents or information

The Agency may use 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 21, which still apply.

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

(a) **use for its own purposes** (in particular, making them available to persons working for the Agency 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 1049/2001[8], 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 Agency.

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 beneficiary), the Agency will insert the following information:

"© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) under conditions."

22.3 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27).

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

ARTICLE 23 — PROCESSING OF PERSONAL DATA

[8] 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.

23.1 Processing of personal data by the Agency and the Commission

Any personal data under the Agreement will be processed by the Agency or the Commission under Regulation No 23/2001[9] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the Agency or the Commission (publicly accessible in the DPO register).

Such data will be processed by the '**data controller**' of the Agency or 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 17).

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 privacy statement(s) on the Agency and Commission websites.

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

23.2 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 Agency or the Commission. For this purpose, they must provide them with the privacy statement(s) (see above), before transmitting their data to the Agency or the Commission.

23.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 23.2, the Agency may apply any of the measures described in Chapter 6.

ARTICLE 24 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE AGENCY

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

If the Agency 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 Agency.

[9] 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).

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES

ARTICLE 25 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES

25.1 Roles and responsibilities towards the Agency

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 Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 28, 29 and 30.

25.2 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 12);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 12);

(iii) submit to the coordinator in good time:

- individual financial statements for itself and, if required, certificates on the financial statements (see Article 15);
- the data needed to draw up the technical reports (see Article 15);
- any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Agency or 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 Agency (in particular, providing the Agency with the information described in Article 12), unless the Agreement specifies otherwise;

(iii) provide a pre-financing guarantee if requested by the Agency (see Article 16.2);

(iv) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;

(v) submit the deliverables and reports to the Agency (see Articles 14 and 15);

(vi) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 16).

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

25.3 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.

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 26 — REJECTION OF INELIGIBLE COSTS

26.1 Conditions

26.1.1 The Agency 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 17).

26.1.2 The rejection may also be based on the **extension of findings from other grants to this grant,** under the conditions set out in Article 17.5.2.

26.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full.

If the Agency rejects costs **without reduction of the grant** (see Article 27) or **recovery of undue amounts** (see Article 28), 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 16.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the Agency 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 27 and 28.

26.3 Effects

If the Agency 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 15.3 and 15.4). It will then calculate the interim payment or payment of the balance as set out in Articles 16.3 or 16.4.

If the Agency — **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 16.3 or 16.4.

If the Agency 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 27 — REDUCTION OF THE GRANT

27.1 Conditions

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

27.1.2 The Agency 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 17.5.2.

27.2 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 Agency 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 Agency 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 16).

27.3 Effects

If the Agency 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 Article 5.3.4 and Article 16.4).

If the Agency reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount (see Article 5.4). If the revised final grant amount is lower than the final grant amount, the Agency will recover the difference (see Article 28).

ARTICLE 28 — RECOVERY OF UNDUE AMOUNTS

28.1 Amount to be recovered — Calculation — Procedure

The Agency will — **at the payment of the balance** or **afterwards** — claim back amount that was paid but is not due under the Agreement.

The coordinator is fully liable for repaying debts of the consortium (under the Agreement) even if it has not been the final recipient of those amounts.

In addition, the beneficiaries (including the coordinator) are jointly and severally liable for repaying any unpaid debts under the Agreement (due by the consortium or any beneficiary, including late-payment interest) — up to the maximum EU contribution indicated, for each beneficiary, in the estimated budget (as last amended; see Annex 2).

28.1.1 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 16.4), the Agency 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 and

- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note** with the terms and the date for payment (together with the notification of amounts due; see Article 16.5).

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

(a) by '**offsetting**' it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, Commission or another executive agency (from the EU or Euratom budget).

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

(b) *not applicable;*

(c) *by holding the other beneficiaries jointly and severally liable — up to the maximum EU contribution indicated, for each beneficiary, in the estimated budget (as last amended; see Annex 2);*

(d) by **taking legal action** (see Article 41) 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 16.11, from the day following the payment date in the debit note, up to and including the date the Agency or 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.

28.1.2 Recovery of amounts after payment of the balance

If — after the payment of the balance — the Agency revised the final grant amount for the action (see Article 5.4), due to a rejection of costs or reduction of the grant, and the revised final grant amount is lower than the final grant amount (see Article 5.3), the Agency will:

- if the rejection or reduction does *not* concern a specific beneficiary (or its affiliated entities): claim back the difference from the coordinator (even if it has not been the final recipient of the amount in question)

or

- otherwise: claim back the difference from the beneficiary concerned.

The Agency will formally notify a **pre-information letter** to the coordinator or beneficiary concerned:

- informing it of its intention to recover, the amount to be repaid and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator or 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 Agency or the Commission will **recover** the amount:

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

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

(b) *by holding the other beneficiaries jointly and severally liable, up to the maximum EU contribution indicated, for each beneficiary, in the estimated budget (as last amended; see Annex 2);*

(c) by **taking legal action** (see Article 41) 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 16.11, from the day following the date for payment in the debit note, up to and including the date the Agency or 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 29 — ADMINISTRATIVE AND FINANCIAL PENALTIES

29.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the Agency 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 Agency or the Commission may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

29.2 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 Agency.

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

29.3 Procedure

Before applying a penalty, the Agency 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 Agency 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 Agency or 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 Agency, Commission or another executive agency (from the EU or Euratom budget).

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

(b) by **taking legal action** (see Article 41) 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.

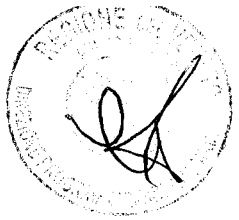
If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 16.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives 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 30 — LIABILITY FOR DAMAGES



30.1 Liability of the Agency

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

30.2 Liability of the beneficiaries

30.2.1 Conditions

Except in case of force majeure (see Article 35), the beneficiaries must compensate the Agency for any damage it sustains as a result of the implementation of the actione or because the action was not implemented in full compliance with the Agreement.

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

30.2.2 Amount of damages - Calculation

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

30.2.3 Procedure

Before claiming damages, the Agency 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 Agency 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 Agency or 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 Agency, Commission or another executive agency (from the EU or Euratom budget).

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

(b) by **taking legal action** (see Article 41) or by **adopting an enforceable decision** under Article 79(2) of the Financial Regulation No 966/2012 and Article 299 of the Treaty on the Functioning of the EU (TFEU).

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 16.11, from the day following the

payment date in the debit note, up to and including the date the Agency or 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 31 — SUSPENSION OF PAYMENT DEADLINE

31.1 Conditions

The Agency may — at any moment — suspend the payment deadline (see Article 16.2 to 16.4) if a request for payment (see Article 15) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 15);

(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.

31.2 Procedure

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

The suspension will **take effect** the day notification is sent by the Agency (see Article 36).

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 Agency 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 15) and the revised report or statement is not submitted or was submitted but is also rejected, the Agency may also terminate the Agreement or the participation of the beneficiary (see Article 34.3.1).

ARTICLE 32 — SUSPENSION OF PAYMENTS

32.1 Conditions

The Agency 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 17.5.2).

32.2 Procedure

Before suspending payments, the Agency 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 Agency 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 Agency.

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

During the suspension, the periodic report(s) (see Article 15.3) must not contain any individual financial statements from the beneficiary concerned. When the Agency resumes payments, the coordinator may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 33.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 34.1 and 34.2).

ARTICLE 33 — SUSPENSION OF THE ACTION IMPLEMENTATION

33.1 Suspension of the action implementation, by the beneficiaries

33.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 35) — make implementation impossible or excessively difficult.

33.1.2 Procedure

The coordinator must immediately formally notify to the Agency the suspension (see Article 36), stating:

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

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

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the Agency 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 39) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 34).

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).

33.2 Suspension of the action implementation, by the Agency

33.2.1 Conditions

The Agency 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 or

(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 17.5.2).

33.2.2 Procedure

Before suspending implementation of the action, the Agency 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 Agency 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 39) — unless the Agreement has already been terminated (see Article 34).

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 Agency (see Article 30).

Suspension of the action implementation does not affect the Agency's right to terminate the Agreement or participation of a beneficiary (see Article 34), reduce the grant or recover amounts unduly paid (see Articles 27 and 28).

ARTICLE 34 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

34.1 Termination of the Agreement, by the beneficiaries

34.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the Agency (see Article 36), 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 Agency the Agreement will be considered to have been '**terminated improperly**'.

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

34.1.2 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 15.3) and

(ii) the final report (see Article 15.4).

If the Agency 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 Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 16.4) 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 27).

After termination, the beneficiaries' obligations (in particular, Articles 15, 17, 18, Section 3 of Chapter 4, 21, 22 and 24) continue to apply.

34.2 Termination of the Specific Agreement, by the Agency

34.2.1 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 Agency (see Article 36) 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 39), 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 40). 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 Agency 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.

34.2.2 Effects

The beneficiary concerned must submit to the coordinator:

(i) a technical report and

(ii) a financial statement covering the period from the end of the last reporting period to the date when termination takes effect.

This information must be included by the coordinator in the periodic report for the next reporting period (see Article 15.3).

If the request for amendment is rejected by the Agency (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 34.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is amended to introduce the necessary changes (see Article 39).

Improper termination may lead to a reduction of the grant (see Article 27) or termination of the Agreement (see Article 34).

After termination, the concerned beneficiary's obligations (in particular Articles 15, 17, 18, Section 3 of Chapter 4, 21, 22 and 24) continue to apply.

34.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

34.3.1 Conditions

The Agency 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 40);

(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 39);

(d) implementation of the action is prevented by force majeure (see Article 35) or suspended by the coordinator (see Article 33.1) 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) 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;

(i) 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;

(j) 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'**).

34.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency 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 (i.ii) above — to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency 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) and (i.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (h), (i.i) and (j) above: on the day after the notification of the confirmation is received by the coordinator.

34.3.3 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 15.3) and

(ii) a final report (see Article 15.4).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 15.7 and 34.3.1), the coordinator may not submit any reports after termination.

If the Agency 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 Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 16.4) 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 Agency's right to reduce the grant (see Article 27) or to impose administrative and financial penalties (Article 29).

The beneficiaries may not claim damages due to termination by the Agency (see Article 30).

After termination, the beneficiaries' obligations (in particular Articles 15, 17, 18, Section 3 of Chapter 4, 21, 22 and 24) 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 a request for amendment (see Article 39), 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 40). 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.

The beneficiary concerned must submit to the coordinator:

(i) a technical report and

(ii) a financial statement covering the period from the end of the last reporting period to the date when termination takes effect.

This information must be included by the coordinator in the periodic report for the next reporting period (see Article 15.3).

If the request for amendment is rejected by the Agency (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 34.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 39).

After termination, the concerned beneficiary's obligations (in particular Articles 15, 17, 18, Section 3 of Chapter 4, 21, 22 and 24) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 35 — 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 36 — COMMUNICATION BETWEEN THE PARTIES

36.1 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, the partner must have designated— before the signature of the Framework Partnership 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 Agency and Commission websites.

36.2 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.

36.3 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 Agency 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 Agency** must be sent to the following address:

Consumers, Health, Agriculture and Food Executive Agency (CHAFEA)
Health
Drosbach Building
L-2920 Luxembourg

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 37 — INTERPRETATION OF THE AGREEMENT

37.1 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.

37.2 Privileges and immunities

Not applicable

ARTICLE 38 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[10], 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 39 — AMENDMENTS TO THE AGREEMENT

39.1 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.

39.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 36).

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, and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The Agency 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 Agency 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 40 — ACCESSION TO THE AGREEMENT

[10] 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).

40.1 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 36) within 30 days after its entry into force (see Article 42).

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 42).

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 Agency's right to terminate the Agreement (see Article 34).

40.2 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 39. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 36).

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 41 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

41.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium.

41.2 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 Agency and 'HELSEDIREKTORATE', 'OSLO UNIVERSITETSSYKEHUS HF', the competent Belgian courts have sole jurisdiction.

If a dispute concerns administrative or financial penalties, offsetting or an enforceable decision under Article 79(2) of the Financial Regulation No 966/2012 and Article 299 TFEU (see Articles 28, 29 and 30), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. Actions against enforceable decisions must be brought against the Commission (not against the Agency).

ARTICLE 42 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the Agency or the coordinator, depending on which is later.

SIGNATURES

For the coordinator

Sylviane INOCENCIO with ECAS id ninocesy signed in the Participant Portal on 30/07/2015 at 08:30:40 (transaction id SigId-2363-ZBAuE2AY3ihztRezSTBqWmE7ogzSLkrAKPGARaZPLZK4wzobndvZZ7YqRgAFlYQMgOZRE1qtVxRWM60ilwgKzhB-PHslUMVSXYCH3xcLZM8UuW-WzgBQznSnb2pEVpltmfztkVMKupVm4A873zrUGQmCiPw). Timestamp by third party at
Thu Jul 30 09:30:45 CEST 2015

For the Agency

Luc BRIOL with ECAS id briollu signed in the Participant Portal on 06/08/2015 at 08:51:52 (transaction id SigId-5083-Sk6u5zusPdkiLLZzqpYCHa7bxbKfFBaxuiZiL2gO7GGbhOEfG4x9E!autGuzkti2Qzwg88TzkApXLFmW5st4E5J-PHslUMVSXYCH3xcLZM8UuW-8u9EDrv3Aq4yG3MhBIJXpTK4rVzn6YAo9zv6i5gnPMzS). Timestamp by third party at
Thu Aug 06 09:51:54 CEST 2015

EUROPEAN COMMISSION
Consumers, Health, Agriculture and Food Executive Agency
Health

ANNEX 1 (part A)

Project

NUMBER — 677024 — RD-ACTION

Table of Contents

1.1. The project summary

Project Number [1]	677024	Project Acronym [2]	RD-ACTION

One form per project	
General information	
Project title [3]	Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases
Starting date [4]	01/06/2015
Duration in months [5]	36
Call (part) identifier [6]	HP-JA-2014
Topic	JA-06-2014 Rare Disease Joint Action
Fixed EC Keywords	
Free keywords	rare diseases, database, codification, healthcare, network (networking)

Abstract [7]

Rare diseases (RD) have been identified as one of the paradigmatic fields in which actions conducted at the European level constitute the adequate response to their specific problems: poor recognition leading to diagnostic delay and inappropriate management including adapted social services, poor health outcomes, social burden, limited knowledge on natural history and pathophysiology leading to an insufficient development of new therapies. The low prevalence and the specificity of RD make that a global, multi-stakeholder approach, intended to gather specific expertise and to build shared strategies is necessary to address these issues.
The general objectives of RD-Action are to:
- Support the further development and sustainability of the Orphanet database, the biggest global repository of information on RD
- Contribute to solutions to ensure an appropriate codification of RD in health information systems
- Continue implementation of the priorities identified in Council Recommendation 2009/C151/02 and the Commission Communication (COM 2008 679) on RD, with a view to ensuring the sustainability of the recommended priority actions and to support the work of the Commission Expert Group on Rare Diseases (CEGRD).

This JA will expand and consolidate the achievements of the former JAs on RD supported by the European Commission: the Orphanet JA and the EUCERD JA. More precisely, this proposal has the ambition to help member states to implement the recommended measures adopted or to be adopted by the CEGRD and to produce the data necessary for countries to do so. Interactions between the production of data at the Orphanet database level and the implementation of policy priorities including codification will be strengthened during this JA.RD-Action large geographical coverage is key to success as it will promote the transfer of European recommendations into national policies and the collection of information and concerns from MS to the CEGRD, thus to the European Commission.

1.2. List of Beneficiaries

Project Number [1]	677024	Project Acronym [2]	RD-ACTION

List of Beneficiaries

No	Name	Short name	Country	Project entry month[8]	Project exit month
1	INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM)	INSERM	France	1	36
2	MEDIZINISCHE UNIVERSITAET WIEN	MUW	Austria	1	36
3	SERVICE PUBLIC FEDERAL SANTE PUBLIQUE, SECURITE DE LA CHAINE ALIMENTAIRE ET ENVIRONNEMENT	SPF	Belgium	1	36
4	INSTITUT SCIENTIFIQUE DE SANTE PUBLIQUE	WIV-ISP	Belgium	1	36
5	BULGARIAN ASSOCIATION FOR PROMOTION OF EDUCATION AND SCIENCE	BAPES	Bulgaria	1	36
6	HRVATSKI SAVEZ ZA RIJETKE BOLESTI	HSRB	Croatia	1	36
7	FAKULTNI NEMOCNICE V MOTOLE	NKCVO	Czech Republic	1	36
8	TARTU ULIKOOL	UTARTU	Estonia	1	36
9	RINNEKOTI SAATIO	RINNEKOTI	Finland	1	36
10	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS	APHP	France	1	36
11	EURORDIS - EUROPEAN ORGANISATION FOR RARE DISEASES ASSOCIATION	EURORDIS	France	1	36
12	MEDIZINISCHE HOCHSCHULE HANNOVER	MHH	Germany	1	36
13	DEUTSCHES INSTITUT FUR MEDIZINISCHE DOKUMENTATION UND INFORMATION (DIMDI)	DIMDI	Germany	1	36
14	ORSZAGOS TISZTIFOORVOSI HIVATAL	OCMO	Hungary	1	36
15	SEMMELWEIS EGYETEM	SE	Hungary	1	36
16	HEALTH SERVICE EXECUTIVE HSE	HSE	Ireland	1	36
17	OSPEDALE PEDIATRICO BAMBINO GESU	OPBG	Italy	1	36
18	REGIONE DEL VENETO	VR-IIBRD	Italy	1	36

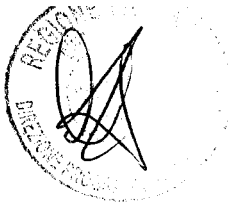
1.2. List of Beneficiaries

No	Name	Short name	Country	Project entry month[8]	Project exit month
19	SLIMIBU PROFILAKSES UN KONTROLES CENTRS	SPKC	Latvia	1	36
20	VIESOJI ISTAIGA VILNIAUS UNIVERSITETO LIGONINES SANTARISKIU KLINIKOS	VULSK	Lithuania	1	36
21	ACADEMISCH ZIEKENHUIS LEIDEN	LUMC	Netherlands	1	36
22	HELSEDIREKTORATE	HDIR	Norway	1	36
23	OSLO UNIVERSITETSSYKEHUS HF	NKSD	Norway	1	36
24	INSTYTUT POMNIK CENTRUM ZDROWIA DZIECKA	IPCZD	Poland	1	36
25	MINISTERIO DA SAUDE - REPUBLICA PORTUGUESA	DGS	Portugal	1	36
26	UNIVERSITATEA DE MEDICINA SI FARMACIE GRIGORE T.POPA IASI	UMF	Romania	1	36
27	UNIVERZITA KOMENSKEHO V BRATISLAVE	CUMS	Slovakia	1	36
28	UNIVERZITETNI KLINICNI CENTER LJUBLJANA	UKCL	Slovenia	1	36
29	CENTRO DE INVESTIGACION BIOMEDICA EN RED	CIBER	Spain	1	36
30	STOCKHOLMS LAENS LANDSTING	KS	Sweden	1	36
31	UNIVERSITY OF NEWCASTLE UPON TYNE	UNEW	United Kingdom	1	36
32	Department of Health	UK PHE	United Kingdom	1	36
33	Ministere des Affaires Sociales et de la Sante	DGS FR	France	1	36
34	ISTITUTO SUPERIORE DI SANITA	ISS	Italy	1	36

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	Coordination	1 - INSERM	40.00	1	36
WP2	Dissemination	11 - EURORDIS	119.00	1	36
WP3	Evaluation	2 - MUW	10.00	1	36
WP4	Orphanet, the European database for rare diseases	1 - INSERM	1,403.20	1	36
WP5	Steering, maintain and encourage the adoption of Orphacodes across MS	13 - DIMDI	68.10	1	36
WP6	Policy Development for RD and Integration with other relevant initiatives	31 - UNEW	139.30	1	36
		Total	1,779.60		



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	Kick off meeting & report	WP1	1 - INSERM	Report	Public	2
D1.2	Annual meeting & meeting reports	WP1	1 - INSERM	Report	Public	24
D1.3	Interim reports	WP1	1 - INSERM	Report	Public	24
D1.4	Final report	WP1	1 - INSERM	Report	Public	36
D2.1	JA Dissemination plan	WP2	11 - EURORDIS	Other	Public	6
D2.2	Newsletter Orphanews	WP2	11 - EURORDIS	Other	Public	36
D2.3	Two editions of the State of the Art Report	WP2	31 - UNEW	Other	Public	30
D2.4	Leaflet	WP2	1 - INSERM	Other	Public	3
D2.5	Layman version of the final report	WP2	1 - INSERM	Report	Public	36
D2.6	Website	WP2	1 - INSERM	Websites, patents filling, etc.	Public	3
D2.7	Progress dissemination report on health systems equity	WP2	34 - ISS	Report	Public	24
D2.8	Final dissemination report on Sustainable health systems for rare diseases	WP2	34 - ISS	Report	Public	36
D3.1	Evaluation of the deliverables compared to plans	WP3	2 - MUW	Report	Public	36
D3.2	Reports on the external evaluation of Orphanet	WP3	2 - MUW	Report	Public	12
D3.3	Sustainability plan for Orphanet core activities	WP3	2 - MUW	Report	Public	24
D4.1	Orphanet nomenclature with mappings and annotations	WP4	1 - INSERM	Other	Public	36
D4.2	Web-based knowledge management platform	WP4	1 - INSERM	Other	Public	36
D4.3	Orphanet DB versionning and differentials between versions	WP4	1 - INSERM	Other	Public	36

Deliverable Number [14]	Deliverable Title	WP number [9]	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D4.4	Annual updates of Orphanet knowledge base of expert resources	WP4	1 - INSERM	Other	Public	36
D4.5	Orphanet Report Series	WP4	1 - INSERM	Report	Public	36
D4.6	Orphanet users'survey	WP4	1 - INSERM	Other	Public	36
D5.1	Review document of existing technical implementations for RD coding of MS	WP5	10 - APHP	Other	Public	12
D5.2	Standard procedures and guide for the coding with Orpha codes	WP5	10 - APHP	Other	Public	18
D5.3	An European integrated master file	WP5	13 - DIMDI	Other	Public	36
D5.4	A set of coding helping tools for rare diseases	WP5	18 - VR-IIBRD	Other	Public	36
D5.5	Draft recommendation for routine maintenance	WP5	10 - APHP	Other	Public	36
D6.1	Progress report on policy delivery and implementation	WP6	31 - UNEW	Report	Public	18
D6.2	Final report on policy delivery and implementation	WP6	31 - UNEW	Report	Public	36
D6.3	2016 Edition of the State of the Art Report	WP6	31 - UNEW	Report	Public	18
D6.4	2017 Edition of the State of the Art Report	WP6	31 - UNEW	Report	Public	30

1.3.3. WT3 Work package descriptions

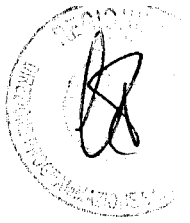
Work package number [9]	WP1	Lead beneficiary [10]	1 - INSERM
Work package title	Coordination		
Start month	1	End month	36

Objectives

The main objective of this WP is to manage the action and to make sure that it is implemented as planned. The coordination team will establish an effective and efficient governance (for the overall JA management structure see section 9), ensuring smooth communication and information exchange amongst JA participants and stakeholders. It will allow monitoring of the activities and ensure quality of the JA implementation and risk management. It will also provide day-to-day administrative support to the partners. It will ensure budget management. Timely communication with the CHAFEA and the DG SANTE will be assumed by the JA coordinator.
The specific objectives of this WP are to
1. Establish and effective and efficient governance
2. Ensure smooth communication and information exchange amongst Joint action participants & stakeholders
3. Monitoring of the activities & ensure quality of the JA implementation
4. Provide day to day administrative support to the partners
5. Ensure all communication with the CHAFEA and the DG SANTE: including timely presentation of all deliverables, technical and financial reports.
6. Ensure risk management

Description of work and role of partners

WP1 - Coordination [Months: 1-36]
INSERM, UNEW
Task 1.1 : Organisation of the Joint-action kick-off meeting.
Leader (lead applicant): Ana Rath [Inserm]
Start date: M1 End date: M6
It implies preparing a detailed workplan containing a detailed description of all activities of the project, milestones and deliverables to be approved during the kick off meeting.
Task 1.2 : Monitoring of the activities and overall quality of the project
Leader (lead applicant): Ana Rath [Inserm] Contributors: WPs leaders
Start date: M1 End date: M36
The Steering committee composed of WPs leaders will monitor the progress achieved (compliance with the milestones and timetable validated during the kick-off meeting) and address the possible difficulties and opportunities arising during the project. They will also process the information coming from the evaluators, the international advisory board and from the CEGRD. Dissemination issues will also be discussed and validated by the Steering Committee.
Task 1.3: Ensure communication and information exchange amongst Joint action participants
Leader (lead applicant): Sylvie Maiella [Inserm], Contributors: WPs leaders/project managers
Start date: M1 End date: M36
An internal newsletter will be edited every two months in order to ensure a smooth communication among WPs. Where necessary in between newsletters, emails and conference calls will be organized. It aims to inform the partners on the conclusions of the Monitoring meeting. It will also ensure circulation of information, among all partners, relating to each team's activities and outputs in order to facilitate the acquisition of comprehensive knowledge regarding the big consortium. Two annual meetings will be organised after the kick-off in Y2 and Y3, in order to allow Management Board to meet. A private space intended to allow JA partners to share documents will be created in the JA website.
Task 1.4 : Intermediary for all communication with the Chafea and the DG SANTE
Leader (Inserm): Ana Rath [Inserm]
Start date: M1 End date: M36
The project coordinator will act as the official representative towards the Chafea and DG SANTE. The project coordinator will provide them two interims and a final report, assisted by the Project Manager and the Financial Officer.



Participation per Partner

Partner number and short name	WP1 effort
1 - INSERM	37.00
31 - UNEW	3.00
Total	40.00

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D1.1	Kick off meeting & report	1 - INSERM	Report	Public	2
D1.2	Annual meeting & meeting reports	1 - INSERM	Report	Public	24
D1.3	Interim reports	1 - INSERM	Report	Public	24
D1.4	Final report	1 - INSERM	Report	Public	36

Description of deliverables

D1.1 Kick off meeting and report
Meeting organisation and meeting report
D1.2
Annual meetings organisation and meetings reports.
D1.3
Interim reports, these reports describe the activities carried out, milestones and results achieved.
D1.4
Final report, this report describes the project implementation and the results achieved. The deliverables are annexed.

D1.1 : Kick off meeting & report [2]

Meeting organisation and meeting report

D1.2 : Annual meeting & meeting reports [24]

Meeting organisation and meeting report. Delivered M12&M24.

D1.3 : Interim reports [24]

This report describes the activities Carried out, milestones and results achieved in the first half of the project. Deliverables can be attached as annexes. Will be delivered at M12 and M24.

D1.4 : Final report [36]

This report describes the project implementation and the results achieved. The deliverables are annexed.

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS1	Organisation of kick-off completed (meeting,agenda & preparatory documents)	1 - INSERM	2	

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS2	Timetable/workplan with detailed description of tasks	1 - INSERM	2	
MS3	Draft interim reports completed	1 - INSERM	18	
MS4	Organisation of meetings completed (meeting,agenda & preparatory documents)	1 - INSERM	29	M17-M29

Work package number [9]	WP2	Lead beneficiary [10]	11 - EURORDIS
Work package title	Dissemination		
Start month	1	End month	36

Objectives

Leader: EURORDIS
Co-Leader: ISS
Contributors: UNEW, INSERM, MoH BG, MoH Cyprus, BAPES, INERP, PTE, Landspitali University Hospital Ragnar, HSE, MEH (Malta)

The overarching goal of this WP is to disseminate rare diseases-related information and improve the two-way information flow between the national and European levels, to ensure the appropriation of the EU-level regulatory framework and policy environment at national level, to facilitate the integration of EU developments within the national systems, by the national authorities and other stakeholders, and to ensure that EU policy-makers keep an eye on the diverse national situations and local contexts.
This EU strategy includes, in addition to the JA activities which represent the main focus, policy initiatives taken by different Directorates General of the European Commission, relevant activities within Horizon 2020 and the Health for Growth programmes, the recommendations adopted by the CEGRD, as well as the activities related to rare diseases at national level, whether the ones included in the National Plans or other initiatives outside the scope of these official plans.
WP2 will apply a maximum level of inclusiveness of all stakeholders to all dissemination activities performed throughout the period covered by the JA. WP2 will elaborate a "dissemination plan" (D2.1) of the JA that will therefore include a detailed description of the "what, why, to whom, when and how" of the dissemination activities. For each component of the dissemination WP, the dissemination plan will encompass the identification of end users (type of users, geographical scope in particular), dissemination partners, communication tools, correlation to other WP deliverables, evaluation of the plan and timing.

The main target groups of the dissemination activities to be performed within the different tasks described in this WP will include the following stakeholders groups: Partners of the Joint Action themselves; CEGRD; National and local competent authorities; EU decision-makers; Patients, families and their representatives; Industry; Academia,learned societies; Health professionals; Researchers; Regulators; HTA bodies/reimbursement authorities
The main channels of dissemination to be used in order to achieve the dissemination objectives of the Joint Action include the following ones: The JA dissemination tools themselves, including the dedicated JA website, the layman brochure (10 pages) summarising the final report and targeted to the public at large; Leaflet promoting and explaining the JA activities elaborated and translated in all the partners languages; The Newsletter of the rare disease community (Orphanews; 20 issues per year); the websites of EURORDIS, Orphanet and of all the JA partners as well as their contacts databases and mailing for targeted communication; Press Releases, traditional media relations and Social Media updating and posting (Facebook, blogs, Twitter, etc.).; EURORDIS e-news and other partners newsletters; the European Conference for Rare Diseases (Edinburgh 2016) and the Conference on Sustainable health systems for rare diseases (Rome, 2017).
The following statement will be included in all communications or publications by the beneficiaries related to the action: "The [communication/publication] arise from the joint action RD-action which has received funding from the EU in the framework of the health program ".
The specific objectives of this WP are to perform the following dissemination activities:
1. To set up and maintain the Joint Action dissemination tools
2. To produce a twice-monthly newsletter of the rare disease community, Orphanews.
3. To hold the European Conference on Rare Diseases and Orphan Medicinal Products in May 2016, in Edinburgh
4.To support the national workshops aimed at disseminating at national level the JA activities and the Recommendations produced and adopted by the EUCERD/Commission Expert Group on Rare Diseases (CEGRD)
5. To support national authorities for sustainable and resilient health systems.

Description of work and role of partners

WP2 - Dissemination [Months: 1-36]
EURORDIS, INSERM, UNEW, ISS
Task 2.1 : To set up and maintain the Joint Action dissemination tools

Task Leader (lead applicant): Sylvie Maiella [Inserm] Contributors: All partners
Start date: M1 End date: M36

• A website containing information on the action will publish information on the partners of the JA, on the JA progress from the different stakeholders and, at the end of the contract, the layman brochure of the final report.
• A leaflet promoting and explaining the JA activities will be prepared and translated in all partners languages
• The State of the Art 'Report/Resource' will be disseminated/promoted via JA tools

Task 2.2: To produce the Orphanews newsletter
Task Leader (lead applicant): Ana Rath [INSERM], Contributors: all
Start date: M1 End date: M36

Twenty electronic issues of the twice-monthly Newsletter of the Rare Diseases Community - Orphanews - will be produced per year. This will amount to a total of 60 issues during the whole duration of the JA. A section dedicated to this JA will be included in Orphanews in order to communicate timely the progresses to the 15,000 registered readers. The Editorial Board of the new version of Orphanews will be composed at least of WP2 contributors.

Task 2.3: To hold the reference European Conference on Rare Diseases and OrphanProducts in 2016
Leader: EURORDIS, Contributors: All partners
Start date: M17 End date: M17

The European Conference on Rare Diseases and Orphan Products (ECRD) which will be held in May 2016 in Edinburgh will be the 8th ECRD. The ECRD is a major dissemination tool and represents an important platform for policy promotion that covers all areas of relevance for the Rare Disease Community at large. As such, this Conference is considered as a priority event by all stakeholders active in the field of rare diseases and has been officially mentioned in the "Commission Communication on Rare Diseases: Europe's challenges", in the Governance and Monitoring Chapter. The ECRD 2016 Edinburgh will involve all stakeholders relevant to the Rare Disease Community at large. The Program Committee in charge of developing the Conference's program comprises of a representative from all main stakeholders groups, patients, national decision-makers/national authorities, European policy makers. Members of the CEGRD industry representatives, researchers, academics, learned societies and medical experts. In 2016, more than 800 participants are expected to attend the ECRD (in Berlin in 2014 there were 768 participants representing 43 countries). The program of the Conference, including all the different sessions within the specific themes, is focused around the main structuring measures impacting on the rare diseases field that are taken and implemented at national and European levels, such as the ones deriving from the CEGRD recommendations, the Council Recommendation on rare diseases, as well as from other pieces of legislation, e.g. the Cross-Border Healthcare Directive and the various national transposition laws.

Task 2.4: To support national and European integration through national workshops
Leader: EURORDIS, Contributors:, ISS, UNEW.
Start date: M9 End date: M36
This task aims at supporting the development of the content of the national workshops to be organised by National Alliances, in close collaboration and with the support of national authorities, at least one in every Member State. The overarching goal of the national workshops and their substantial added-value is that they will ultimately facilitate the integration of rare diseases-related activities at national and European levels.
These workshops have the specific objectives:
1. To disseminate at national level the JA activities and the Recommendations discussed and adopted by the CEGRD, and previously by the EUCERD. As well as to facilitate their appropriation by different actors at national and local levels.
2. To accompany the implementation of these recommendations in the specific national contexts, by allowing open and fruitful debate on their implementation and with a view at optimising their concrete implementation;
3. To facilitate feedback from the national experience "in real life" to the CEGRD and relevant decision-makers;
4. To sustain and improve the dynamic of further development and implementation of the National Plans or Strategies on Rare Diseases, ensuring the thorough involvement of all relevant stakeholders.
This task builds on the EUROPLAN project (2008-2011) and on the WP4 EUCERD Joint Action (2012-2015). This upcoming JA is aimed at disseminating and implementing policy and technical guidance based on the EUCERD/ CEGRD recommendations to focus on key priorities and foster European integration. These three different phases, with distinct objectives and methods, are nevertheless intimately connected and represent a coherent process; therefore, it is advisable to keep the denomination "EUROPLAN" workshops as this is now a well-established "label" recognised by all stakeholders.

The main organiser of the national workshops will be the National Alliance of Rare Diseases in the country concerned. The national authorities will co-finance the workshop taking place in their country, through direct funding and/or through in-kind support. National authorities may support the National Alliance in the organisation of the workshop.
One very important element to secure the overall good governance of these workshops is to ensure the presence of patients' representatives within the Program Committees of the Workshops. The representatives of the National Alliance, as main workshop organiser, are members of the Program Committee. EURORDIS and ISS will collaborate to the workplan of the National Workshops. The organisation process should be inclusive of representatives from academia, industry, patients, medical experts, etc. Building on the experience of the "EUROPLAN" meetings, the workshop organisers will secure wide participation of all relevant stakeholders to the national workshops. Therefore, WP2 will support, together with the relevant National Alliances (and National competent authorities when needed), the development of the programs and the content of between 25 and 28 in the EU (4000 participants overall are expected). Travels of EURORDIS staff will be covered to attend between 2 and 5 workshops outside EU.

Task 2.5 : Promote sustainable health systems for rare diseases
Leader (lead applicant): Istituto Superiore di Sanita (ISS)
Start date: M1 End date: M36

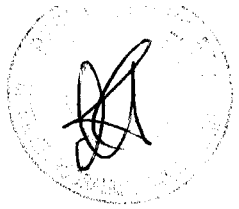
The implementation of a EU-MSs integrated approach to RDs calls for more comprehensive public health policies addressing the issue of sustainability. This can be achieved through a series of policy communication activities, building on other EU public health policy activities. Capitalising on experience and work carried out over recent years, and with a view to further developing approaches at EU level, the "Communication from the European Commission on effective, accessible and resilient health systems" focuses on actions to strengthen the effectiveness of health systems, increase the accessibility of healthcare and improve the resilience of health systems. In relation to the resilience, and building on experience of recent reforms, the Commission has identified the resilience factors that helped some health systems safeguard accessible and effective healthcare services for their population. In recent years, European countries have been involved in international projects and activities on RDs aiming to accelerate scientific research and attain the overarching goal of improving the health outcomes of people affected by these diseases. The purpose of this specific dissemination task is to focus the debate on sustainable and resilient health systems for RDs, taking into account principles of equity, quality and efficiency. This debate will involve policy makers, civil servants in charge of national strategies on RDs and all stakeholders in a collective responsible approach.
Cooperation will be ensured with WP5 and WP6 and the final documents produced in the present task will be shared with these WPs.

Participation per Partner

Partner number and short name	WP2 effort
1 - INSERM	28.00
11 - EURORDIS	29.00
31 - UNEW	26.00
34 - ISS	36.00
Total	119.00

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D2.1	JA Dissemination plan	11 - EURORDIS	Other	Public	6
D2.2	Newsletter Orphanews	11 - EURORDIS	Other	Public	36



List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D2.3	Two editions of the State of the Art Report	31 - UNEW	Other	Public	30
D2.4	Leaflet	1 - INSERM	Other	Public	3
D2.5	Layman version of the final report	1 - INSERM	Report	Public	36
D2.6	Website	1 - INSERM	Websites, patents filling, etc.	Public	3
D2.7	Progress dissemination report on health systems equity	34 - ISS	Report	Public	24
D2.8	Final dissemination report on Sustainable health systems for rare diseases	34 - ISS	Report	Public	36

Description of deliverables

D2.1: JA dissemination plan. An elaborated dissemination plan indicating for each dissemination action 'what will be disseminated' (key message), 'to whom' (audience, 'why' (purpose), 'how' (method and 'when' (timing).
D2.2: Newsletter Orphanews. 60 Newsletter will be produced during the JA.
D2.3 Dissemination of the State of the art report on key developments in the field, at national and EU level.
D2.4 Leaflet. A leaflet promoting the project.
D2.5 Layman version of the final report. A short version of the final report written for the general public.
D2.6 Website. A dedicated website will be made available online, administrated and maintained.
D2.7 Progress dissemination report on health systems and equity. Report on the sustainable health systems for rare diseases preparatory work.(workshop and working group discussions).
D2.8 Final dissemination report on sustainable health systems for RD.

D2.1 : JA Dissemination plan [6]

Elaborated dissemination plan indicating for each dissemination action : - what will be disseminated (key message) - to whom (audience) - why (purpose) - how (method) - when (timing

D2.2 : Newsletter Orphanews [36]

Produce 60 twice-monthly newsletters of the rare disease community

D2.3 : Two editions of the State of the Art Report [30]

Dissemination of the Annual Report on key developments in the field, at national and EU levels Delivered at M6&M30

D2.4 : Leaflet [3]

A leaflet to promote the project must be produced at the beginning

D2.5 : Layman version of the final report [36]

This is a short (e.g. 10 pages) version of the final report, written for the interested public.

D2.6 : Website [3]

Dedicated website set up and maintenance

D2.7 : Progress dissemination report on health systems equity [24]

Report on the sustainable health systems for rare diseases preparatory work (workshop and working group discussions)

D2.8 : Final dissemination report on Sustainable health systems for rare diseases [36]

Report on the final conference on health systems for rare diseases workshops

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS5	Stakeholder analysis: identification of target groups and adequacy of channels to be used	11 - EURORDIS	3	
MS6	Graphic Identity of Website and Newsletter	1 - INSERM	6	
MS7	Internal Newsletter	1 - INSERM	1	M6, M12, M18, M24, M30
MS8	Editorial board meetings (Orphanews)	1 - INSERM	36	Every 2 months
MS9	Identification of the Member States and themes for the National Workshops	11 - EURORDIS	12	

Work package number [9]	WP3	**Lead beneficiary** [10]	2 - MUW
Work package title	Evaluation		
Start month	1	**End month**	36

Objectives

Leader: Till Voigtländer [MUW] - Contributors: INSERM, French General Directorate of Health (DGS FR), Bulgarian Ministry of Health, BAPES, HSE, all WP leaders

The main objective of this WP is to evaluate the action activities and to set up a sustainability plan for databasing activities after the end of the JA
The specific objectives of this WP are to:
1. Measure the indicators per WP, internally
2. Evaluate Orphanet in view of its long-term sustainability

Description of work and role of partners

WP3 - Evaluation [Months: 1-36]
MUW, DGS FR
Task 3.1 : Evaluation of the Joint action achievements
Leader (lead applicant): Medical University of Vienna; Contributors (applicants involved): Eurordis, INSERM, UNEW
Start date: M1 End date: M36
Overall Joint action evaluation will be based on indicators measuring the process, output, outcome and impact. (please refer also to section 2.2)
In particular:
- European Conference on Rare Diseases (ECRD). Process indicators will include: well defined steps necessary in the overall preparation of the conference (i.e., the nomination of a program and an organising committee, meetings and conference calls of these committees, the development of a conference website and of other information tools like stakeholder-tailored flyers), the range of different themes and topics of the ECRD including accompanying satellite meetings and tutorials, as well as the coverage of the different stakeholders participating in the program committee and the conference. Output indicators will include the number of invited lectures, the number of oral presentations and posters selected from submitted abstracts, and the production of further information material like newsletters or an online conference report. Outcome indicators comprise, inter alia, the total number of participants, as well as by stakeholder groups. Impact indicators will include the degree of dissemination of the final conference report, the coverage of the conference in classical media as well as in social media. On-site participant satisfactory surveys for each session, as well as a more general online participant satisfactionory survey will provide information on the impact of the conference, and information on the general organisation of the conference and the quality of the content.
• Conference on sustainable health systems for RD. Process indicators will include: well defined steps necessary in the overall preparation of the conference, preparatory steps conducted (literature review, analyses, preparatory workshop, eventually establishement f specific working groups). Output indicators will include one analysis on epidemiological data on RD and one review on sustainable health systems carried out, policy briefs delivered. Outcome indicators comprise, inter alia, the total number of participants, as well as by stakeholder groups. Impact indicators will include the degree and quality of the dissemination of the conference conslusions and, inter alia, the workshops participants' satisfaction (86 expected), by means of survey during and/or after the meeting
- To evaluate the testing phase of the master-file with Orpha-codes and the related guidelines, a set of common indicators for all participating countries will be developed including process indicators (like, inter alia, compatibility with and easy integration into existing health information and coding systems and applicability of the guidelines) and output indicators (like, for instance, the number of single RD entities registered using the master file, the number of more specific codings and the ratio of correct and incorrect coding entries). The workshop addressing the information about the strategies and tools to implement the Orpha codes in the European countries will be evaluated by means of a set of specifically developed indicators including outcome indicators (for instance the number of participants and the number of Member States represented), output indicators (like information materials provided in the workshop intended for the distribution within the Member States and/or a workshop report) and – if applicable – impact indicators (like decisions on the further implementation of Orpha codes in individual Member States). The assessment by indicators will be accompanied by an online user satisfactory survey for all participants.

- All workshops organized in the context of the Policy Development for RD and Integration with other relevant initiatives will be evaluated by online participant satisfactory surveys and by a set of appropriate indicators, including output and outcome indicators. However, apart from some general indicators like number of participants and coverage of Member states within the workshop, the majority of these indicators depend on the overarching theme and the concrete topics of the individual workshops, and will be elaborated as soon as individual workshops contents are known.

Task 3.2 : Evaluation of the European database for rare diseases, Orphanet
Leader (lead applicant): Medical University of Vienna; Contributors (applicants involved): MS representatives, French General Directorate of Health (DGS), INSERM.
Start date: M1 End date: M36
The aim of this task is to assess the adequacy of database core activities to both the MS needs at their national level, and to the European level. These activities include the development of a specific nomenclature and classification for RD, the cross-referencing with other terminological resources, the scientific annotations and cross-referencing with scientific databases (genetics, pathways, pharmacology, etc), the development of an offer of textual information on RD, the inventory of orphan designations and drugs, the mapping of expert resources both patient-oriented and research-oriented, in European countries. They also include the necessary IT infrastructure to host these data (database, tools) and the definition and dissemination of a methodology and standard operating procedures.
An evaluation process will be organized in order to assess the member states and the European Commission needs in terms of database, so as to define the core activities that should be sustained in the long term. This process is described in Methaods and Means. It will take into account the results of the evaluation process being taking place in France where the coordinating team is by the INSERM and the DGS, which largely fund the database central facility, and whose evaluation report should be released at M6. It will also take into account an external audit of the IT Information system (IS) asked by Orphanet to an independent society (YOTTA Conseil) in order to have a diagnosis of Orphanet's IS and recommendations to make it evolve. The whole evaluation process should give raise to a report in M12.
Evaluation reports will be one of the elements feeding the elaboration of the Orphanet sustainability plan (Task 3.3).

Task 3.3: Develop a sustainability plan for the Orphanet core activities fitting the needs of European member states, including RD nomenclature and classification.
Task Leader: Patice Ddosquet [French DGS, Ministry of Health], Contributors: MUW, INSERM, MS representatives
Start date: M1 End date: M36
Orphanet became a major resource for both public health and research across the years, as it constitutes a unique source of integrated, validated information specific on RD providing structured datasets for re-use in different settings, comprising scientific information and mapping expert resources across Europe and beyond. Orphanet nomenclature represents the common language allowing for interoperability among different resources (registries, databases, EHR...).
Making Orphanet sustainable is a major need for the RD community. Especially in light of WP5, which develops a routine coding resource and an implementation plan, it is absolutely essential to guarantee long-term availability of Orphanet classification and database.
Sustainability options will be explored during the JA based on the evaluation that will be conducted in task 3.2.
To structure and facilitate the informed decision process of the Member States on an Orphanet sustainability plan, the central Orphanet team together with the MUW will elaborate a "modular representation" of the database and services, providing Member States with a tool to easily prioritise their needs and their support for the database on the national and the European level. (please, refer to method and means section). The possible legal instrument as well as the possibilities for financial contribution of the European Commission, European MS, and participating countries outside Europe, to the core activities will be explored (could be considered, for instance and not exclusively, becoming a European institute, an ERIC or a European grouping of territorial cooperation) . The ultimate goal is to design a model to fund permanent positions and infrastructure to allow the modules considered as essential both by the European commission and MS to develop in the long term.

Participation per Partner

Partner number and short name	WP3 effort
2 - MUW	7.00
33 - DGS FR	3.00
Total	10.00

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D3.1	Evaluation of the deliverables compared to plans	2 - MUW	Report	Public	36
D3.2	Reports on the external evaluation of Orphanet	2 - MUW	Report	Public	12
D3.3	Sustainability plan for Orphanet core activities	2 - MUW	Report	Public	24

Description of deliverables

D3.1
Individual task-related evaluation reports for WP2,4,5, and 6
Each evaluation report will be based on (1) the analysis of all relevant, task-related indicators as outlined in item 2.2 ("Specific objectives of the action"), methods and means specific objective 6 and task 3.1, as well as (2) the analysis of the intended satisfactory surveys.
D3.2
Reports on the external evaluation of Orphanet
Reports summarizing the independent evaluations of Orphanet by French institutions and by MS representatives. This deliverable specifically addresses the exercise described under task 3.2 consisting of two separate external evaluation assessments, one by French institutions focusing on the structure, content and functioning of the database and one by representatives of different stakeholders in each MS to assess their needs regarding the database. This "double approach" is also briefly described in the contents field of this deliverable.
D3.3
Sustainability plan for Orphanet core activities
Development of a modular representation of Orphanet and elaboration of strategies for a secured legal framework and a sustainable funding of Orphanet in the EU

D3.1 : Evaluation of the deliverables compared to plans [36]

This evaluation is based on the reports of WP leaders to the Steering committee M12,18,24,30,36

D3.2 : Reports on the external evaluation of Orphanet [12]

INSERM-DGS (FR) – MUW Reports summarizing the independent evaluations of Orphanet by French institutions and by MS representatives

D3.3 : Sustainability plan for Orphanet core activities [24]

INSERM- DGS (FR) – MUW Development of a modular representation of Orphanet and elaboration of strategies for a secured legal framework and a sustainable funding of Orphanet in the EU

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS10	Partner's survey	2 - MUW	24	M12,M24
MS11	Adhoc users 'surveys	2 - MUW	18	
MS12	External evaluation of Orphanet from French institutions ready	2 - MUW	18	

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS14	Annual Orphanet Management Board meeting organised (agenda and preparatory documents) and held	1 - INSERM	30	M2-M17-M30

Work package number [9]	WP4	Lead beneficiary [10]	1 - INSERM
Work package title	Orphanet, the European database for rare diseases		
Start month	1	End month	36

Objectives

Leader: INSERM, Participants: GOG, MUW, FPS, WIV-ISp, BAPES, HSRB, NKCVO, UT, Rinnekoti, MoHCY, RKI, OCMO, PTE, SE, OPBG, SPKC, VULSK, MEH MT, LUMC, NKSD, IPCZD, DGS PT, UMF IASI, UNIBA FOB, UKC Ljubliana, CIBER, KI, PHE, Center of medical genetics and primary health Armenia, Office population Health Genomics, Gvmt of WA, Garvan Institute of Medical Research, University hospital of Aarhus, GeRaD,
The Chaim Sheba Medical center, Institut national d'hygiène- Maroc, Mc Gill University, Belgrade University, University of Istanbul, CMU Switzerland

Orphanet became, over the years, the backbone for the community of rare diseases, having developed a substantial amount of data essential as leverage for projects and policies related to rare diseases in Europe, as well as for increasing the awareness and the dissemination of knowledge on RD. The Orphanet database for RD includes a core set of structured scientific information on RD including: an inventory and classification of RD giving raise to a nomenclature that is specific for RD, the phenotypic and genotypic characterization of each RD, annotations including prevalence, incidence, distribution by age and by geographical region, and a collection of textual descriptions for RD, from disease definitions to articles, an inventory of orphan drugs at different phases of development, and a collection of expert resources specific for RD in each country of the Orphanet consortium that are linked to RD and, if applicable, to genes and to drugs.

The main objective of this WP is to make the Orphanet database of rare diseases evolve to a European, sustainable model. During this JA, Orphanet will evolve into a new model : new IT infrastructure, from a relational database to a more fexible knowledge base, in order to be able to share the IT development effort with the consortium partners in the future; new organization model evolving to a more decentralized and open one, by transferring progressively core activities to participating countries and by developing a community-driven edition-process of the database involving expert groups and individual experts, patient representatives and users at large, and increasing transparency and traceability. Thanks to these evolutions, the sustainability plan built in WP3 will be facilitated by increasing the database ownership by consortium partners.
The specific objectives of this WP are to:
1. Coordinate the activities of the Orphanet consortium (26 associated partners in this JA and 14 collaborating partners)
2. Maintain, update and expand the rare diseases database: the inventory and classification of RD and its alignments with other terminologies (i.e. ICD10, SNOMED CT); links between rare diseases, phenotypes and genes, including cross-references with other resources (i.e. OMIM, HPO); the professional encyclopedia of RD by providing a definition for all RD to be included in the content model of ICD11 and SNOMED CT, as well as in the Orphanet Rare Diseases Ontology (ORDO) and by producing new and updated abstracts and disseminating new content produced by others.
3. Develop the necessary tools to track changes of the Orpha nomenclature, classifications and scientific database content, including an interactive platform allowing for managing input from the community.
4. Provide a directory of expert services in every MS, including centres of expertise, clinical laboratories, patient registries, mutation databases, biobanks, research infrastructures, patient organisations, European reference networks when set up.
5. Provide overarching database data management, quality control and IT support, including training MS teams.
6. Produce reports (Orphanet Report Series) intended to provide compiled pieces of information required for supporting CEGRD activities.

Description of work and role of partners

WP4 - Orphanet, the European database for rare diseases [Months: 1-36]
INSERM, MUW, SPF, WIV-ISP, BAPES, HSRB, NKCVO, UTARTU, RINNEKOTI, MHH, OCMO, SE, HSE , OPBG, SPKC, VULSK, LUMC, NKSD, IPCZD, DGS, UMF, CUMS, UKCL, CIBER, KS, UNEW, UK PHE
Task 4.1 : Coordination of the Orphanet consortium
Task Leader (lead applicant): Ana Rath (INSERM) Contributors (applicants involved): All WP4 members
Start date: M1 End date: M36
26 associated partners in this JA and 14 collaborating partners are involved in the Orphanet consortium activities. The completeness, consistency and quality of the final database largely depend on the efficacy of the coordination of these

partners. The INSERM is coordinating the Orphanet consortium since 2000. The coordination of Orphanet consortium activities includes:
1. Ensure smooth communication and information exchange related to Orphanet database activity through a Supplement edited with the RD-action newsletter, and bi-monthly management board conference calls.
2. Provide day to day technical support to the partners
3. Perform the annual Orphanet user's survey and the Orphanet annual activity report

Task 4.2 : Maintain and expand the rare diseases database
Task Leader (lead applicant): Annie OLRY (INSERM) Contributors (applicants involved): All WP4 and WP5 members
Start date: M1 End date: M36
During this task, the inventory and classification of RD annotated with genes cross-referenced with other resources will be expanded and maintained. A definition for all RD to be included in the content model of ICD11 and SNOMED CT will be produced and the professional encyclopaedia of RD will be further populated and updated.
The aim of the Orphanet nomenclature and classification is to provide the RD community, from healthcare to research, with a well-structured hierarchy specific for RD with different degrees of granularity so as to allow linking data coming from healthcare (i.e. clinical diagnosis in health records) to data coming from research (i.e. genetic entities in databases). The Orphanet nomenclature is at the centre of a rich network of relations inside the Orphanet database and its ontological expression (ORDO, for Orphanet rare diseases ontology), comprised of genes interrelated with other resources (HGNC, OMIM, UniProt, ensembl, Reactome, IUPHAR, Genatlas), epidemiological data (prevalence, incidence, age of onset, age of death, geographical distribution), medical terminologies (MeSH, MedDRA, SNOMED CT, ICD10, UMLS) and resources (OMIM, and, in the near future, HPO). It is therefore considered as a standard nomenclature for rare diseases, and promoted as such by the IRDiRC. This nomenclature is intended to multiple uses (codification in health information systems, registries, research databases...). Therefore this task is interrelated with WP5 for it provides the core nomenclature to be adapted to patient codification needs.
The Orphanet database is completed by producing textual information for each rare disease. In the context of this JA, a new, decentralized organization will be established with two goals: a) to have a definition for every RD in the Orphanet database, and to expand and update the encyclopaedia, and b) to disseminate high-quality articles produced by others in order to provide complete, useful and timely information to physicians and patients, as well as to other actors in the field of information, such as help-lines and national contact points. In order to achieve the first goal, the core editorial activities will be progressively transferred from the central facility at the INSERM to other participating countries, starting at M18 with Ireland, The Netherlands and Slovakia, and to others that manifest the interest and the possibility to assume this task. This transfert will be facilitated by the tools developed in Task 4.3. Translations of all or part of the website will be encouraged as a national effort in each country. To achieve the second goal, partners in WP4 will contribute identifying and assessing relevant articles according to Orphanet's quality standards that will be published in the website for transparency.

Task 4.3 : Develop the necessary tools to track changes of the Orpha nomenclature, classifications and scientific database content, including an interactive platform allowing for managing a community-driven curation and edition process.
Task Leader (lead applicant): Marc Hanauer [INSERM] Contributors (applicants involved): Garvan Institute [Bio-Lark, Australia, collaborating partner]
Start date: M1 End date: M36

In order to allow end-users to submit their demands of modification (creation of new terms, addition of synonyms, modify the classification, update the annotations and the textual information) and to have a traceable, transparent decision process, a ad hoc interface will be developed to decentralize expert curation and to ease the edition process. Another specific need to be addressed in this task is to provide end users with metadata in a computable format necessary for the implementation of nomenclature updates in HIS. Metadata include details in differences between versions necessary to manage updates of the nomenclature and to the master file when available (cross-talking with WP5), whatever structural or terminological.These informatics improvements will build on the parallel evolution of the Orphanet IT infrastructure from a relational database towards a knowledge base.

Task 4.4 : Provide a directory of expert services in every MS, including centres of expertise, clinical laboratories, patient registries, mutation registries, biobanks, patient organisations, European reference networks when set up.
Task Leader (lead applicant): Martin Arles-Soler [INSERM] Contributors: GOG, MUW, FPS, WIV-ISp, BAPES, Croatian alliance for RD, NKCVO, UT, Rinnekoti, MoHCY, RKI, OCMO, PTE, SE, OPBG, SPKC, VULSK, MEH MT, LUMC, NKSD, IPCZD, DGS PT, UMF IASI, UNIBA FOB, UKC Ljubliana, CIBER, KI, PHE, Center of medical genetics and primary health Armenia, Office population Health Genomics, Gvmt of WA, Garvan Institute of Medical Research, University hospital of Aarhus, GeRaD,

The Chaim Sheba Medical center, Institut national d'hygiène- Maroc, Mc Gill University, Belgrade University, University of Istanbul, CMU Switzerland
Start date: M1 End date: M36

The directory of expert resources allows for identification of expert centres, clinical laboratories, patient organisations, registries and biobanks, research projects and clinical trials in all the countries of the Orphanet consortium.
Data collection on expert resources in MS provides a unique source of added-value information for analysis, therefore valuable in the scope of providing support the CEGRD in its policy work (cross-talk with WP6). These data have been one of the pillars of the EUCERD State of the Art documents, and reflect the landscape of expert resources on RD in partner countries. The inventory of expert resources allows for the publication of compiled data in the Orphanet Reports Series collection (cf. Task 4.5) in a user-friendly way.
More particularly, and in the scope to provide information to the CEGRD, this task will continue identifying expert centres and networks of expert centres so as to reflect healthcare pathways at national and European level, of importance in the process of ERNs identification and establishment; identifying patient registries; identifying clinical laboratories performing NGS, including their coverage in terms of diseases and genes; maintaining the inventory of orphan designations and orphan drugs and encouraging Orphanet national representatives to document the availability of orphan drugs in their respective countries as much as possible.

Task 4.5 : Provide overarching database data management, quality control and IT support, including training MS teams.
Task Leaders: Marc Hanauer et Charlotte Gueydan [INSERM]
Start date: M1 End date: M36

Currently, Orphanet lays on a relational database that stands on a multi-server IT infrastructure completed by a software suite necessary to run the Orphanet website, the download platform (Orphadata) and to manage the database content. This model will evolve towards a more flexible knowledge base, in order to stick to most up-to-date data management technologies and to allow smoother partnerships and development sharing, to ease data collection, edition and quality control, as well as exploitation of data, as well as to allow the information to be provided in all the European languages (depending on the translation capacity of each country). During this task, tooling will be further improved and adapted to better fit the data collection, edition and validation process. Maintaining a high-standard database requires having a quality assurance policy in place, including adapting Standards Operating Procedures, training information scientists and country coordinators, and implementing quality control measures to ensure internal coherence, transversal consistency and completeness of the database. Quality control of the directory of expert resources, in particular, allows national teams in member states to improve the quality and accuracy of their data. Data collection, validation and quality control are organized by the coordinating facility at the INSERM. A training meeting intended to national information scientists will be organized once a year and distant meetings will be set up on specific topics regularly.
Task 4.6: Produce reports (Orphanet Report Series) intended to provide compiled pieces of information required for supporting CEGRD activities.
Task Leader: Charlotte Rodwell [INSERM]; Contributor: UNEW
Start date: M1 End date: M36
Orphanet Reports are a series of texts providing aggregated data covering topics relevant to all rare diseases. New reports are regularly made available online and are periodically updated. They are available in 7 languages. These texts are published as PDF documents accessible from the homepage and from every other page of the website. New versions of these publications are advertised in the newsletter (OrphaNews). Examples of these reports are: the list of rare diseases with Orphacodes, data on prevalence of rare diseases, the list of registries on RD in Europe, the list of orphan drugs with their indications and linked to RD, ... Orphanet Report Series are heavily downloaded: in 2014, Orphanet Report Series were consulted more than 2,250,000 times. This very high consultation rate reflects the need of the different stakeholders to having access to such user-friendly document providing aggregated data on RD in different languages. The production of Orphanet Report Series reports will continue and will be expanded in cross-talk with WP6, so as to provide compiled pieces of information required for supporting CEGRD activities.

Participation per Partner

Partner number and short name	WP4 effort
1 - INSERM	602.00
2 - MUW	36.00
3 - SPF	3.50

Partner number and short name	WP4 effort
4 - WIV-ISP	18.00
5 - BAPES	49.00
6 - HSRB	30.00
7 - NKCVO	11.80
8 - UTARTU	14.40
9 - RINNEKOTI	19.50
12 - MHH	42.20
14 - OCMO	11.00
15 - SE	11.20
16 - HSE	51.00
17 - OPBG	77.00
19 - SPKC	10.80
20 - VULSK	30.40
21 - LUMC	37.00
23 - NKSD	7.20
24 - IPCZD	51.70
25 - DGS	39.50
26 - UMF	32.40
27 - CUMS	57.00
28 - UKCL	12.50
29 - CIBER	86.40
30 - KS	19.90
31 - UNEW	4.00
32 - UK PHE	37.80
Total	1,403.20

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D4.1	Orphanet nomenclature with mappings and annotations	1 - INSERM	Other	Public	36
D4.2	Web-based knowledge management platform	1 - INSERM	Other	Public	36

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D4.3	Orphanet DB versionning and differentials between versions	1 - INSERM	Other	Public	36
D4.4	Annual updates of Orphanet knowledge base of expert resources	1 - INSERM	Other	Public	36
D4.5	Orphanet Report Series	1 - INSERM	Report	Public	36
D4.6	Orphanet users'survey	1 - INSERM	Other	Public	36

Description of deliverables

D4.1: Orphanet nomenclature with mappings and annotations. Inventory of RD names, classification, mappings to ICD10, OMIM, SNOMED CT and others. Links to genes and annotations with epidemiological data. Monthly release.
D4.2 Web-based knowledge management platform. Data management facility allowing for suggestions updates, to assess demands, to approve/reject and to insert into DB.
D4.3 Orphanet DB versioning and differentials between versions to be delivered annually.
D4.4 Annual updates of the Orphanet knowledge base of expert resources. Annual mailing to the registered professionals.
D4.5 Orphanet report series. Thematic reports (frequency depending on each report)
D4.6 Orphanet users'survey. Annual online survey intended for the website users

D4.1 : Orphanet nomenclature with mappings and annotations [36]

Inventory of RD names, classification, mappings to ICD10, OMIM, SNOMED CT, and others, links to genes, annotations with epidemiological data M1 to M36 monthly

D4.2 : Web-based knowledge management platform [36]

Data management facility allowing for suggesting updates, to assess demands, to approve/reject, and to insert into the DB To be delivered at M12,24,36.

D4.3 : Orphanet DB versionning and differentials between versions [36]

Produce annual versions with differentials between versions To be delivered at M12,24,36.

D4.4 : Annual updates of Orphanet knowledge base of expert resources [36]

Mailing to professionals annually To be delivered at M12,24,36.

D4.5 : Orphanet Report Series [36]

Thematic reports (frequency depending on each report) To be delivered at M12,24,36

D4.6 : Orphanet users'survey [36]

Perform an online survey intended to website's users M12,24,36

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS13	Orphanetwork: internal website and newsletter	1 - INSERM	36	To be produced every 2 months (M2,4,6,8,10,12,14,16,18,20,22,24,28,30,
MS15	Establishment of working groups with representatives from EU Member States to define the scope and the objects of sustainable health systems study	34 - ISS	3	
MS16	Establishment of specific working groups on areas of application for sustainability issues	34 - ISS	15	
MS17	Establishment of a European network (consisting of partners from EU member States) to reduce health inequalities and to promote measures for sustainability of National strategies for RDs	34 - ISS	30	
MS18	Editorial boards of the internal newsletter during which the newsletter content is validated before online publication	1 - INSERM	36	Every 2 months
MS19	Users survey available online	1 - INSERM	36	M12-24-36
MS20	Organisation of trainings completed	1 - INSERM	24	M12-24
MS21	KM platform tested	1 - INSERM	24	
MS22	Data collection for ORS completed	1 - INSERM	36	Every 6 months

Work package number [9]	WP5	Lead beneficiary [10]	13 - DIMDI
Work package title	Steering, maintain and encourage the adoption of Orphacodes across MS		
Start month	1	End month	36

Objectives

Leader: DIMDI (Germany),
Contributors: APHP, Regione del Veneto; INSERM; SPF; WIV-ISP; Medical University Sofia ; DGS; HSE; LUMC; HDIR; UNEW; GOG; MUW; BAPES; NKCVO; OCMO; ISS; VULSK; Poznan University of Medical Sciences, Instituto de Salud Carlos III and FISABIO-Salud Pública , DGS Fr

The proposition carried in this WP is based on the CEGRD's "Recommendation on Ways to Improve Codification for Rare Diseases in Health Information Systems". In order to enable countries to implement coding of rare diseases in a standardized and interoperable way the work package aims at developing a toolset to assist member states in implementing the Orphacodes in their health system. A steering group of MS will be set up to learn from local experiences already in place and better define the required steps and strategy of such a generalization of codification of RD at EU level. The definition of common guidelines addressing the issues of both quality of codification and coherence of exploitation at the European level is a major ambition of this WP. In a second step the development of a European file holding all necessary Orphacodes to be used for implementation in countries will be developed. It will be tested together with the guidelines against already existing systems and fine-tuned according to the test results. This WP is in close cross-talk with WP4, for it is necessary that Orphanet continues its work of keeping the central resource up to date, multi-lingual and interoperable with other resources in use by MS in their HIS. This WP does not address local implementation of the Orpha coding. It is meant to provide guidance and common standards in order to make sure data will be exploitable and comparable at EU level.
The specific objectives of this WP are to:
1. Define the common objectives for coding RD in MS, the common level of granularity to be used and guide the implementation
2. Define a codification resource aimed at having consistency across MS coding for RD
3. Tune the codification resource after having tested it in a subset of coding groups through pre-existing tools.

Description of work and role of partners

WP5 - Steering, maintain and encourage the adoption of Orphacodes across MS [Months: 1-36]
DIMDI, INSERM, APHP, VR-IIBRD, HDIR
Task 5.1: To define and set the necessary strategy and tools to implement the Orpha codes in the European countries.
Task Leader: Remy Choquet, [BNDMR, APHP,France] - Contributors: All WP5 contributors
Start date: M1 End date: M36
Some MS have already started the work of introducing the Orphacode in their registries or health information systems, and others have expressed their interest adopting them. Different approaches have already been implemented and start producing results, raising problems and bringing solutions that are of interest for all MS. A coding nomenclature alone is not enough to guarantee that the patient data will be comparable from a member state to the other. Along with the right and quality assessed nomenclature of rare diseases (Orphanet), it is required to provide the coders with the right instructions and clear objectives of coding. Also, given the nature of the rare diseases patients and the celerity of new discoveries, it is required to handle uncertainty in diagnoses and frequent updates of the nomenclature.
All MS use morbidity and mortality recording systems. Morbidity recording systems utilize, for the generality of diseases and for the majority of countries, ICD classification. Only in a few countries other systems like SNOMED CT are utilized. The Orpha code classification is specifically dedicated to rare diseases and is used only in few countries. Taking into account these ongoing experiences, the contexts, the prerequisites, the methods to implement specific monitoring systems of RD patients will be defined.
In this part of the work, we will use a bottom-up approach to reach a consensus in defining guidelines to implement RD monitoring in MS. Starting from the existing experiences, a set of rules and guidelines will be produced in order to support the MS in implementing RD monitoring systems and the use of Orpha codes.
A steering group, comprised from the contributing institutions, will be set up by the task leader. The steering group will identify the common denominator of already existing approaches in the different countries and based on that will define:

• A complete review of current coding systems actually in place in member states and actual plans. This review should give a clear overview of possible strategies and planning as to identify RD patients in each MS. This review will help in setting the master file. (deliverable D5.1)
• The level of granularity of Orphacodes that are essential for all systems working with Orpha codes (registries, centres of expertise, others). Additional level of detail may be used but does not have to be used right from the start. (deliverable D5.2)
• A data exploitation plan, with clear objectives to be addressed by the coding investment (deliverable D5.2)
The Steering group will work during the three-year length and will meet face-to-face at each JA annual meeting and will set up a series of distant meetings. A virtual working space will be shared. A workshop will be organized during year 3 in order to present the results of the whole WP and to promote their use in countries.

Task 5.2: Specification of the required resources for coding RD consistently across Europe
Task Leader: Stefanie Weber, [DIMDI , Germany]. Contributors: All WP5 contributors
Start date: M13 End date: M24
Within the second year of the project a master file will be created and populated with preexisting data from countries. It will be further specified according to the guidelines and granularity results from year 1.
The master file will be defined bringing together the current experiences of implementation in countries already using the Orphacodes, and will probably combine the definition of a significant subset of codes needed for interpretation at the European level, their alignments with ICD-10 national extensions and the minimum multi-hierarchical classification structure derived from the Orphanet central resource. (Deliverable 5.3).
Guidelines on how and why to code with Orpha codes in health systems in order to generate standardized and comparable data all over member states ("coding guidelines") thereby taking into account that already existing coding systems and possible coding guidelines in national settings need to be continued in use. The guidelines should include rules for coding cases (confirmed, suspected, coding with group of diseases when the disease is still unknown, multiple coding situations). These guidelines should state clearly upfront the objectives of the coding to avoid miscoding depending on coding habits and structures of each MS (deliverable D5.2 together with the coding resource).
As well ways and methods will be developed to merge the results to a permanent maintenance facility (e.g. Orphanet, WP4) and to make sure that long term mechanisms are set into place to guarantee that the use of the file and the guidelines will be possible long term. A mechanism for routine feedback from countries and users need to be set into place to allow for adaptation of file content and of guidelines according to member-state needs, as well as to impact the central Orphanet nomenclature.

Task 5.3 : Promoting the Orpha codes across MS by sharing coding tools and testing the master resource
Task Leader: Paola Facchin, [Veneto, Italy]. Contributors: All WP5 contributors
Start date: M25 End date: M36
The use of ICD classification and Orpha codes classification should be time-consuming and burdensome when it is based on a manual double codification process. This element could strongly jeopardize the implementation of RD monitoring systems and, in particular, of orphan codes. Besides, giving each professional the task of manually assigning the codes implies a great inter-observer variability and thus a poor quality of collected data, which might frustrate the effort of implementing complex coding systems useful to identify precisely RD patients in a population. On the other hand, problems are encountered when non-physician coders should attribute ICD and Orpha codes to diagnoses made by physicians. It is expensive, has bias due to the coders' subjective assessment, and is inaccurate, because of the lack of coders' knowledge about the patients and their phenotype. For these reasons, electronic tools that automatically assign ICD and Orpha codes to the specific diagnoses given by physicians (as proposed by Veneto registry in Italy) or providing assistance to the identification of correct codes (as proposed by BNDMR in France) are designed to minimize these difficulties.
The utilization of the coding results in a standardised way through the master resource provided in Task 5.2, would bring consistency across coding systems and reduce inter-observer variability. It should cut time and costs, linking tightly the diagnoses to the codes.
In the last year of this WP the developed products will be tested in the countries and results will be collected through two different tools, as to share developments conducted in Italy and in France. The results will be used for fine tuning and adapting of coding rules and content. In order to test the new file and the guidelines previous coding exercises can be repeated and the results can be checked for proof of concept. As well, countries that have not yet used Orphacodes will be introduced to and trained on the use of the master file and the coding guidelines and can then test the file and guidelines in specific settings, even small scale, and give feedback on usability of file and guidelines as well as on content of them. The results will be compiled and the master file and guidelines will be adapted accordingly before merging them to routine implementation. (Deliverable D5.6)
Experiences already done in Italy and in France will be enhanced based on local resources.(Deliverable 5.4)

Task 5.4. Plan for next steps needed to address long-term maintenance. and sustainability of the resources and guidelines.
Task Leader: Stefanie Weber, [DIMDI, Germany] - Contributors: All WP5 contributors
Start date: M30 End date: M36
Building of the lessons learned on the 3-years experience and on the results obtained, the working group will set up recommendations on next steps which will help to merge the project results to a long-term maintenance which is stable and available for member states. These recommendations will include an estimation of resources to be allocated at national and European level. (Deliverable 5.5)

Participation per Partner

Partner number and short name	WP5 effort
1 - INSERM	3.00
10 - APHP	19.00
13 - DIMDI	30.00
18 - VR-IIBRD	16.00
22 - HDIR	0.10
Total	68.10

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D5.1	Review document of existing technical implementations for RD coding of MS	10 - APHP	Other	Public	12
D5.2	Standard procedures and guide for the coding with Orpha codes	10 - APHP	Other	Public	18
D5.3	An European integrated master file	13 - DIMDI	Other	Public	36
D5.4	A set of coding helping tools for rare diseases	18 - VR-IIBRD	Other	Public	36
D5.5	Draft recommendation for routine maintenance	10 - APHP	Other	Public	36

Description of deliverables

D5.1 Review document of existing technical implementation of RD coding of MS. Analyse at each MS level the situation for RD coding base don previous general work done through precedent JA. This work includes deep analysis

of current and future situation. Existing systems in each country might already give satisfactory data from some RDs. Granularity analysis for further coding requirements.
D5.2 Standard procedures and guide for the coding with Orpha codes. To guarantee comparable datasets from MS a clearly procedure will be clearly defined.
D5.3 European integrated master file. Table fine-tuned according to the test results and containing all the information that was provided by MS over the project period
D5.4 Set of coding help tools for RD. electronic sheet and relational DB for the automatic coding of RD (experimentally for a group of RDs)
D5.5 Draft recommendation for routine maintenance. APHP, VENETO and DIMDI set of next steps which will help to merge the project results to a long-term maintenance which is stable and available for MS in the draft form of a recommendation.

D5.1 : Review document of existing technical implementations for RD coding of MS [12]

Analyse at each MS level the situation for RD coding based on previous general work done through precedent JA. This work includes deep analysis of current and future situation. Existing systems in each country might already give satisfactory data from some RDs. Granularity analysis for further coding requirements.

D5.2 : Standard procedures and guide for the coding with Orpha codes [18]

To guarantee comparable datasets from MS, a coding procedure should be clearly defined

D5.3 : An European integrated master file [36]

Table fine-tuned according to the test results and containing all information that was provided by member states over the project period

D5.4 : A set of coding helping tools for rare diseases [36]

Electronic sheet and relational DB for the automatic coding of RD (experimentally for a group of RD)

D5.5 : Draft recommendation for routine maintenance [36]

APHP, VENETO, DIMDI Set of next steps which will help to merge the project results to a long-term maintenance which is stable and available for member states in the draft form of a recommendation.

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS23	The complete state of the art of MS situations in identifying RDs possible solutions and strategies	10 - APHP	12	
MS24	Specifications for an integrated coding application with Orphacodes	18 - VR-IIBRD	12	
MS25	Specifications of a master file taking into account existing implementation and strategies of MS	13 - DIMDI	18	
MS26	The set of clear objectives and coding rules propositions for RD at EU level	18 - VR-IIBRD	18	

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS27	A beta master file version to be tested in some selected MS together with the correct coding procedures	13 - DIMDI	24	DIMDI/APHP
MS28	Finalised Master File and Guidelines available together with plan on how the two items could be merged to routine use and availability	13 - DIMDI	36	APHP, DIMDI, VR-IIBRD

Work package number [9]	WP6	Lead beneficiary [10]	31 - UNEW
Work package title	Policy Development for RD and Integration with other relevant initiatives		
Start month	1	End month	36

Objectives

Leader: UNEW
Contributors: MUW, SPF, WIV-ISP, Bulgarian Association for promotion of education and Science/Rare Diseases institute,MoH Cyprus, NKCVO, EURORDIS, French DGS, INSERM, UKF, Medizinischen Fakultät der Otto-von Guericke-Universität Magdeburg, PTE, SE, OPBG, VR-IIBRD, ISS, VULSK, HDIR, Poznan University of Medical Sciences, Portuguese DGS, UKC Ljubljana, CIBER, Instituto de Salud Carlos III , FISABIO-Salud Pública, INERP, Office population of health genomics (WA)

The main objective of this WP is to support the development of policies and recommendations for consideration and adoption by the Expert Group on Rare Diseases and subsequent delivery to the European Commission. The WP will collaborate with relevant projects and initiatives within the RD field and in pertinent related areas to ensure cross talk and integration to support the tasks. By providing information (including through the production of the State of the Art on RD in Europe) and through the development of policy recommendations this WP will support the work of the Commission Expert Group on Rare Diseases and also support the MS in implementing Recommendations and policies relating to RD .
The specific objectives of this WP are to:
1. Develop and implement a methodology to support the development of policies and recommendations in association with all relevant stakeholders.
2. Provide information and policy support to the Expert Group on Rare Diseases
3. Produce the Report/Resource on the State of the Art of Rare Diseases Activities in Europe

Description of work and role of partners

WP6 - Policy Development for RD and Integration with other relevant initiatives [Months: 1-36]
UNEW, APHP, HDIR
This WP will build on the work previously developed within the Eucerd Joint Action (EJA) intended to support the implementation of the EC recommendations on rare diseases at the MS level, by establishing position papers and recommendations issued from high-level multidisciplinary working groups in which all the stakeholders were represented. During this WP a methodology will be developed in order to prioritize areas for which there is still need to foster implementation of policies. A pre-selection of topics are proposed below as areas in which substantial unmet needs remain with respect to rare diseases and / or where a cycle of ongoing or updating of current recommendations will be required over the period of the Joint Action. For all of these subject areas, synergies will be assured with other funded initiatives and their leadership engaged. These topics largely correspond to Operational Actions defined under the Commission Communication (COM 2008 679), where work remains to be carried out (Operational actions related to improving recognition and visibility of RD will primarily be addressed by WP4 and WP5).
These topics include, but are not limited to, the following:
Thematic Priority Proposed for WP6
European Reference Networks (ERNs)
Centres of Expertise and healthcare pathways
Objective of the Commission Communication underpinning this work:
5.1: Improving universal access to high-quality healthcare for rare diseases in particular through development of national/regional centres of expertise and establishing EU Reference network

Registries, databases and data collection (including quality, and access and sharing)
Objective of the Commission Communication underpinning this work: 5.11 : Registries and databases

Integration of RDs into Social Policies and Specialised Social Services
Objective of the Commission Communication underpinning this work: 5.2 Access to specialised social services

Genetic testing/Next Generation Sequencing; Genetic Counselling; neonatal screening, Primary Prevention of rare congenital anomalies

Objective of the Commission Communication underpinning this work: 5.9 Quality management of diagnostic laboratories; and
5.10 Primary prevention

Coordinated approaches to pricing and innovative mechanisms to improve access to rare diseases therapies, including HTA
Comprehensive information systems (Help-lines, information points)
Objective of the Commission Communication underpinning this work:
5.3 Access to Orphan Drugs
5.4 Compassionate use programmes
5.5 Medical devices
5.6 Incentives for Orphan Drug Development

Comprehensive information systems (Help-lines, information points)
Objective of the Commission Communication underpinning this work: Mentioned in 5.2, as above.

E-health
Objective of the Commission Communication underpinning this work: e-health

The WP may also explore, as deemed necessary by the Consultative Group, partners and the Expert Group, topics beyond the immediate scope of the Commission Communication, where these are deemed to meet the changing needs of the field: suggested topics in this category include Best Practices / guidelines on diagnostics, Public Health Indicators and care and Methodology for assessing the Socio-economic Burden of Illness of Rare Diseases.
The precise scope of work in the above areas will form the basis of annual workplanning to reflect current and changing priorities over the course of the JA.

Task 6.1 : Implement a robust policy methodology to support the work of the Expert Group on Rare Diseases
Task Leader (Kate Bushby, UNEW) Contributors (MUW, FPS Health, WIV-ISP, BAPES, MoH CY, MoH Fr, NKCVO, INSERM, EURORDIS, UKF, INERP, OVGU, PTE, SE, OPBG, Veneto, ISS, VULSK, HDIR, Poznan University, DGS, UKCL, FISABIO-Salud Pública, CIBER, ISCIII, WADOH via the Consultative Group)
Start date: M1 End date: M12
The partners in WP6 together with the Orphanet team and EURORDIS will be constituted to form a Consultative Group to support the development and implementation of the methodology to support the whole policy cycle and topic areas, from identification/confirmation of priority areas through to development of Opinions and Recommendations of the Expert Group.
This methodology will also include ongoing systematic review and updating of outputs on a regular basis, and in line with current work of the Expert Group and European Commission. As above, this policy cycle will include, but not be limited to: ERNs, Centres of Expertise, Registries and Data Collection (including quality issues), Integrating rare diseases into social policies, Genetic testing/screening and NGS, Comprehensive information systems, Generation and sharing of best practice and guidelines on diagnostics and care, Pricing and access to therapies (HTA), e-health, Prevention of congenital anomalies, and Evaluation of the socio-economic burden of RD. As the RD field can change quite dramatically over a period of three years, flexibility to ensure responsiveness in the relevant areas will be important, so the workplan at this stage cannot be completely prescriptive.
UNEW will lead the task, with support from all partners and feedback from the Expert Group. The main output of this task will be the agreed methodology, identification of key groups for interactions and agreed outputs for each policy area (to include information, opinions, and recommendations) and, with the Commission and Expert Group, a suggested timeline for each area of interest.
Task 6.2: Provide comprehensive policy support to the Expert Group on Rare Diseases
Task Leader (Kate Bushby, UNEW): Contributors (MUW, FPS Health, WIV-ISP, BAPES, MoH CY, MoH Fr, NKCVO, INSERM, EURORDIS, UKF, INERP, OVGU, PTE, SE, OPBG, Veneto, ISS, VULSK,HDIR,Poznan University,DGS; UKCL,FISABIO-Salud Pública,CIBER, ISCIII, WADOH via the Consultative Group)
Start date: M1 End date: M36
This task addresses a key target area of the Commission Communication on Rare Diseases:
"Efficient and effective action for rare diseases depends on a coherent overall strategy for rare diseases mobilising scarce and scattered resources in an integrated and well-recognised way, and integrated into a common European effort. That common European effort itself also depends on a common approach to work on rare diseases".
Through implementation of the policy methodology in task 1 WP6 will provide support to the Expert Group in terms of the provision of information on relevant initiatives as well as the drafting, elaboration and revision of Recommendations, Reports and Opinions for approval and adoption by the Expert Group.

The timeline for each thematic area will vary – in some cases work will foreseeably be constant and ongoing, via conference calls, meeting and workshops (e.g. ERNs). Others will have more sporadic periods of intense activity in terms of preparation for a workshop. In all cases, the timeline for these policy areas will be developed by UNEW with the input of the Consultative group and agreed with the Expert Group and European Commission and will support the ongoing implementation on the Commission Communication on Rare Diseases and Council Recommendation on an action in the field of rare diseases. All of these areas of research and co-ordination will be performed by the Newcastle team, in conjunction with the Consultative group.
There are many additional initiatives which will also be engaged so that their outputs can be further integrated into the policy work of the Joint Action as necessary including RD-Connect; JRC; OSSE; National Registries; IRDiRC; GA4GH; E-Rare3 and many more. It will be the responsibility of the UNEW team to liaise with these groups and produce updates for the JA and CEGRD.
Outputs of this task will include material for the Expert Group and its outputs in terms of opinions, recommendations and other documents. In collaboration with WP2, relevant documents will also be prepared for other dissemination routes, including via the National meetings, ECRD, Orphanews, website etc.
Task 6.3 Produce the Report/Resource on the State of the Art of Rare Diseases Activities in Europe
Task Leader (UNEW, 25 PM): Contributors (INSERM, EURORDIS, all MS)
Start date: M18 End date: M30
A key part of UNEW's work will involve collating and analysing data for the State of the Art report. The intention is to revise this (traditionally) annual report and utilise the data to follow MS progress and identify good practices nationally and internationally. It will therefore be transformed into a more dynamic and interactive web-based resource, to make it easier to monitor progress in terms of RD-related activities in each MS. An annual summary report will be produced (twice during the course of this JA) but it is intended that the resource itself is frequently updated and thus more able to support MS in implementing their national plans and strategies for RD.
The Debrief Reports generated during the EJA will form the basis for ongoing review of national activities in RD – these will be updated following the respective national conferences organised under WP2. In parallel, it is envisaged that WP6 task 3 will oversee completion of the EUCERD Recommendations on Core Indicators for RD National Plans , and that the SoA resources will display these tables, to support transparency. The aim is to engage with not only the CEGRD MS representatives here, but also ideally the Orphanet national teams, to collate the data and cement links between the Policy WP (6) and the other core WPs of this JA. There could also be opportunities for wider public comments, i.e. via the National Alliances. In addition, thematic area forums will be set-up, to promote key resources relevant to that topic and also to support MS in sharing ideas and challenges relating to national implementation.
The State of the Art document will be disseminated through WP2.

Participation per Partner

Partner number and short name	WP6 effort
10 - APHP	26.00
22 - HDIR	0.10
31 - UNEW	113.20
Total	139.30

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D6.1	Progress report on policy delivery and implementation	31 - UNEW	Report	Public	18
D6.2	Final report on policy delivery and implementation	31 - UNEW	Report	Public	36

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D6.3	2016 Edition of the State of the Art Report	31 - UNEW	Report	Public	18
D6.4	2017 Edition of the State of the Art Report	31 - UNEW	Report	Public	30

Description of deliverables

D6.1 Progress report on policy delivery and implementation. This report will be structures to include specific updates on the thematic areas
D6.2 Final report on policy delivery and implementation. this report will be structures to include specific updates on the thematic areas.
D6.3 2016 edition of the State of the art report. Annual report on key developments in the field, at national and EU level.
D6.4 2017 edition of the State of the art report. Annual report on key developments in the field, at national and EU level.

D6.1 : Progress report on policy delivery and implementation [18]

This report will be structured to include specific updates on the thematic areas.

D6.2 : Final report on policy delivery and implementation [36]

This report will be structured to include specific updates on the thematic areas

D6.3 : 2016 Edition of the State of the Art Report [18]

Annual Report on key developments in the field, at national and EU levels

D6.4 : 2017 Edition of the State of the Art Report [30]

Annual Report on key developments in the field, at national and EU levels

Schedule of relevant Milestones

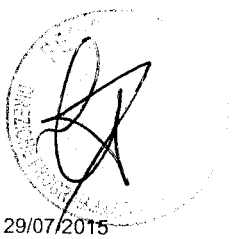
Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS29	Agree draft policy methodology with Expert Group	31 - UNEW	6	
MS30	Agree WP6 Workplan	31 - UNEW	3	
MS31	Review/Update WP6 Workplan (I)	31 - UNEW	14	
MS32	Review/Update WP6 Workplan (II)	31 - UNEW	24	
MS33	Review by Expert Group of activities (I)	31 - UNEW	14	
MS34	Review by Expert Group of activities (II)	31 - UNEW	26	
MS35	Agree format for new SoA Resource	31 - UNEW	6	

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS36	Report on the policy cycle and methodology to support the Expert Group	31 - UNEW	12	

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	Organisation of kick-off completed (meeting,agenda & preparatory documents)	WP1	1 - INSERM	2	
MS2	Timetable/ workplan with detailed description of tasks	WP1	1 - INSERM	2	
MS3	Draft interim reports completed	WP1	1 - INSERM	18	
MS4	Organisation of meetings completed (meeting,agenda & preparatory documents)	WP1	1 - INSERM	29	M17-M29
MS5	Stakeholder analysis: identification of target groups and adequacy of channels to be used	WP2	11 - EURORDIS	3	
MS6	Graphic Identity of Website and Newsletter	WP2	1 - INSERM	6	
MS7	Internal Newsletter	WP2	1 - INSERM	1	M6, M12, M18, M24, M30
MS8	Editorial board meetings (Orphanews)	WP2	1 - INSERM	36	Every 2 months
MS9	Identification of the Member States and themes for the National Workshops	WP2	11 - EURORDIS	12	
MS10	Partner's survey	WP3	2 - MUW	24	M12,M24
MS11	Adhoc users 'surveys	WP3	2 - MUW	18	
MS12	External evaluation of Orphanet from French institutions ready	WP3	2 - MUW	18	



Milestone number [18]	Milestone title	WP number [9]	Lead beneficiary	Due Date (in months) [17]	Means of verification
MS13	Orphanetwork: internal website and newsletter	WP4	1 - INSERM	36	To be produced every 2 months (M2,4,6,8,10,12,14,16,18,20,22,24,28,30,3
MS14	Annual Orphanet Management Board meeting organised (agenda and preparatory documents) and held	WP3	1 - INSERM	30	M2-M17-M30
MS15	Establishment of working groups with representatives from EU Member States to define the scope and the objects of sustainable health systems study	WP4	34 - ISS	3	
MS16	Establishment of specific working groups on areas of application for sustainability issues	WP4	34 - ISS	15	
MS17	Establishment of a European network (consisting of partners from EU member States) to reduce health inequalities and to promote measures for sustainability of National strategies for RDs	WP4	34 - ISS	30	
MS18	Editorial boards of the internal newsletter during which the newsletter content is validated before online publication	WP4	1 - INSERM	36	Every 2 months
MS19	Users survey available online	WP4	1 - INSERM	36	M12-24-36
MS20	Organisation of trainings completed	WP4	1 - INSERM	24	M12-24

Milestone number [18]	Milestone title	WP number [9]	Lead beneficiary	Due Date (in months) [17]	Means of verification
MS21	KM platform tested	WP4	1 - INSERM	24	
MS22	Data collection for ORS completed	WP4	1 - INSERM	36	Every 6 months
MS23	The complete state of the art of MS situations in identifying RDs possible solutions and strategies	WP5	10 - APHP	12	
MS24	Specifications for an integrated coding application with Orphacodes	WP5	18 - VR-IIBRD	12	
MS25	Specifications of a master file taking into account existing implementation and strategies of MS	WP5	13 - DIMDI	18	
MS26	The set of clear objectives and coding rules propositions for RD at EU level	WP5	18 - VR-IIBRD	18	
MS27	A beta master file version to be tested in some selected MS together with the correct coding procedures	WP5	13 - DIMDI	24	DIMDI/APHP
MS28	Finalised Master File and Guidelines available together with plan on how the two items could be merged to routine use and availability	WP5	13 - DIMDI	36	APHP, DIMDI, VR-IIBRD
MS29	Agree draft policy methodology with Expert Group	WP6	31 - UNEW	6	
MS30	Agree WP6 Workplan	WP6	31 - UNEW	3	
MS31	Review/Update WP6 Workplan (I)	WP6	31 - UNEW	14	

Milestone number [16]	Milestone title	WP number [9]	Lead beneficiary	Due Date (in months) [17]	Means of verification
MS32	Review/Update WP6 Workplan (II)	WP6	31 - UNEW	24	
MS33	Review by Expert Group of activities (I)	WP6	31 - UNEW	14	
MS34	Review by Expert Group of activities (II)	WP6	31 - UNEW	26	
MS35	Agree format for new SoA Resource	WP6	31 - UNEW	6	
MS36	Report on the policy cycle and methodology to support the Expert Group	WP6	31 - UNEW	12	

1.3.5. WT5 Critical Implementation risks and mitigation actions

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
R1	Conflict between partners	WP1	Consortium agreement
R2	Misunderstanding/ misinterpretation of objectives /deliverables	WP1	Effective communication strategy
R3	withdrawal of beneficiaries	WP1	Consortium agreement
R4	delays in completion of deliverables	WP1	Regular monitoring of activities and evaluation
R5	For the ECRD 2016: fluctuations of the exchange rate between the euro and the pound	WP2	Use of Forward Contracts which binds to buying a set amount of currency at a set price and within a certain time frame or at a specified point in time agreed upon within the contract
R6	Low level of participation due to unforeseen circumstances	WP2	We will secure dissemination of save-the-dates and invitations well ahead of the event and advertise the Conference on all relevant supports (on websites EURORDIS and partners, distributing flyers to relevant meetings / conferences, etc.)
R7	Coordination difficulties with local authorities and national alliances	WP2	We will ensure good communication / coordination levels by starting relevant activities well ahead of the national workshops themselves and by ensuring high communication flows + Rely on the local JA partner
R8	Misunderstanding/ misinterpretation of objectives /deliverables	WP2	Effective communication strategy
R9	Delays in completion of deliverables	WP2	Regular monitoring of activities and evaluation
R10	Coordination difficulties with local authorities	WP2	Effective communication strategy
R11	MS unavailable to collaborate	WP2	Strengthening of literature review
R12	French institutions unavailable to perform external evaluation	WP3	Institutions already engaged in the evaluation process

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
R13	MS unavailable to perform external evaluation	WP3	The CEGRD will be solicited to engage the evaluation process
R14	MS unable to find a consensual agreement regarding the long term sustainability of Orphanet	WP3	Development of an explanatory document with a modular dissection and representation of all Orphanet services and tools combined with a checklist to facilitate informed decision of the MS according to their national needs and to the European perspective and added value of the database
R15	Hacking of the database accessible on the web	WP4	Secured database, recovery program in place
R16	Delay in producing/ updating the information/ encyclopaedia due to turn-over	WP4	Replacement of information scientists/medical writers, redistribution of tasks to minimize the impact
R17	Failure to a partner to deliver for expert resources data collection in a country	WP4	The coordination team in Paris will carry out the task; the replacement of the country team will be demanded as soon as possible
R18	Delay/failure of health authorities to validate the expert resources data	WP4	User-friendly tools are set up to ease the validation tasks. In case of need, data will be quality controlled by other means depending on the nature of data and delivered if appropriate with the mention of the validation status (validated yes/no).
R19	Too high variability of the existing situations in MS	WP5	Aggregation of MS per macro-groups of existing situation: different recommendations for macro-group of MS
R20	Lack of agreed rules to allocate nosologic entities in ICD	WP5	High expertise of the involved professionals and decision taken at majority
R21	Great complexity of the network of relations between ICD classification and orphan one	WP5	Experimentation applied only to specific groups of rare diseases

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
R22	Lack of engagement by community	WP6	All partners tasked with ensuring national contacts and organisations are aware of the work plan and able to contribute to the outputs
R23	Lack of clarity on needs of the Expert Group and EC	WP6	Regular calls with the EC and partners to agree and communicate areas which need work

1.3.6. WT6 Summary of project effort in person-months

	WP1	WP2	WP3	WP4	WP5	WP6	Total Person/Months per Participant
1 - INSERM	37	28	0	602	3	0	670
2 - MUW	0	0	7	36	0	0	43
3 - SPF	0	0	0	3.50	0	0	3.50
4 - WIV-ISP	0	0	0	18	0	0	18
5 - BAPES	0	0	0	49	0	0	49
6 - IISRB	0	0	0	30	0	0	30
7 - NKCVO	0	0	0	11.80	0	0	11.80
8 - UTARTU	0	0	0	14.40	0	0	14.40
9 - RINNEKOTI	0	0	0	19.50	0	0	19.50
10 - APHP	0	0	0	0	19	26	45
11 - EURORDIS	0	29	0	0	0	0	29
12 - MHH	0	0	0	42.20	0	0	42.20
13 - DIMDI	0	0	0	0	30	0	30
14 - OCMO	0	0	0	11	0	0	11
15 - SE	0	0	0	11.20	0	0	11.20
16 - HSE	0	0	0	51	0	0	51
17 - OPBG	0	0	0	77	0	0	77
18 - VR-IIBRD	0	0	0	0	16	0	16
19 - SPKC	0	0	0	10.80	0	0	10.80
20 - VULSK	0	0	0	30.40	0	0	30.40
21 - LUMC	0	0	0	37	0	0	37
22 - HDIR	0	0	0	0	0.10	0.10	0.20
23 - NKSD	0	0	0	7.20	0	0	7.20

	WP1	WP2	WP3	WP4	WP5	WP6	Total Person/Months per Participant
24 - IPCZD	0	0	0	51.70	0	0	51.70
25 - DGS	0	0	0	39.50	0	0	39.50
26 - UMF	0	0	0	32.40	0	0	32.40
27 - CUMS	0	0	0	57	0	0	57
28 - UKCL	0	0	0	12.50	0	0	12.50
29 - CIBER	0	0	0	86.40	0	0	86.40
30 - KS	0	0	0	19.90	0	0	19.90
31 - UNEW	3	26	0	4	0	113.20	146.20
32 - UK PHE	0	0	0	37.80	0	0	37.80
33 - DGS FR	0	0	3	0	0	0	3
34 - ISS	0	36	0	0	0	0	36
Total Person/Months	40	119	10	1403.20	68.10	139.30	1779.60

1.3.7. WT7 Tentative schedule of project reviews

Review number [19]	Tentative timing	Planned venue of review	Comments, if any
RV1	12	Chafea	
RV2	24	Chafea	
RV3	36	Chafea	

1.4. Ethics Requirements

No ethics requirements indicated

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 fillings, 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)
EU-RES Classified Information: RESTREINT UE (Commission Decision 2005/444/EC)
EU-CON Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC)
EU-SEC Classified Information: SECRET UE (Commission Decision 2005/444/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

Answers to the evaluators (2nd round of evaluation of the revised proposal submitted on June 04)

Again we are grateful to the evaluators for further constructive comments and criticism allowing for further refine- and improvement of our proposal. Below, we indicate all modifications included in the new proposal, each being related to the evaluator's comments.

1. **Comment on nominated partners:**

"...Also some of the bodies nominated as associated partners changed their roles to collaborating. This should be justified" has not been taken into consideration by the coordinator. It still needs justification.

A sentence was added to paragraph 10.1 to explain the following :
« Some nominated partners agreed on being collaborating partners instead of beneficiaries : in WP4, when more than one institution was nominated to conduct Orphanet activities in the same country, some partners decided to have all the budget managed by one of the institutions while others participate as collaborating partners ». Partners concerned : Austria (MUW beneficiary and GOEG collaborating), Croatia (HSRB beneficiary and HZJZ collaborating) , German (MHH beneficiary and RKI collaborating), Hungary (OTH and SE beneficiaries and PTE collaborating);
« in workpackages in which the work will be done through workshops and meetings, participating institutions were consulted and agreed to have the budget centralised at the WP/tasks leaders level, in order to optimise the allocated resources and to ease managing funding and administrative issues (WPs 2, 5, 6) » .
Partners concerned : Goeg (AT), MoH (BG), MU-Sofia (BG), MoH (CY), University of Franckfurt (DE), University of madgeburg (DE), INERP (GR), MoH (LU), Poznan University of Medical Sciences (PL), ISCIII (ES), FISABIO (ES))

Comment on WP3 – Description of deliverables

« This section does not describe the deliverables. It repeats the section under the same WP which describes the work and the role of the partners. »

The evaluation performed under WP3 will result in a number of individual reports, each addressing the relevant tasks in workpackages 2, 4, 5, and 6, as described in Task 3.1 and 3.2 of this WP. To this end, the appropriate, task-tailored process, output, outcome and impact indicators described in:

- chapter 2 ("Aims and objectives of the action"), item 2.2 ("Specific objectives of the action"),
- chapter 5 ("Methods and means"), item General objective 1, WP4 ("Orphanet, the European database for rare diseases") specific objective 6 ("Make the European database for RD sustainable"),
- chapter 7 ("Work Packages"), item 7.2 ("Work packages description"), WP3, Task 3.1 ("Evaluation of the Joint action achievements")

as well as the results of the intended satisfacoty surveys (where described in the proposal) will be used for the assessment of the individual tasks. To better indicate this procedure, we have changed the wording of deliverable D3.1, pointing out that individual **task-related evaluation reports** are the ultimate deliverable. We further added a more detailed description of the content of the deliverable summarizing the process details described above.

Comment on WP3 – Task 3.2

« There is no deliverable related to task 3.2. »

A new deliverable D3.2 was added, named "**Reports** on the external evaluation of Orphanet". This deliverable specifically addresses the exercise described under task 3.2 consisting of two separate external evaluation assessments, one by French institutions focusing on the structure, content and functioning of the database and one by representatives of different stakeholders in each MS to assess their needs regarding the database. This "double approach" is also briefly described in the contents field of this deliverable.

Comment on WP3 – Evaluation related to the achievement of the JA objectives

« An evaluation related to the achievement of the JA objectives (based on the indicators presented under item 2.2. Specific objectives of the action) is not planned. »

We apologize for not being clear enough in our proposal, but the indicators presented under item 2.2 are one key instrument in the evaluation of the achievements of the project. To stress this fact, we have adapted deliverable D3.1 as described above, including the use of the aforementioned indicators in the contents description of this deliverable (see above).

In addition, the previous deliverable D3.2 is now **re-numbered as deliverable D3.3** (Sustainability plan) and its content description has been elaborated in more detail.

D3.1	Individual task-related evaluation reports for WP2,4,5, and 6	3	MUW	Each evaluation report will be based on (1) the analysis of all relevant, task-related indicators as outlined in item 2.2 ("Specific objectives of the action"), methods and means specific objective 6 and task 3.1, as well as (2) the analysis of the intended satisfactory surveys	PU	M12,18,24, 30,36
D3.2	Reports on the external evaluation of Orphanet	3	INSERM-DGS (FR) – MUW	Reports summarizing the independent evaluations of Orphanet by French institutions and by MS representatives	CO	M6-12
D3.3	Sustainability plan for Orphanet core activities	3	INSERM DGS (FR) – MUW	Development of a modular representation of Orphanet and elaboration of strategies for a secured legal framework and a sustainable funding of Orphanet in the EU	PU	M24

5. **Comment on WP2:** *it is better to say joint action instead of project in the disclaimer.*
Changed (part A). "The [communication/publication] arise from the Joint Action RD-Action which has received funding from the European Union in the framework of the Health Program"

Comments on BUDGET

1. Partner 3 – SPH, Dr Mertens: no information on the concrete activities that this expert will be implementing. The same is for Dr Van den Bogaert.
Justification has been included in partB
2. Partner 4- WIV-ISP: there is a discrepancy between the persons' position and the justification.
Justification has been included in partB
3. Partner 11 _ EURORDIS: positions of the staff members are presented but justification related to the tasks to be performed by the staff members is missing
Justification has been included in partB
4. Partner 21 – LUMC: justification related to the tasks to be performed by the following staff members is missing: P. van Overveld and the medical writer
Justification has been included in partB
5. Partner 29 – CIBER: the staff members' experience is presented instead of justification related to the tasks to be performed
Justification has been included in partB
6. Partner 34 – ISS: justification related to the tasks to be performed by the staff members is missing
Justification has been included in partB

Answers to the evaluators (first evaluation)

We are grateful to the evaluators for their constructive comments and criticisms that allowed the participants improving the proposal. We indicate here below what was modified according to each particular matter pointed out by the evaluators.

Comments on Criterion 1 - Contribution to public health in Europe

« It is strongly recommended to have a specific objective on implementation, together with clear indicators related to the real impact on policy. Especially this being the third consecutive JA, in this area, one would expect the consortium to be pushing towards having impact on the policies, beyond the drafting reports or other documents. As it stands, the role of supporting the MS in implementing real policies seems week. »

In order to make more clear the way tailored support to MS will be provided by RD-ACTION, specific objectives under the general objective #3 **(To continue implementation of the priorities identified in Council Recommendation 2009/C151/02 and the Commission Communication (COM 2008 679) on RD, with a view to ensuring the sustainability of the recommended priority actions, and to support the work of the Commission Expert Group on Rare Diseases (CEGRD) by gathering expertise and producing data necessary to its action.)** were better defined, and a specific objective on supporting MS implementing recommendations has been identified. See sections 2.2 (process, output and outcome indicators have been noted for each specific objective) and Methods and means, General objective 3. Proper mechanisms to allow forth-and-back communication between MS and JA participants, in order to timely identify problems, share/promote solutions and retrieve indicators of implementation have been described.

A specific task on dissemination of ways that sustainability issues could be addressed in each MS health system has been added to WP2 (see explanations at the end).

« The proposal does mention the social and cultural aspects, but should have defined in more details, as for example in how many languages the website will be available. »

A sentence was added to paragraph 4.4 to explain that, as part of the overall evolution of the Orphanet model, the website will be able to host as many languages as desired by MS, knowing that translation is a national decision run with national funding.

Further to this, and to address social and cultural aspects, the specific task on health systems for RD added in WP2 takes into account the political, economic and social context of each MS.

« The proposal does mention the empowerment of patients, but it is not so clearly stated how they will achieve it, apart from the conferences and workshop. It is important to clearly describe their role throughout the whole project. »

Empowerment of patients was better described. See for instance paragraph 4.1 and a dedicated paragraph in Methods and means section.

Comments on Criterion 2 - Technical quality

- Concerns about dissemination issues:

« Dissemination itself is a big part of this JA, as per its core objective to improve information and build toward better health for all. But a more innovative approach, apart from the already well known newsletter could have been foreseen (videos, blogs, social networks, etc) in view of strengthening the 'Rare Disease Community' building. The dissemination plan is briefly mentioned, with specific attention to relevant stakeholders and messages, but it could have been more detailed. Apart from guidelines on coding, some training sessions could have been foreseen in the forthcoming conferences and workshops. Strongly linking to the work of EURORDIS could be mutually very beneficial, also in light of the comment on patient empowerment made above. »

The evaluators have correctly underpin the main importance of dissemination in this Joint Action. This WP not only deals with the classical dissemination of the joint action per se, but makes part of the whole dynamic in

promoting the implementation of policy recommendations for RD. EURORDIS plays a major role here, for it participates to WP6 activities and is leading the dissemination WP. It ensures a virtuous cycle between stakeholders and the CEGRD and the European Commission. Its role is explicit at the Methods and means section, paragraphs on specific objectives 8 and 9.

The dissemination plan is one of the deliverables of WP2, therefore it cannot be described in depth in the text of the proposal. It is of course foreseen to integrate new dissemination means of which EURORDIS has a solid experience. An explanation was added to WP2 description for more clarity.

- Concerns about sustainability issues:

« The strive towards sustainability is mentioned through the preparation of a sustainability workplan, but it could have been useful to have a first insight into ideas of a sustainability strategy, and thoughts on how to ensure continuity of the Orphanet. If the reason not to provide such elements at the time of the proposal is to involve more openly the MS in such a document and further planning of sustainability linked activities some preliminary possible scenarios could have still been briefly outlined. »

- Sustainability of policy measures

A new task has been added to WP2 (Task 2.5) in order to address both dissemination and sustainability issues, as well as to clarify the role of ISS that was pointed out by the evaluators. A task on sustainable health systems for rare diseases was added in order to ensure that the work undertaken in this JA address the sustainability of foreseen policy priorities taking into account the Communication from the European Commission on effective, accessible and resilient health systems and that the conclusions of this specific task are disseminated to all the stakeholders via a conference at the end of the joint action.

- Sustainability plan for Orphanet

A sentence was added to Task 3.3 in WP3 description, which remains voluntarily vague in order to allow MS and the EC to openly explore all the possible scenarios. However, a method to support this exploration is described, leading partners to define the perimeter (modules) of what should be co-funded in the long term, then to select the right legal instrument (becoming a European institution, forming, for instance, a European grouping of territorial cooperation ...) to ensure permanent positions and collaboration models to sustain the Orphanet modules judged essential at the European level.

- Concerns about evaluation :

« Evaluation is also described, but it appears that it will be performed by the partners, in relation with monitoring activities of WP1. An external evaluation is beneficial, to ensure impartiality. »

Monitoring is performed by WP1 coordination. Task 3.1 is more about evaluation of process, output, outcome and impact indicators.

Task 3.2 is intended to evaluate the Orphanet database compared to MS and EC needs. External expertise will be used (in particular, Orphanet has asked for an external audit of its IT information system that was conducted by an independent society at the end 2014 during the preparation of this Joint Action; the conclusions issued from this independent audit will be shared with WP3 to support the evaluation) but unfortunately the limited budget avoids for subcontracting an external evaluator. However, as described in the Methods and means paragraph, a sound methodology aims at performing an unbiaised evaluation as possible.

- Concerns about the methodology :

« The methodology presented in WPs 4,5 and 6 should be more specific. A recommendation is to add outcome and output indicators to ensure quality and better understanding on how the processes will be put forward. Target values should be added where possible. »

Methods and means have been revised for more clarity and specificity.

Following the discussions with the evaluators, it was decided to introduce the future evolution of the Orphanet model, making a more open and shared system. It is now shown that a web-based curation platform will be developed so as to allow for sharing some core activities with WP4 partners, i.e. the encyclopaedia. The further

evolution of the Information system, following the recommendations of the external audit performed, will also allow to share IT developments.

Output and outcome indicators have been added, as well as target values, in section 2.2.

- Concerning the co-leadership in WP2 :

Co-leadership is now possible because of the contribution of ISS as beneficiary partner (see specific point at the end).

- Concerning the visibility of EC co-funding :

A sentence was added to WP2 description: "The following statement will be included in all communications or publications by the beneficiaries related to the action: "The [communication/publication] arise from the project RD-action which has received funding from the European Union in the framework of the Health Program"

Comments on Criterion 3 - Management quality

« A chart lays out the organisational structure, including the previous Orphanet structure, resulting in different bodies and functions, that seem to have somewhat unclear and overlapping roles. »

Following the evaluator's comments and suggestions during our discussions, a new, simplified management structure chart has been established. Special attention was kept to harmonise the wording « beneficiary » and « collaborating » across the whole proposal.

The role and composition of the International advisory Board of Orphanet have been explained.

Deliverables have been revised so as to move some to milestones and to make them public.

Comments on Criterion 4 - Overall and detailed budget

One of the major criticism is the overall budget allocated to the Orphanet database. Even if it is well-established, maintain information up-to-date and adapt the content to the evolution of knowledge is costly. The budget allocated in this Joint action is less than in the former one. However, in order to prepare the future and to make the database sustainable, some actions are being conducted or are planned during this joint action: the first one is to make the IT system evolve so as to share the informatics effort and to lessen costs in the future; the second one is to develop a platform that makes the curation of the scientific content easier (Task 4.3). It will allow for sharing some core activities such as the encyclopaedia with other consortium members. Following the evaluator's suggestion, the proposal was made to those countries that are not already contributing to the encyclopaedia (translating it) to share the editorial responsibilities. Three countries have accepted, and some budget from the Inserm has been transferred to them in order to carry on medical writer activities from M18 on, that is, when the web-based curation platform is developed. These countries are Ireland (15 PM for medical writer activities added), The Netherlands (14 PM for medical writer activities added) and Slovakia (18 PM for medical writers activities added), which will share the edition effort with the INSERM. Other countries could join later on. This is intended to be the first step to a more open model, with the hope it will contribute making the whole database sustainable after the end of this Joint action, by strengthening the ownership of MS vis-à-vis of Orphanet.

As explained above, budget is limited to cover external evaluation, but the methodology adopted is intended to ensure that the evaluation will be as unbiaised as possible. Extra PMs were transferred to WP3.

- **Answers to the concrete points to be reviewed:**

- Very low allocation of person days on the evaluation WP.

This point has been addressed by adding 5 PM to the WP3

- Partner 3 – SPH, expert Mertens – 14.167 Euro for 1 month

The partner has confirmed this is the salary of the expert Justification of the cost of the experienced staff has been included in the budget table*

- Partner 11 – EURORDIS – 116.051 Euro for 15.9 PM

Justification of the cost of the experienced staff has been included in the budget table.

- Partner 14 – Subcontracting – 3.000 Euro for Regional Co-ordination of data upload

Three institutions were designated by the Hungarian Ministry for the WP4 tasks. The teams have decided to have only two beneficiaries in Hungary while the third will be subcontracted.

- Partner 25 – DGS – Subcontracting 43 253 Euro for Data collection, coding research and website management

DGS decided to conduct Orphanet activities by themselves, so there is no more subcontracting here.

- The travel costs for the three 2 days consortium meeting defer substantially from country to country e.g. 2 700 EUR for partner MUW and 6 705 EUR for partner APHP (BNDMR) France, moreover that one of the meetings is to be carried out in France. The same is for partners DIMDI,VR-IIBRD, UKC, CUMS (8 000 EUR), CIBER (9 600 EUR).

All travel budgets have been adjusted in order to follow this rule: max 2 persons per meeting and one person per training per team. Except for WPs leaders for which 3 persons are allowed to travel. The rule has been included in the proposal.

- The tasks which the partner WIV-ISP is going to implement are not presented in the budget under "justification". The same is for partners HSE, OPBG, LUMC, CUMS, CIBER.

All the tasks have been included in the justification boxes

- No justification of the costs (231 000 EUR) under budget line "Other goods and services" for the partner EURORDIS. Justification of the tasks to be performed by the staff is missing as well.

The justification of costs has been added in the budget table

- The total number of PM for the partner OPBG (information scientist) is 54. The project duration is 36 months. This needs clear justification, which is missing in the proposal.

Justification has been included, 54 PM correspond to 2 staff persons.

The same is for CIBER –36 PM for ME Mateo without justification of the tasks to be performed. The same for UK PHE – 36PM for information scientist

The justification has been included in the boxes. These are information scientists working full time for national data collection for WP4.

- IPCZD has two country coordinators. Based on the justification it seems overestimated.

We have modified to: one country coordinator and one project manager.

- For the partner DGS the justification related to the subcontracting is not convincing. 73% of the direct costs for subcontracting cannot be accepted: Ministry of health has nominated itself. ***See above***

- The costs for equipment of partner UNEW are not justified. 6 000 EUR audit costs should be clarified as well.

The audit costs should be included for all beneficiaries with eligible costs superior to 750 000. In this JA Inserm and Unew will be asked an audit. Inserm will use independent budget while Unew cannot cover it and therefore has included it in the budget. Also for UNEW it is the usual accounting practice of the Beneficiary to consider Office Stationary and supplies costs as direct costs

Inclusion of ISS – Italy as associated partner co-leading WP2 and leading Task 2.5.

The Istituto Superiore de Sanità (ISS) hosts the National Center for RD in Italy, and has given significant contribution in the past and currently in many European initiatives for rare diseases, making it a valuable partner for the joint action for their particular experience in public health. Despite having agreed the previously submitted proposal, ISS has suggested to add in WP2 a specific action on sustainable health systems for rare diseases and, as per this major contribution, and ISS historical involvement in EUROPLAN which evolution is foreseen in this JA, has asked to co-lead WP2.

This new dissemination tasks was judged as important contribution to the JA proposal. It addresses the important subject on how to render sustainable health policies for RD while taking into account the European Commission Communication on efficient, accessible and resilient health systems. However, further budget was necessary to

run this action without unbalancing the actions already planned and agreed. An increase of 90 000 Euros to the total EC co-funding is then asked to cover this piece of work that adds to the overall value of RD-ACTION.

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1. PROBLEM ANALYSIS INCLUDING EVIDENCE BASE

Rare diseases (RD) have been considered a challenge for Europe, for they have been identified as one of the paradigmatic fields in which actions conducted at the European level constitute the adequate response to their specific problems: poor recognition leading to diagnostic delay and inappropriate management including adapted social services, poor health outcomes, social burden, limited knowledge on natural history and pathophysiology leading to an insufficient development of new therapies. The low prevalence and the specificity of rare diseases make that a global, multi-stakeholder approach, intended to gather both specific expertise and to build transversal, shared strategies is necessary to address these issues. The challenges and foreseen solutions for rare diseases are well established and gave raise to several European documents: a Commission Communication on Europe's challenges in the field of rare diseases (2008), Council Recommendation in the field of rare diseases (2009), and to the establishment of a dedicated Commission Expert Group for RD (CEGRD; 2013).

The European Commission has supported key actions over the years, in order to produce data necessary to improve identification and knowledge on rare diseases, as well as to support policy decision-making and to issue recommendations on specific areas in order to guide Member states (MS) policies on RD. These actions comprise the development of Orphanet, a comprehensive European database dedicated to rare diseases, and the establishment of, successively, a RD Task Force, the EUCERD (European committee of experts on rare diseases) and, more recently, the Commission expert group on rare diseases (CEGRD). All three aimed at assisting the European Commission in the preparation and implementation of Community activities in the field of rare diseases. These initiatives gave raise to two Joint Actions that have produced a consequent work in data production and policy position documents and recommendations, respectively: the Orphanet Europe Joint Action (OJA) and the EUCERD Joint Action (EJA).

The efforts conducted up to now at the European level in this field allowed for achieving a degree of maturity so as to move from recommendations to implementation of policies for RD at the MS level. Indeed, most MS have now a national plan or strategy for RD. However, there is still a need to enhance trans-national cooperation, harmonisation and sharing both data and experience in a number of areas including policy, RD codification and databasing. Furthermore, national plans or strategies should contribute to the global objective to have sustainable and resilient health systems in MS, as underlined by the EC Communication on effective, accessible and resilient heath systems (COM(2014) 215 final).

The current JA will allow helping countries to take the step implementing harmonious policies for RD, by supporting the action of the CEGRD on priority fields, such as, for instance, improving universal access to high-quality healthcare for rare diseases through the establishment of Expert reference networks (ERNs) for RD, improving universal access to next-generation genetic testing, allowing access and data sharing for databases and registries on RD, improving universal access to appropriate social services, and promoting innovative strategies to ensure access to rare diseases therapies. A particular attention will be kept at producing evidence in order to help MS to implement RD policy priorities taking into account factors such as effectiveness, accessibility and resilience of health systems, thus determining the sustainability of RD-related policy measures.

One of the already identified priorities is to allow for identification of patients in health care systems and for inter-operability between different sources of data through the consolidation of the Orphanet nomenclature for RD. This nomenclature already exists and is maintained and freely available in computable formats. However, the real-life implementation in health information systems (HIS) is challenging due to the heterogeneity of coding systems and practices, and tools. During this JA, we will produce practical guidance in order to help MS to implement a codification system specific for RD based on this nomenclature, and methods intended to allow consistent codification of patients across Europe in order to produce sound clinical data.

Finally, there is a need to produce and deliver up-to-date information on RD, as well as useful data to monitor MS activity in the field of RD. This is currently achieved by Orphanet, which is the European database for RD spreading beyond the European boundaries. However, most of the database activities are concentrated at the coordination level, and there are concerns sustaining the whole model in the long term. During the current JA, a new Orphanet organization will make it evolve towards a more open and shared model by implementing innovating methods, and will explore strategies and build plans to make this database sustainable so as to still

improve the knowledge on RD, empower patients, disseminate best practice, and produce data necessary to make decisions in public health and research at both European and MS level.

2. AIMS AND OBJECTIVES OF THE ACTION

2.1 General objective of the action

General objectives of the JA are:

- Support the further development and sustainability of the Orphanet database on rare diseases, which is run by a large consortium of European partners and is the biggest global repository of information about rare diseases.
- Contribute to solutions to ensure an appropriate codification of rare diseases in health information systems
- Continue implementation of the priorities identified in Council Recommendation 2009/C151/02 and the Commission Communication (COM 2008 679) on RD, with a view to ensuring the sustainability of the recommended priority actions, and to support the work of the Commission Expert Group on Rare Diseases by gathering expertise and producing data necessary to its action.

This Joint Action aims at expanding and consolidating the achievements of the former joint actions on rare diseases supported by the European Commission, the Orphanet Joint Action -aimed at developing a comprehensive European database for rare diseases- and the EUCERD Joint action -aimed at delivering recommendations for a shared European policy on rare diseases. More precisely, this proposal has the ambition to help member states to implement the recommended measures adopted or to be adopted by the Commission Expert Group on Rare Diseases (CEGRD) and to produce the data necessary for countries to do so. Interactions between the production of data at the Orphanet database level and the implementation of policy priorities including codification will be strengthened during this JA.

2.2 Specific objectives of the action

Specific Objective Number	**1**	
Specific Objective	Maintain, expand and update the nomenclature and classification of RD and its alignments with other terminologies (including ICD10, SNOMED CT, ICD11 and OMIM)	
Process Indicator(s)	Ouput indicator	Outcome indicator
Creation of newly described RD, and new categories and subtypes to improve RD classification	Around 500 created entries per year	-Increase in the number of visits of the website according to the baseline of 3,660,000 visits in 2014 -Satisfaction and utility of the relevant categrory according to the end users (assessed through online survey and proactive surveys) -Number of downloads of the relevant category: increase compared to data presented in the 2014 activity report.
Inclusion of RD in ICD11	Around 6000 RD transmitted for inclusion in the ICD11 at M36	
Alignment of Orphanet entries with ICD10, OMIM , SNOMED CT, UMLS and MedDRA	Around 6000 RD aligned with ICD10, updated alignments with OMIM, SNOMED CT, UMLS and MedDRA completely processed	
Inclusion of RD in SNOMED CT	Around 6000 RD transmitted for inclusion in SNOMED CT at M36	
Specific Objective Number	**2**	

Specific Objective	**Expand and update the encyclopedia of RD**	
Process Indicator(s)	Ouput indicator	Outcome indicator
Production of definitions for RD	Around 6000 definitions produced by M36	As above
Update of existing abstracts and production of those lacking	500 new or updated texts produced per year	
Specific Objective Number	**3**	
Specific Objective	**Produce scientific annotations for RD**	
Process Indicator(s)	Ouput indicator	Outcome indicator
Annotation with epidemiological data	Around 6000 RD with at least one epidemiological data (prevalence, incidence, birth prevalence or number of case/families) at M36	As above
Annotation with genes	450 new gene-diseases links/year	
Production of cross-references with genetic databases (HGNC, OMIM, UniProtKB, Reactome, ensembl, IUPHAR)	All the genes included in the database cross-referenced at least with HGNC. Exhaustivity for the other cross-references.	
Specific Objective Number	**4**	
Specific Objective	**Improve database transparency and traceability and manage stakeholders contributions and database curation process**	
Process Indicator(s)	Ouput indicator	Outcome indicator
Web-based knowledge management services	Web service fully functional at M36	Number of external curators (superior to 32 active expert groups or individual experts assigned to a group of disorders – at least 1 per classification-)
Publication of procedures and data sources and updates history	Sources available on Orphadata Versions and differentials available in Orphadata Procedures published in the website orpha.net	Number of downloads of procedures documents (no baseline available)
Specific Objective Number	**5**	
Specific Objective	**Update and expand the directory of expert services in every MS, including centres of expertise, clinical laboratories, patient registries, mutation registries, biobanks, patient organisations, European reference networks when set up.**	
Process Indicator(s)	Ouput indicator	Outcome indicator

Expansion, update and quality control of directory of expert resources in each participating MS	Exhaustivity of the representation of expert resources in each country Annual mailing to the professionals database for updating expert resources Dates of last updates displayed in the Orphanet website Post-release quality assessment by MS scientific advisory boards once a year.	-Increase in the number of visits of the website according to the baseline of 3,660,000 visits in 2014 -Satisfaction and utility according to the end users (assessed through online survey and proactive surveys) -Number of downloads of the relevant category: increase compared to data presented in the 2014 activity report.
Specific Objective Number	**6**	
Specific Objective	**Make Orphanet, the European database for RD sustainable**	
Process Indicator(s)	Ouput indicator	Outcome indicator
Elaboration of information material explaining the different modules of the Orphanet database specifically designed for the MS authorities to allow informed decision on all parts of Orphanet	Information material distributed by M18	All MS interviewed and feedback retrieved. Number of MS committed to participate in the elaboration of the sustainability plan.
Elaboration of a sustainability plan based on the evaluation conclusions	Sustainability plan proposal by M24	Adoption of a sustainability plan by participating MS and EC.
Specific Objective Number	**7**	
Specific Objective	**To define and set the necessary strategy and tools to implement the Orpha codes in the European countries.**	
Process Indicator(s)	Ouput indicator	Outcome indicator
Complete review of current coding systems actually in place in member states and actual plans.	Review document of existing technical implementations for RD coding of MS by M12	Review paper published for all Consortium partners (e.g. at RD-ACTION-workspace) and results presented at Consortium meeting
Production of guidelines on how and why to code with Orpha codes in health systems in order to generate standardized and comparable data all over member states	Standard procedures and guide for the coding with Orpha codes by M24	Guidelines published for all consortium partners (e.g. EU workspace)
Elaboration of a coding file allowing for good quality and consistency coding across MS	An European integrated master file by M24	Draft coding file published for all Consortium partners (e.g. at RD-ACTION workspace)
Testing of coding file and guidelines in existing coding tools	Test results and a refined file and guidelines by M36. Number of single RD entities registered using	Final coding file Version 1 published for all Consortium partners (e.g. at Orphanet-website and/or RD-ACTION workspace)

	the master file, number of more specific codings and ratio of correct and incorrect coding entries	
Plan for routine maintenance and update of developed resources	A draft recommendation on how to guarantee long term availability of developed resources by M36	Presentation of draft recommendation in paper and at final Consortium meeting and/or to CEGRD for further consideration and decision-making.
Specific Objective Number	**8**	
Specific Objective	Support the work of the Commission Expert Group on Rare Diseases	
Process Indicator(s)	Ouput indicator	Outcome indicator
Implement a policy methodology to support the work of the Expert Group on Rare Diseases	Methodology published by M12	Recommendations, reports and opinion papers disseminated to the CEGRD on a regular basis
Drafting, elaboration and revision of recommendations, reports and opinions for approval and adoption by the Expert Group	Reports, recommendations and policy position papers issued from eigth workshops during the JA until M36	Satisfaction assessed through post - workshops surveys Number of approved recommendations/updates/reports/Opinions
Production of data to support policy analyses and decisions	Publication of compiled data (Orphanet Report Series) on specific areas (publication rates depending on the topic). At least 13 different ORS	Number of downloads of the ORS (2014 baseline: 2,250,000) Satisfaction assessed through the online satisfaction survey and pro active surveys
Specific Objective Number	**9**	
Specific Objective	Support the implementation of EUCERD/CEGRD Guidance and Recommendations in MS, and follow ongoing progress and best-practices in RD	
Process Indicator(s)	Ouput indicator	Outcome indicator
Present the State of the Art of RD activities in Europe	An ongoing, electronic State-of-the-Art resource on policies for RD across the EU MS (with an annual summary report)	Web-stats on the number of visitors to the online resource Number of downloads of the SoA annual summary (maintain current level of 15,000 per year) Number of countries contributing national information each year (28)
Ensure an efficient information flow between the European level and the MS level	Involvement in approximately 30 national conferences on implementation of European RD policy for RD in MS during the JA. Publication of 20 Orphanews issues per year and monitoring the subscription and satisfaction rates.	Conference reports each detailing number of participants and the stakeholder group to which they belong (e.g. patient, clinician, policy-maker etc.) Satisfaction of Orphanews readers and number of subscribers increased compared to 15,700 subscribers in 2014

Facilitate the dissemination of knowledge and information and allow input between all the stakeholders	Organisation of the European Conference on Rare Diseases involving patients, healthcare professionals, researchers, policy-makers, industry	Number of participants (800) Satisfaction survey of the participants
Monitor MS developments in implementing national RD activities	Coordinate annual MS completion of the EUCERD Recommendations on Core Indicators and upload to the SoA resource.	Number of MS completing the Indicators table each year (28)
Provide tailored support to MS in implementing national policies relating to RD	Evidenced a) during the national conferences themselves and b) by building on Debrief Reports to generate external analyses of national strengths and challenges, following each national conference.	Number of updated Debrief Reports (20 by the end of the JA
Facilitate sharing of experiences on how to implement RD Recommendations and Policy outputs at national level	Set-up forums on SoA resource dedicated to thematic areas, making accessible the key resources and enabling online discussions via interested stakeholders	Number of visitors to these subject-specific pages Number of countries visiting these pages
To support national authorities to quantify the burden of RDs and available resources for sustainable and resilient health systems	Set-up a workshop to share the analysis of the context (epidemiological, political and health situation) within M12. Set-up a workshop to develop common knowledge on equity and resilience of health systems for RD within M24. Set up a conference to disseminate tools and recommendations on sustainability of implementations RD policy priorities at M36. Policy briefs produced to support national authorities for sustainable heatl systems for RD.	Shared analysis of the context (epidemiological, political and health situation) to be presented in the workshop report. Increased knowledge on sustainability of RD-policies assessed by questionnaires after working sessions. Number and satisfaction of attendees to the conference on sustainability by means of survey during and/or after the meeting. Establishment of a network for sustainable health systems for RD
Disseminating information on RD-Action and the RD field to groups/domains outside the 'traditional' RD sphere, and enabling the integration and engagement of these stakeholders alongside ongoing RD-specific groups	Conference Calls and attending meetings and workshops of initiatives from fields including - though not limited to- e-health, chronic diseases, medical education, and social services, and reporting on these integration activities in policy reports to the	Number of individual non-RD-specific projects/initiatives the Policy WP has engaged with directly, as reported in the policy reports at M18 and M36 (target is 10 by M36)

and initiatives	CEGRD at M18 and M36	

3. TARGET GROUPS

Actions in this proposal are intended to meet the needs of patients and their relatives, healthcare professionals, researchers, industry and policy makers.

The current proposal targets experts and policy-makers to support them in their work delivering recommendations and position documents on RD policy. Patients are not only ultimately taking benefit from these policies, but are involved, through their patient organizations, in them. The JA will thus work with experts, patients, policy-makers, people involved in codification and in registries, industrials, and all the stakeholders in the field.

As far as Orphanet database is concerned, it is a strategic element in national policies for RD. The nomenclature and classification of RD are the basis for codification in health information systems (see below). The Orphanet encyclopedia is intended to help professionals in their clinical practice, but patients and their relatives also benefit from it. The high-quality directory of expert resources and patient organizations is of help both for health professionals and for patients, improving referrals and patient orientation. Directory of resources related to research promotes networking and collaborations. Industrials can identify experts and resources by this mean. Directory of orphan designations and drugs linked to their indications and to rare diseases is also an important piece of information for patients, healthcare professionals, researchers and pharma industry. Production of reports (ORS) containing compiled data and analysis is of help for policy-makers, and for experts in the CEGRD. Data is delivered through the Orphanet website, which is accessed more than 20,000 times/day from more than 200 countries, as well as massive datasets for free re-use in machine-readable formats through Orphadata (approximately 14,000 downloads/month) [figures from the "Orphanet-2014 activity report"]. The Orphanet website is currently available in 7 languages, but the textual information is translated in many more languages. The IT evolution of the database during this JA will allow to translate the website in virtually every EU language, depending on MS translation capability.

Through the development of coding guidelines and master file all routine users (collectors as well as users) of data on rare diseases will be guided in how to collect data in a standardized way thereby allowing a more reliable interpretation of the collected data. Patient groups, decision makers as well as politics will benefit as they will be able to compare more reliable data and identify patients better once the standardized way of coding is used. Investigators in clinical research will benefit from a reliable identification of RD patients in health information systems and will be able to capture data from the clinical setting. People involved in the codification will be guided in the coding process, which will make it more easy and reliable.

4. POLITICAL RELEVANCE

4.1 Contribution to meeting the objectives and priorities defined in the annual work programme

The current proposal is in perfect line with the objectives of the a third Programme for the Union's action in the field of health (2014-2020), in particular those concerning RD. The aims of this proposal include improving coordination of the action of health professionals, patient organizations and stakeholders in areas in which the European level provides an added value, in particular ERNs, cross-border healthcare and genetic testing, interoperability between databases and registries, and consistent codification of patients suffering from RDs. Moreover the proposal will explore the issues of resilience and sustainability of health systems for RDs. We will

provide efficient support implementing EC recommendations to both the CEGRD and to MS, disseminate best practice guidelines and provide practical guidelines and instruments for RD codification in health information systems in order to achieve better and safer care for European citizens suffering from rare diseases.

This support includes producing and maintaining a standard nomenclature for RD and the European database on RD, Orphanet, that aggregates data on RD, both scientific and related to MS activities, in a structured, re-usable way.

Patient empowerment is particularly addressed by the delivery of information on rare diseases and on expert services in Europe through the Orphanet website. One of the Orphanet aims is to contribute to « the transparency of healthcare activities and systems and the availability of reliable, independent and user-friendly information to patients ». Patients are also actively involved in the definition of policy priority areas to be implemented in MS (WP6) as well as in disseminations activities (WP2) through both the European Conference on Rare Diseases and in National conferences, so as to ensure a back-and-forth communication between patients and decision-makers.

4.2 Added value at EU level in the field of public health

RD-Action EU added value will be demonstrated by:
- Promoting implementation of EU recommendations on RD at the national level
- Promoting best practice through European Reference networks and through dissemination of best practice guidelines through the Orphanet website.
-Consolidating Orphanet as the European database for RD by developing a sustainability plan involving both EC and MS.
-Developing guidelines and adaptable tools for codification of RD in HIS in a consistent way across Europe
- Allowing back-and-forth information between MS and the CEGRD, thus the EC, in order to achieve coherent policies at both European and MS levels.
- Strengthening networking activities across Europe (ERNs, registries, integration of data production and policy making)

Although each rare disease affects a small number of persons, RD patients are numerous and scattered across countries. Expertise is also scattered and networking is necessary in order to achieve results both in research as in healthcare. Sharing both expertise and data at the European level as well as harmonising practice and mutualising human and technical resources and methods (such as codification methodology) is necessary to overcome the problems posed by rare diseases.

The availability of a common multilingual added-value database for RD is beneficial to all European MS that do not need to duplicate the efforts on this matter. The availability of a unique repository expert resources information collected in every country according to standard common procedures and quality assessed is extremely useful both for data analysis by country and at the European level (using comparable data), which can help identifying issues, set target and take actions.

The standardization on how to code RD patients with the necessary detail allows for reliable epidemiological data at the European level, and for identification of patients in order to achieve a critical mass of cases for transnational clinical research.

Expertise gathered from stakeholders across the European Union allows to support the work of the CEGRD in order to promote implementation of the priorities identified in Council Recommendation 2009/C151/02 and the Commission Communication (COM 2008 679) on RD, producing knowledge to guide this implementations in a sustainable way, in compliance with the principles conveyed by the EC Communication on effective, accessible and resilient heath systems (COM (2014) 215 final). This work is intended to harmonise policies for RD in MS.

MS and the CEGRD will be engaged in an evaluation process resulting in a sustainability plan in order to ensure long-term sustainability of both the Orphanet database and the nomenclature, for the latter is necessary to address coding needs.

4.3 Pertinence of geographical coverage

This JA puts together efforts from 53 partners (beneficiary and collaborating) from all MS, achieving a full European coverage. It is a key of success for it will allow for promoting transfer of European recommendations into national policies, and to collecting information and concerns from MS to the CEGRD, thus to the European Commission, so completing the virtuous circle.

Furthermore, this JA benefits from the input from 11 collaborating partners outside the EU, contributing to its international impact. In particular, the visibility, in the Orphanet database, of expert services outside Europe contributes to facilitate the establishment of collaborations and networking. This is particularly true when considering interactions with international research initiatives such as IRDiRC (i.e. Hugh Dawkins, country coordinator for Orphanet Australia, is acting as vice-president of the IRDiRC executive committee).

4.4 Consideration of the social, cultural and political context

The current Joint Action aims at promoting the implementation of EU policy recommendations on RD at the MS level. A key of success is to ensure two-ways information between the European and the National level, taking into account the economic, social and political context in each country. This will be achieved through both the policy areas prioritisation methodology set up in WP6 and the specific dissemination activities developed in WP2, i.e. the European Conference on Rare Diseases, the National conferences (building on the achievements of EUROPLAN) and a conference on sustainable health systems for RD (at M36). Special attention will be kept in making the key information available in as many languages as possible, depending on local resources, both concerning dissemination channels and the Orphanet website, including its national entry points maintained by Orphanet national teams in local languages. The necessary evolutions of the database language standards will be performed in order to deliver translations produced by countries contributing to this effort.

The Orphanet database only contains data submitted voluntarily or recorded with the consent of those concerned. This applies to all email addresses and/or nominative data recorded. Orphanet data collection and dissemination of information abide by the legal provisions in force in the countries concerned: the professional code of ethics, any law on computing and liberties, on intellectual property rights, electronic data protection and any law or regulation applicable.

The French personal data protection committee (*Commission Nationale de l'Informatique et des Libertés; CNIL*) gave a favourable opinion for the creation of *Orphanet* on 5 May 1997. Whenever someone's name is mentioned, this person has given his/her authorisation to quote his/her name.
This proposal does not include studies involving human beings.

5. METHODS AND MEANS

General objective 1: Support the further development and sustainability of the Orphanet database on rare diseases

WP4. Orphanet, the European database for rare diseases

The Orphanet's overall methodology for data production follows four steps, adapted to the specificity of each piece of information: data capture and selection, data collection or production, validation, and quality control. During the JA, a substantial effort will be directed to optimize the whole process, in order to automatise as much as possible the data capture, to ease the way the community can input the database, to ease the edition and curation process, to make the latter traceable and transparent, and to improve the quality assurance strategy.

Specific objective 1: Maintain, expand and update the nomenclature and classification of RD and its alignments with other terminologies (including ICD10, SNOMED CT, ICD11 and OMIM). During this JA, the nomenclature and classification, together with mappings to other terminologies, will be maintained and expanded, so as to follow the evolution of knowledge. The methodology involves a comprehensive and regular literature survey monitoring >50 core journals and regular Medline queries, to detect newly described rare disorders – around 5-10 per month-, and new facts on already known disorders, and to capture good-quality articles on RD to be disseminated in the Orphanet website. It also includes taking into account the input from the RD community in a more

systematic way. Demands are analyzed and validated by an internal committee and/or external experts, before the nomenclature and classification are adapted. Changes are submitted to expert validation and quality control. Mappings to ICD10, OMIM, SNOMED CT, UMLS, MedDRA and ICD11 are produced and updated. In particular, Orpha-ICD11 mappings give rise to new proposals for addition/corrections in ICD11, and during this JA a more systematic mapping and update process intended to represent RD in SNOMED CT will be developed. Mappings are expert-curated together with the annotation if the alignment is exact or partial.

Specific objective 2: Expand and update the encyclopedia of RD. The Orphanet encyclopedia is produced by medical writers based on literature reviews and peer-reviewed by internationally recognized experts. The strategy producing new and updated information on RD will be adapted during this JA so as to optimise the use of other sources of information avoiding duplicating efforts (i.e. expert networks, learned societies, patient organisations). The ultimate goal is to have at least a definition for each rare disease (that will be exported to ICD11 and SNOMED CT), and up-to-date structured abstracts for the less rare diseases. It will be achieved by expanding the editorial teams to other participating countries progressively, while offering a web-based curation platform to the community of experts (see below). New teams will be trained and coordinated in order to ensure compliance to the standard Orphanet procedures.

Specific objective 3: Produce scientific annotations for RD. Links between genetic RD and genes based on the survey of most recent publications will continue, as will the cross-referencing with other genetic databases (OMIM, HGNC, and others) in use in patient registries and mutation databases, which is made by semi-automatic cross-reference each month. The role of genes in the aetiology of RD is also provided (causative, major susceptibility factor, modifier, etc) and submitted to validation criteria and to expert validation. Epidemiological figures are also produced proactively querying the literature and submitted to expert validation (prevalence, incidence, birth prevalence, lifetime prevalence, and number of cases/families) per geographical area. Data produced by registries (such as EUROCAT) and by European projects (such as RareCareNet) are surveyed and incorporated to the database.

Specific objective 4: Improve database transparency and traceability and manage stakeholder's contributions and database curation process. The web Orphanet knowledge management platform will be jointly developed by the INSERM and Bio-Lark, whose experience in this field is already in use for the edition of the Bone Dysplasia Ontology. INSERM will scientifically drive the developments and contribute to the bio-informatic effort. Authorisation to input, edit or curate the different information (nomenclature, genes, epidemiology, alignements to external resources and definitions (abstracts) will be given to experts or groups of experts (learned societies, networks etc), the final curation by the different Oprhanet teams allowing publication of pre-release validated data. The web-based curation plateform will be integrated to a new IT system involving knowledge bases and APIs in order to ease the update end publication process. An Orphanet database versioning will also be established and differential files produced and published in Orphadata (Orphanet download platform) with timely adaptations to the codification needs defined by WP5. Data sources and information on validation status of the data (metadata) will be produced by the improvement of edition tools able to store metadata.

Specific objective 5. Provide a directory of expert services in every MS, including centres of expertise, clinical laboratories, patient registries, mutation registries, biobanks, patient organisations, European reference networks when set up. In order to perform expert resources data collection and update in each country member of the Orphanet consortium, a team is set up composed by a Country coordinator and one or several information scientists depending on the foreseen amount of data to be collected and updated. The workload of data collection in each country depends on the size and the country population, and also if national collection has already began in the previous Joint action. Data collection methodology includes: identification of the sources of information in the country, collection of the information on expert services according to the SOPs, validation of the data according to the workflow established by the country coordinator, publication of the data using the edition tools developed at the coordination level (INSERM) and communication with the coordinating team. These tasks are the responsibility of the information sicentist, and the whole cycle is managed through a web-based curation tool (called Collector). He/she is under the supervision of the country coordinator to whom he/she should report to. He/she is technically supervised by the INSERM-based Quality Manager (Task 4.5). The country coordinator is responsible for data quality management of expert resources in the country but also of the

organisation of the governance of the project at national level, including liaison with learned societies, health authorities and patient organisations, and the build-up of the Orphanet team if applicable.

Specific objective 6. Make Orphanet, the European database for RD sustainable. This objective will be addressed in WP3, and comprises an evaluation phase prior to the elaboration of a sustainability plan.

- **Evaluation of Orphanet**: it will be carried out using three complementary approaches:

- A series of interviews of Orphanet officers and of other stakeholders conducted by the INSERM (thematic institutes of Public Health and of Genetics) and by the French DGS as major funding bodies of Orphanet, resulting in a report;

- Online user satisfaction surveys targeting active users of the database at predefined time intervals in all participating European countries and beyond;

- A user satisfaction survey that will be proactively sent to representatives of all stakeholders in the field of RD in all Member States (MS) in order to guarantee participation of all stakeholder groups in at least one survey instrument.

In order to assess the results of the interviews and surveys, appropriate general, as well as stakeholder-specific indicators will be developed in advance, including process, outcome, coverage, and - if applicable - impact indicators. The assessment itself will be summarized in an evaluation report that will be sent to the MS representatives in the CEGRD, as well as representatives of the Ministry of Health and, where applicable, the Ministry of Research of each MS, seeking a re-assessment of the quality, value and impact of the Orphanet database from the European point of view (evaluated by the CEGRD) and the national point of view (evaluated by these Ministries). To support the latter, the evaluation report will be accompanied by a comprehensive survey, covering inter alia their needs on information, codification, follow-up of health policy and research measures in their countries. Information material explaining the different modules of the Orphanet database specifically designed for the MS authorities (see below) will be sent as well.

Development of an Orphanet sustainability plan. Further to the evaluation process, and to structure and facilitate the informed decision process of the MS on such plan, a "modular representation" of the database will be elaborated with the help of the Orphanet central team, describing each service or tool as an elementary module that cannot be further subdivided into smaller units (like the hard- and software IT platform including the core personnel to run this platform as one basic module, the management structure as another basic module, the database of expert clinics as another basic module, etc), and and the budget needed to run each module.This representation will be accompanied by a brief description of the content, impact, and national, as well as European value of each module. In addition, a checklist with a graphical representation of this modular system will be developed and distributed to the relevant MS authorities, providing Member States with a tool to easily prioritise their needs and their support for the database on the national and the European level. All documents will be further explained to the relevant MS representatives in physical and distant meetings by Orphanet country teams as well as the central team in order to prepare the decision process and initiate the following development of a concrete sustainability plan. To this end, a special session at the 2nd annual meeting will be arranged, and distant work will be organised to set up a sustainability plan during year 2.

General objective 2: Contribute to solutions to ensure an appropriate codification of rare diseases in health information systems

WP5. Steering, maintaining and promoting the adoption of Orphacodes across MS

Specific objective 7: To define and set the necessary strategy and tools to implement the Orpha codes in the European countries. In order to capitalize on the experiences already ongoing in some European countries implementing the Orpha code as a specific codification system for RD, a Steering group will work during the three-year JA length by face-to-face and distant meetings. A virtual working space will be shared. During the first year, a project manager will coordinate a draft compilation of use-cases necessary to draft coding guidelines and master-file content and will present the results in a document. In the second year a master-file (IT-specifications will be based on the document established in year one) and codification guidelines will be produced according to the conclusions of the steering group in order to ensure consistency in codification amongst MS so as to derive conclusions at the supranational level. In the 3rd year of the JA, a testing phase of the master-file will be

performed, resulting in the necessary improvement of the master-file and guidelines, which will then be implemented. Tests will be performed with existing national tools (experiences for France and Italy) that can then be shared amongst MS. During year 3, the task leaders and the steering group will design a draft recommendation for next steps needed to address long-term maintenance, and sustainability of the developed resources and guidelines in the realm of the Orphanet database, which will be presented to the CEGRD for consideration and decision-making.

General objective 3. To continue implementation of the priorities identified in Council Recommendation 2009/C151/02 and the Commission Communication (COM 2008 679) on RD, with a view to ensuring the sustainability of the recommended priority actions, and to support the work of the Commission Expert Group on Rare Diseases (CEGRD) by gathering expertise and producing data necessary to its action.

WP6. Policy Development for RD and Integration with other relevant initiatives

Specific objective 8: Support the work of the Commission Expert Group on Rare Diseases.

The methodology to be used to underpin the development and delivery of policies and recommendations will involve all Associated and Collaborating partners in the WP as a Consultative Group who will advise the UNEW development team and participate in workshops and other meetings according to expertise and interest. The cycle of work will include identification of priority areas, integration of relevant initiatives and projects, identification of other stakeholders to provide relevant feedback, compiling of documentation and organising workshops, feedback and consultation with the CEGRD, and ongoing review and updating of outputs as required.

Each topic area will be assigned to a member of the development team at UNEW who will lead on production of preparatory documents, definition of the participants and contents of relevant workshops, provision of secretariat support for the workshops (to be hosted by Contributing Partners), production of reports and consultation papers. The development team will also be responsible for updating the CEGRD on relevant initiatives as well as delivering recommendations and opinions for approval and adoption. Priority areas will be identified by the Joint Action in conjunction with the CEGRD and European Commission. Interactions with the Orphanet national teams (WP4) into policy areas will also be developed over the course of the JA, thereby providing linkage with the Member States across the different areas of activity.

The principal forum for bringing together stakeholders to discuss draft outputs will be the thematic workshops, 8 of which have been foreseen in the budget of this WP. They will be organised in different Member States represented in the WP on specific themes. The organisation of these workshops, and all pre- and post-workshop activities, will be the responsibility of UNEW. =The workshops will be hosted by members of the Consultative Group (other WP participants) and attended by leaders in the various areas. In addition, the Policy Researchers will act as the key point of contact and facilitator to engage relevant expertise in order to prepare draft policy documents for workshops and meetings and eventual presentation to the CEGRD.

EURORDIS will specifically support UNEW in this policy work through the following tasks: to represent RD patients in WP6 management activities, including conference calls, workshops and development and dissemination; to build awareness and capacity of patient organisations to support the emerging grouping of rare diseases into thematic RD ERNs and their stepwise expansion to ensure coverage of all RDs; to support the organisation of patient involvement and advocacy into the governance of new healthcare pathways, CoE and RD ERNs structures; to collect, and act on, RD patient experience of care and ensure this experience informs the development of best practice guidelines for coordination of care, timely diagnosis and access to high quality care and treatment; to support the development and revision of policy, guidelines and recommendations to ensure they continue to be patient-centric and based on the current needs of this population; to ensure the CEGRD is informed by RD patients and to contribute to the Report on the State of the Art of Rare Diseases in Europe; to contribute to promoting the alignment and dissemination of knowledge and experience of the Joint Action WPs into other EU funded project, such as RD Connect, Registries, RareBestpractices.

Specific Objective 9: Support the implementation of EUCERD/CEGRD Guidance and Recommendations in MS, and monitor ongoing progress and best-practices in national plans/strategies for RD

There are two dimensions to supporting the implementation of EUCERD/CEGRD Guidance and Recommendations at the national level: one is via dissemination and engagement activities, and the other entails a tailored approach to support individual MS in implementing RD-related policies.

The organisation of the **European Conference on Rare Diseases (ECRD; WP2)** in 2016 is a major dissemination and engagement activity, which will involve all relevant stakeholders, including the CEGRD, the EMA (in particular the COMP and CHMP), IRDiRC, E-RARE, Orphanet, learned societies, such as the European Society of Human Genetics (ESHG), the European Federation of Internal Medicine (EFIM), the European Hospital and Healthcare Federation (HOPE), the International Federation of Social Workers (IFSW), industry representatives, including EFPIA, EUCOMED and EuropaBio. All stakeholders will be actively involved, through the Programme Committee, the selected speakers and the participants in regular consultation with members of the CEGRD. Wide dissemination and call for participation will be performed (allocated to the Operating Grant of EURORDIS) including amongst others: call for sessions and posters, dedicated website and mailing; media, e-news, press releases, websites, social media, etc.; dissemination of the outcomes of the Conference through newsletters (EURORDIS, Orphanews), EURORDIS website, and partner websites.

The national **workshops** organised under WP2 are essential avenues for the dissemination of EUCERD/CEGRD policy documents. The methodology of these includes the following:
The development of the common elements of the programmes based on the technical and policy guidance of the EUCERD/CEGRD recommendations and other relevant activities that will result from the JA; ensuring a common quality and methodological process throughout the Member States in which the workshops will take place; the signature of the letter of agreement with local authorities laying down the respective engagements of relevant national authorities and workshop organisers vis-à-vis the JA and amongst themselves; the definition, together with the National Alliances for Rare Diseases, of their tasks and responsibilities in the workshop organisation; ensuring that all main stakeholders are involved and invited to attend; ensuring that the report of the workshops is produced in national language by national organisations and that it is translated in English; dissemination of the reports through EURORDIS websites, through other stakeholder networks built in relevant EU funded projects and activities, such as RareBestPractices and by co-organisers through their websites, newsletters, as well as through the JA website.

The methods for the dissemination task on **sustainable health systems for RD** is as follows: the literature about health policy performance in Europe shows the availability of process' and 'outcome' indicators, 'intermediate' and 'final' outcomes measuring the impact of different factors on population health. These allow developing hypotheses that might explain why countries had adopted different policies with different impacts on health. These hypotheses take into account survival values, self-expression values, democracy, party politics, ethnic fractionalisation, and government effectiveness. These variables will be examined in the literature review in order to assess their fitness and to identify adequate tools for studying health systems resilience for RD. The method will use a systems dynamic approach, which lends itself to group model building through intensive, participatory consultation with stakeholders and representation and refinement of models using graphical systems tools, offering an effective means of exploring the determinants of systems resilience. The initiative will be developed through the following steps:

1. Establishment of working groups with representatives from EU Member States to share and better define the scope and the objects of study
2. Literature review of available documents on health systems equity and resilience for RDs
3. Analysis of the context in which the contemporary health care systems of the different EU Member States are unfolding, through:
    - Analysis of epidemiological data on RDs (starting from by the existing sources e.g. Platforms, Registries, Orphanet, etc.)
    - Analysis of the political situation
    - Analysis of the health situation

   A workshop will be organised to share this analysis
4. Assessment of the burden of diseases, the political and health situation in order to identify appropriate actions for sustainable health systems for RD. A Workshop will be organized with the main stakeholders for characterising equity and resilience of health systems for RDs
5. Establishment of Working groups on specific topics such as prevention, diagnosis, treatment of RDs, to provide Evidence-Based and useful Recommendations in order to reduce health inequalities and promote measures for sustainability of National strategies on RDs.

6. Production of policy briefs according to the best evidence for decision making on equity and resilience of health systems for RDs.
7. Final Conference (in Rome) to be organized at the end of the Joint Action.

The **Orphanews** newsletter (WP2) will continue to be produced at a twice a month pace. The editorial board and the overall methodology will be agreed during the JA kick-off meeting. The proposed methodology comprises a systematic literature review prior to the selection at the editorial meeting with the editor-in-chief. JA articles definition and content will be agreed with WPs leaders before submitting it to the newsletter editor. The editorial board composed by WP2 participants will contribute to the content of the newsletter and will review the newsletter before publication.

The **State of the Art report**, planned under this JA (WP6) as an online resource, will play an important role in supporting MS in implementing national policies and activities pertaining to RD, and will also be a mean of monitoring progress and identifying good practices in each MS. The overall methodology for creating and updating this resource will be agreed in M6, but the aim is to have a regularly updated site demonstrating how each MS is addressing the challenges of RD (usually within the NP/NS for RD). The table of Core Indicators for RD NP will foreseeably be completed annually, and this will be uploaded to the State of the Art resource, for transparency. In addition, thematic area forums will be set-up, to promote key resources relevant to that topic and also to support MS in sharing ideas and challenges relating to national implementation. Finally, tailored support will be provided to MS, based initially on the Debrief Reports of the EJA and then updated after each national workshop/conference (organised as above under WP2).

Patient empowerement

EURORDIS will work as an interface between the JA and the CEGRD, and rare disease patient groups, facilitating patient consultation, participation and engagement in the work of the different thematic areas of the JA. EURORDIS will ensure that the work within the field of Social Policies continues to be performed in liaison with the CEGRD, MS, patient representatives and other key stakeholders in the field of social policies and social innovation, whilst taking into account the implementation of NPs for RDs and the measures in the social field that are being gradually adopted in MS.

6. EXPECTED OUTCOMES

The overall expected outcome of this JA is the effective and sustainable implementation in MS of the Council recommendations on an action in the field of rare diseases and, in particular, the appropriate and consistent identification of patients in health information systems across Europe as a result of the implementation of the Orpha codification by MS. This constitutes a milestone for interoperability between HER, registries and databases, therefore allowing to generate data necessary to improve knowledge on RD and to produce indicators to follow the impact of the implemented RD policies. Another outcome is to achieve the goal of having a sustainable European database for RD, providing information and data, both scientific and on expert resources across Europe and beyond. This database, Orphanet, will be made more open and dynamic so as to stick to the rapidly evolving field of RD.

7. WORK PACKAGES

7.1 Overview on work packages

The JA work is organized in three horizontal WPs and three core WPs. Horizontal WPs include the coordination of the whole JA; the dissemination of JA activities and more widely of the policy documents and decisions by a large panel of dissemination tools; the evaluation of the JA achievements and in particular of the Orphanet database for RD in view to set up a long-term sustainability plan.
Core WPs include the Orphanet database for RD (WP4), the guidance and support to implement the Orpha codification in health information systems (WP5), and the prioritization of thematic policy areas in which support is needed to achieve effective implementation (WP6).
Cross-talk between WPs is a major operational objective of this JA in order to build a virtuous circle of

functioning. As a result, the database will be adapted to the policy needs that will benefit from the data in the database. Both will benefit from the input of stakeholders achieved by a back-and-forth dissemination strategy. That management structure and the contribution of each WP representatives in every other WP, as well as the large consortium of partners participating in virtually all the WPs, guarantee the overall coherence of the JA.

7.3. Gantt Chart

		Year 1	Year 2	Year 3
WP1 - Coordination				
T1.1	Organization of the Joint-action kick-off meeting			
T1.2	Monitoring of the activities and overall quality of the project			
T1.3	Ensure communication and information exchange amongst JA participants			
T1.4	Intermediary for all communication with the Chafea and the DG Sanco			
D1.1	Kick off meeting & report			
D1.2	Annual meeting & meeting reports			
D1.3	Interim reports			
D1.4	Final report			
WP2 - Dissemination				
T2.1	To set up and maintain the Joint Action dissemination tools			
T2.2	To produce the Orphanews newsletter			
T2.3	To hold the reference ECRD and OrphanProducts in 2016			
T2.4	To support national and European integration through national workshops			
D2.1	JA Dissemination plan			
D2.2	Newsletter Orphanews			
D2.3	Two editions of the State of the Art Report			
D2.4	Leaflet			
D2.5	Layman version of the final report			
D2.6	Web-site			
D2.7	Progress dissemination report on health systems equity and resilience for			
D2.8	Final dissemination report on Sustainable health systems for rare diseases			
WP3 - Evaluation				
T3.1	Evaluation of the Joint action achievements			
T3.2	Evaluation of the European database for rare diseases, Orphanet			
T3.3	Develop a sustainability plan for the Orphanet core activities			
D3.1	Evaluation of the deliverables compared to plans			
D3.2	Reports on the external evaluation of Orphanet			
D3.3	Sustainability plan for Orphanet activities in the future			
WP4 - Orphanet, the European database for rare diseases				
T4.1	Coordination of the Orphanet consortium			
T4.2	Maintain and expand the rare diseases database			
T4.3	Develop the necessary tools to track changes of the Orpha nomenclature			
T4.4	Provide a directory of expert services in every MS			
T4.5	Provide overarching database data management/quality control/IT support			
T4.6	Produce reports (Orphanet Report Series)			
D4.1	Orphanet nomenclature with mappings and annotations			
D4.2	Web-based knowledge management platform			
D4.3	Orphanet DB versionning and differentials between versions			
D4.4	Annual updates of Orphanet knowledge base of expert resources			
D4.5	Orphanet Report Series			
D4.6	Orphanet users' survey			
WP5 - Steering, maintaining and promoting the adoption of Orphacodes across MS				
T5.1	To define strategy and tools to implement the Orpha codes in the EU			
T5.2	Specification of the required resources for coding RD consistently			
T5.3	Promoting the Orpha codes across MS			
T5.4	Plan for next steps to address long-term maintenance/sustainability			
D5.1	Review document of existing implementations for RD coding of MS			
D5.2	Standard procedures and guide for the coding with Orpha codes			
D5.3	A European integrated master file			
D5.4	A set of coding helping tools for rare diseases			
D5.5	Draft recommendation for routine maintenance			
WP6 - Policy Development for RD and Integration with other relevant initiatives				
T6.1	Implement a robust policy methodology to support the work of the EGRD			
T6.2	Provide comprehensive policy support to the EGRD			
T6.3	Produce the Report/Resource on the State of the Art of Rare Diseases			
D6.1	Progress report on policy delivery and implementation			
D6.2	Final report on policy delivery and implementation			
D6.3	2016 Edition of the State of the Art Report			
D6.4	2017 Edition of the State of the Art Report			

9. ACTION MANAGEMENT STRUCTURE

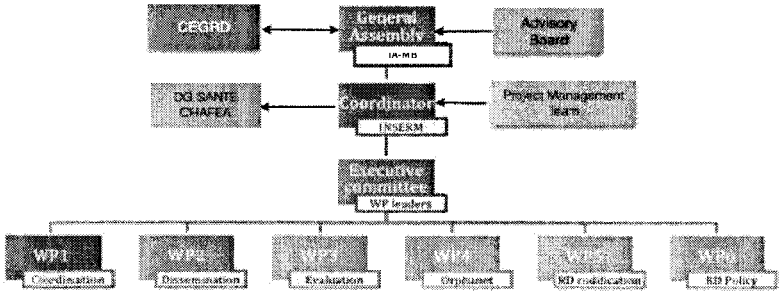


Fig.3 Overall management structure

The management structure of **RD-Action** has been defined to:

- Plan, organize and monitor the effort to achieve the technical objectives within **RD-Action**'s constraints of time schedule and budget.
- Define clearly the decision making procedures and bodies
- Run performance control procedures leading to the expected quality of achievements and deliverables described in the work plan.
- Continually inform the partners on the project status and progress
- Drive the project implementation in accordance with administrative, financial and legal issues defined by the European regulations and national peculiarities.
- Guarantee that the rights and obligations and access rights of the partners are kept compliant with the Grant Agreement signed with the Commission and the Consortium Agreement.
- Implement and follow-up an appropriate strategy for knowledge and intellectual property rights management
- Overview the ethical issues and the gender balance

A **consortium agreement** will be signed between the participants to specify the project governance, the internal organization of the consortium, the management of the project and any other critical aspects of the project like the management of intellectual property and access rights to results and liability and confidentiality arrangements within **RD-Action**.

The organisational structure of the consortium will be as follow:

- The Coordinator Ana Rath (INSERM) will monitor the compliance by beneficiaries with their obligations under the Grant Agreement
- The General Assembly, thereafter Joint Action Management Board (JA-MB) will be responsible for the major strategic, scientific, political and financial decisions to be taken for **RD-Action**
- The Executive Committee, composed by WP leaders, will provide assistance to the coordinator for the scientific monitoring of **RD-Action**
- The Project Management Team will provide assistance to the Coordinator and the JA-MB and ensure the overall management of **RD-Action**
- The Work package Leaders will be in charge of managing their Work Package teams
- The International Advisory Board will advise the JA-MB on strategic directions for the **Orphanet database** to be considered.
- The Commission Expert Group on Rare Diseases (CEGRD) will advise the JA-MB on the priority actions to be

carried out.

Decision making body: the Joint action Management Board

The JA-MB is the decision-making body of the consortium and the supervisory body for the execution of the project.

Composition

The JA-MB consists of one representative of each participant institution, one representative of DGSante and one representative of CHAFEA. It will be permanently chaired by the Coordinator.

Role

The JA-MB is in charge of the overall direction and major decisions with regard to the Project and will principally guide the strategic direction of the project. This will involve:
-Review of project and sub-project status
-Evaluation of external and internal factors impacting on the project
-Decisions on necessary adaptation of the overall strategic plan to the status of the project
-Allocation of budget whenever changes need to be done
-Inclusion and exclusion of partners
-Potential methods to exploit the obtained results

Meetings

The JA-MB will meet once a year from the start of the project execution. Intermediate meetings will be held by web-conference if needed (allowing sharing and modification of documents online while talking over the phone).

The JA-MB meetings will be convened and prepared by the Scientific Coordinator with the support of the Project Management Team. The coordinator will prepare in writing the agenda of the meetings and send it to each JA-MB member before meetings, with all relevant background information and supporting documents to any decision proposed to be taken. For decision-making purposes, each JA-MB member shall have one vote. Quorum and majority requirements will be laid down in the Consortium Agreement. Decisions may be taken via audio- or video-teleconferences or during meetings. Minutes of JA-MB will be sent by the project manager to all members.

Scientific and Administrative Management

The Coordinator

The Coordinator will act as the direct link and intermediary between the Commission and the Consortium, receive and distribute payments, keep accounts of all aspects of the project including financial efforts and reports, and ensure that the project follows the pre-signed contractual obligations. In these tasks, the Coordinator will be assisted by the Project Management Team (PMT) and the Executive Committee (EC). The Coordinator will be responsible for:

- Supervision of the progress of the projects (tasks, milestones, budget)
- Formulation of detailed project plan on a subtask/partner level including detailed budgeting and scheduling;
- Set-up and maintenance of project documentation archive and project procedures manual;
- Preparation, organisation, administration, minutes and follow up of scientific meetings
- Writing/compilation of management summaries, progress reports including mid-term assessment, task reports, periodic reports and final report;
- Monitoring and collection of individual partner administrative documents and statements of expenditures, and transmission to the Commission. Keeping track of payments, which are to be made to each partner;
- Coordination of communication between partners and coordination between the consortium and other parties;
- Composition of exploitation management team and share-out tasks and responsibilities;
- Ensure timely reporting to the Commission
- Hold the accounting of the project
- Final report including a publishable summary report, a plan for use and dissemination of foreground and a

report covering the wider societal implications of the project in conformity with Commission's guidelines. The Coordinator will also act as a mediator in case of conflicts or disagreement between the partners.

The Executive Committee (EC)

The WP leaders will be the interface between the different partners involved in each WP and the Coordinator, ensuring optimised concerted actions and a responsive scientific management of the project. The WP leader is responsible for the overall follow up of the concerned WP and will ensure an efficient communication within the WP including the organisation of periodic WP meetings.

WP leaders are responsible for monitoring the WP progress ensuring that the objectives of the project are performed within the strategy of the work plan. This will entail accordance with the agreed milestones, production of deliverables and ensuring that each participant fulfils its commitment to each WP:

- To present progress report on the state of advancement of the WP
- To make proposals on the allocation of WP tasks, financial need and allocation among the contractors
- To draft and validate project deliverables on the WP to be submitted to the EC
- To identify potential risk(s) within the WP and propose contingency plans
- To inform the JA-MB of any other difficulty arising in connection with the WP.

WP leaders are collectively referred to as the **Executive Committee (EC).** The role of the EC is to provide assistance to the Coordinator for **RD-Action**'s scientific monitoring. The EC specific tasks will thus be to:

- Monitor and review the project's progress at regular Steering Committee meetings (distant conferences every 2 months)
- Prioritize the projects objectives and outcomes as identified in the Grant Agreement
- Formulate risk management strategies and ensure that risks are regularly reassessed
- Help the Coordinator resolve potential conflicts and disputes

The Project Management Team (PMT)

All management activities will be performed in direct collaboration with the Project Management Team (the Project manager Sylvie Maiella and the Financial Officer Corentin Fort).

The PMT will assist the Coordinator and the JA-MB in the following activities:

- Preparation of any document connected to the project (meetings agenda and minutes, consortium agreement, report to the commission, etc)
- Day to day administrative and financial management including the drafting of reports
- Details on management structure, reporting routine, management techniques and communication;
- Organize the foreground management of the project
- Organize reviews and meetings
- Ensure transparency in communication on the project between all participants
- Coordinate activities of the International Advisory Board

The Orphanet International Advisory Board (IAB)

An "International Advisory Board" composed of independent representatives of stakeholders is in charge of peer reviewing the Orphanet project, it reports to the JA- MB and issue comments and recommendations (at the latest one month prior to the annual meeting) which will enable the OMB to define changes to be introduced to the project. The members are nominated by the JA-MB. The membership should cover the following fields: Scientific databases, information technologies, ontology and nomenclature, communication and education, R&D, Rare diseases, orphan drugs and patient organisations. The members are nominated for 3 years. They may be re-nominated.

9.1 Quality of the partnership

All the participants of RD-ACTION have been nominated by the respective MS ministries of Health for their involvement on the field of rare diseases and their capacity to run the activities foreseen in this joint action. Moreover, most of the participants have already successfully collaborated in former projects around RD proving the excellence of the Consortium:

INSERM and GOG, MUW, FPS, WIV-ISp, BAPES, Croatian alliance for RD, NKCVO, UT, Rinnekoti, RKI, OCMO, OPBG, Centre for disease prevention Latvia, VULSK, LUMC, NKSD, IPCZD, UMF IASI, UNIBA FOB, UKC Ljubliana, CIBER, Karolinska, Center of medical genetics and primary health, Belgrade University, CMU Institute of Medical Genetic University of Istanbul, CMU Institute of Medical Genetics Switzerland, have already collaborated on the Orphanet Europe Joint Action 20102206 project (2011-2014).

INSERM and MHH, MUW, BAPES, ICPZ, UMF IASI, UMCL, KI, CIBER and CUNI have also succesfully collaborated in the RDPORTAL 20061109 and RDPORTAL2 20091215(2006-2010)

INSERM and Office population Health Genomics, dept of Health Gvmt of WA, Garvan Institute of Medical Research, University hospital of Aarhus, Foundation for Genetic and Rare Diseases (GeRaD), Institute of Medical Genetics.
The Chaim Sheba Medical center, Institut national d'hygiène, Department of medical genetics Maroc, Mc Gill University currently collaborate within the Orphanet consortium.

INSERM, EURORDIS, UNEW, VULSK, MUW, UKC, BAPES, GERAD, ISS and CIBER have succesfully collaborated in the EUCERD Joint Action (2012-2015). INSERM and EURORDIS have collaborated during the Rare Disease task force (2009-2010)

9.2 Capacity of the staff

1 France – Institut National de la Santé et de la Recherche Médicale (INSERM – Ana Rath

Coordinator institution, description of competence, experience, leadership and authority in the action area
The coordination institution is the French National Institute of Health and Medical Research (INSERM), founded in 1964; it is a public scientific and technological institute which operates under the joint authority of the French Ministry of Health and French Ministry of Research. INSERM has been acting as coordinator of the Orphanet consortium since the beginning of the European project in 2001. The INSERM also acted as co-ordinator of the Rare Diseases Task Force (2004-2009) and the European Union Committee of Experts on Rare Diseases (EUCERD) (2010-2013). The INSERM lead the scientific secretariat of the current EUCERD Joint Action.

Key staff of the coordinator – description of competence (leadership and authority) and experience in the action area.

- The project coordinator Dr. Ana Rath is a medical doctor and has a Master degree in Philosophy. She oriented her career to medical information in 1997 (working in medical information and terminologies) and joined Orphanet (www.orpha.net) in 2005. In Orphanet she has been in charge successively of the Orphanet encyclopaedia, the rare diseases database, and of the Scientific Direction. She became Deputy Director in 2011 and is currently acting as Director of Orphanet since May 2014.
- Ana Rath is the Managing Editor of the WHO's ICD11 Topic Advisory Group for Rare Diseases since 2009. She serves as Editor in the Ontologies section of the Orphanet Journal of Rare Diseases (www.ojrd.com). She chairs the Orphanet rare diseases ontology (ORDO).
- The project manager Sylvie Maiella has a PhD in Human Immunology and has been trained to Transversal management. She oriented her career to scientific project management in 2010 and since 2011 she is has been acting as Orphanet international coordinator and project manager of the previous Orphanet Europe Joint action 20102206.
- The financial and administrative officer Corentin Fort has a bachelor degree in Business management and administration. He has been employed from 2008 to 2013 by the French Ministry of Defence as a HR officer in charge of the strategic workforce planning. He has joined Orphanet in 2013 budget managing amongst other the Orphanet Europe Joint action and the 2013 Operating Grant.
- The disease and classification team manager Annie Olry has a PhD in cellular biology. She has worked for Orphanet since 2007. First in charge of the literature survey, she has been in charge of the diseases inventory and classification system for 4 years. Now, she manages the scientific team and ensures overall scientific validity

of the diseases inventory and classification system, genes inventory, epidemiological and disability data. She is involved in most of the scientific partnerships, notably handling the Orphanet rare diseases ontology collaboration.

- The Quality Manager Charlotte Gueydan has a PhD in molecular biology and biochemistry with a strong background in genetics and has been trained in Quality management. She has worked as a research associate from 2010 to 2012. She joined Orphanet late 2012 and she is in charge of the development of the quality assurance policy of the Orphanet database of organising and implement quality control processes and quality assurance and of coordinating the teams in the Orphanet network in carrying out the actions inherent in the quality assurance process and quality control.
- The data manager for expert resources Martin Arles has a bachelor degree in biological sciences and a master degree on scientific communication. He worked at the communication department of the CRG in Barcelona before joining Orphanet-Spain in 2009 as information scientist. He joined the Orphanet coordinating team in 2014 and he is currently the data manager for the patient care expert resources.
- Marc Hanauer the Chief Technology officer has a master's degree in Sciences Information & communication. From 2000 to 2009 he worked for different Internet Start-ups. He is Engineer at INSERM and CTO of Orphanet since 2009.
- Charlotte Rodwell has a Masters degree in History and Modern Languages and has worked at the INSERM since 2009, coordinating the scientific secretariats of the EC Rare Disease Task Force (2009 -2010) and the European Union Committee of Experts on Rare Diseases (2010-2013). She was the communications officer of the EUCERD Joint Action (2012-2015). From December 2014 she is a public official of the INSERM and is in charge of developing Orphanet's partnerships and strategic communications.

2 Austria - Medical University of Vienna (MUW) - Till Voigtlander

Participant' institution

The Medical University of Vienna (MUW) is Austria's largest medical university and serves since 2004 as the main host of the Austrian Orphanet country team. In these past 10 years, the MUW has proven its capacity to provide the Orphanet country team with all infrastructure and all technical, as well as administrative support necessary to successfully fulfill the tasks of a country team (collection of national data, dissemination of information, etc.).

Key Staff

- A country coordinator with a university degree in medicine, 14 years of professional experience (neurobiological laboratory medicine) in the diagnosis of certain hereditary, as well as acquired rare neurological diseases, 10 years of experience managing the national Orphanet team and 6 years of active participation in several national and European boards and expert groups related to rare disease healthcare policies. High command of English.
- An information scientist with a with a university degree in medicine, 7 years of professional experience (neurobiological laboratory medicine) in the diagnosis of certain hereditary, as well as acquired neurological rare diseases and 6 years of experience working as information scientist and/or internal project manager for the national Orphanet team.

3 Belgium - Federal Public Service Health (FPS) - Pol Gerits

Participant' institution

The mission of the Federal Public Service Health (Service public Fédéral Santé Publique) is to develop a transparent, dynamic and scientifically-based policy that take care of people's health, provide a safe food chain and a better environment for everybody, both today and in the future. The mission of DG GS is to contribute to a health care policy - including the field of rare diseases - in order to provide a continuum of quality care that is financially and geographically accessible to everyone.

Key Staff

- P. Gerits, PhD (Health psychologist) - He is advisor to the DG and member of the Commission Experts Group on Rare Diseases and is participating in the JA Orphanet. In the framework of this Joint Action he will working on WP4 and this in close collaboration with the Scientific Institute of Public Head. He will also be the contact person for this Joint Action at the Federal Public Service Health.
- Dr. I. Mertens is medical doctor and Head of the unit data management. She will participate in WP5 (orphacodes).

- Dr.S. Van Den Bogaert is a medical doctor and is the head of the organization of healthcare unit. She is also responsible for the implementation of the national plan on rare disease and she is the alternate for Belgium in the Commission Experts Group on Rare diseases. She will participate in WP6.

4 Belgium - Scientific Institute for Public Health (WIV-ISP) - Elfriede Swinnen

Participant' institution

The Scientific Institute of Public Health (known as "WIV-ISP") provides support for public health policy through scientific research, expert opinions and divisional tasks. On the basis of scientific research, it formulates recommendations and solutions for a proactive health policy at the Belgian and international levels. The WIV- ISP assesses the status of health and health indicators on the basis of scientific methods which it approves, develops and analyses within a certified quality framework.

Key Staff

- Joint Action manager ; bio-engineer cell&gene technology with PhD in medicine and 8 years of experience with multiple projects in the rare disease field
- Information scientist with a university degree in biology having high familiarity with the activities of genetic centres currently specialising in rare disease coding
- Information scientist with a university degree in biomedicine & biotechnology

5 Bulgaria - Bulgarian Association for promotion of education and Science/Rare Diseases institute (BAPES) - Rumen Stefanov

Participant' institution

Bulgarian Association for Promotion of Education and Science (BAPES) is a non-government non-profit organisation, working in the field of rare diseases since 2003. By participating in a number of EU-funded projects, implementing a series of epidemiological registries and organising public and scientific events, BAPES helps to stimulate research on rare diseases in Bulgaria, as well as to develop and provide care and services for people with rare diseases and their families.

Key Staff

- Rumen Stefanov, MD, PhD is the founder and the Chair of BAPES. He is a professor in public health and Dean of the Faculty of public health at the Medical University of Plovdiv. Dr. Stefanov is a participant in several EU funded projects. He is an active member of the Task Force on Rare Diseases, EU Commitee of Experts on Rare Diseases, Commission Expert Group on Rare Diseases, International Rare Diseases Research Consortium. Dr. Rumen Stefanov was a member of the drafting group of the EU Communication for rare diseases (COM/2008/679) and chair of the drafting group of the National Program for RD at the Ministry of Health of Bulgaria.
- Elena Eneva, MSc is trained psychologist with experience in project management. Ms. Eneva is active in the rare disease community in Bulgarian, being a board member of DEBRA Bulgaria and member of the National Alliance of people with rare diseases.

6 Croatia - Croatian Alliance for Rare Diseases (HSRB) - Anja Kladar

Participant' institution

Croatian Alliance for Rare Diseases works in the field of Rare Diseases since 2007. As the executive body for Orphanet Croatia we work since 2013. The Alliance conduct many activities on national and regional level and gathers 20 member associations and more than 450 inviduals with more than 300 different diagnoses. In our everyday work, we cooperate with different expert associations, institutions on local and national level and other important stakeholders.

Key Staff

- Anja Kladar, physiotherapist and project manager, bacc.oec., active in the field of Rare Diseases since 2006. Fluent English speaker with more than 4 years of experience in project management. During her work she finished different trainings (RD registers, management of volunteers, public policies etc.)
- Tihana Kreso, degree in journalism and political science, active in the field of Rare Diseases since 2012. Fluent English speaker with more than 2 years of experience in activity coordination. Also, she is in charge for project financial reports within the Alliance.

7 Czech Republic - Coordination center for rare diseases in University hospital in Motol (NKCVO) - Milan Macek

Participant' institution

The National Coordination Centre for Rare Diseases (NKCRD) was officially established by the Czech Ministry of Health in 2012 within the frame of the Department of Biology and Medical Genetics of the Second Scool of Medicine of Charles University and University Hospital Motol, Prague. This centre belongs to the top facility in the country in terms of diagnostics and rare for rare diseases. The clinical background of the relies on the comprehensive services offered at the largest university hospital in the country.

Key Staff

- Professor Milan Macek Jr. MD, PhD is the chairman of the largest academic Medical Genetics and DNA diagnostics institution in the Czech Republic. His major specialty comprises DNA diagnostics, counselling and clinical management in the area of rare diseases .He is the President of the Czech Society of Medical Genetics (www.slg.cz), past President (2011) and board member of the European Society for Human Genetics (www.eshg.org), board member of the European Society of Cystic Fibrosis (www.ecfs.eu), ex-Board member of the European Society of Human Reproduction and Embryology (ESHRE.eu) and current member of the EC Expert Group on Rare Diseases (former EUCERD.eu)
- Dipl. Ing. Ivana Funkova - senior FP6/FP7/Horizon2020- project administrator
- Marek Turnovec MD- bioinformatician and biostatistician, with experience in online patient registries and Czech rare-disease-related databases.

8 Estonia - University of Tartu (UTartu) - Vallo Tillman

Participant' institution

University of Tartu (UT) has been teaching medical doctors for more than 380 years and is the only institution in Estonia for that purpose. UT is today among the top 1% of the world's most influential research establishments in clinical medicine. Department of Paediatrics has been the leading partner to establish the national plan for rare diseases in Estonia and has been participating in many EU grants on rare diseases. UT has been the associated partner of Orphanet for many years.

Key Staff

- Prof Vallo Tillmann, MD, PhD, Professor in Paediatrics, the national co-ordinator of the project, is the team leader of UT. He has led also previous Orphanet projects. He has been more than 10 years the Estonian representative at the COMP. He has led the group who established the national plan for rare diseases in Estonian published in May 2014. He has been the national co-ordinator of many EU projects (EUROPLAN, EURO-WABB, etc) and principal investigator of many national research projects on rare diseases.
- Dr Rita Teek, MD, PhD, Research Fellow in Paediatrics, Senior Information assistant, has been participating in the Orphanet project since 2011. Her expertise in medical genetics has been very useful running the project. Mrs Sille Vahtra, Information Assistant, has gained great experience managing the Orphanet Estonia web-page and will be responsible for its everyday management.

9 Finland - Rinnekoti Foundation Norio Centre (Rinnekoti) - Sirpa Ala-Mello

Participant' institution

The Rinnekoti Foundation produces and delivers a wide range of expert healthcare and social inclusion programs for persons with intellectual or developmental features, including rare genetic diseases. The Norio Centre provides services especially for children and families with rare disorders including syndrome diagnostics and genetic counselling, outpatient appointments, genetic laboratory services, wide information services, training and education.

Key Staff

- Country co-ordinator: a medical doctor (1983 University of Turku), PhD (1999) and Associate Professor in Clinical Genetics (2008 University of Helsinki), speciality in clinical genetics (1996 University of Helsinki), the main interest and experience in clinical and research work has focused on rare genetic dysmorphic multianomaly syndromes with developmental disorders. The Norio Centre was formed in 2013 when The Family Federation of Finland´s Medical Genetics Department and The Rinnekoti Foundation´s Rehabilitation Home for Children and the Genetics Services Unit were merged. As the Head of the Norio Centre she will continue as contry co-ordinator starting in 2015 after the retirement of the former contry co-ordinator.

- Information scientist: a master's degree in social science (2003 University of Helsinki, Faculty of Social Sciences) and studies in information science (2005), has worked in Orphanet project since 2007.

10 France - Assistance Publique - Hopitaux de Paris (APHP) - Remy Choquet

Participant' institution

The Necker Hospital for Children is the leading French hospital to support rare and genetic diseases. It carries the national databank for rare diseases project for more than 8 years (beginning with the CEMARA project) that describes more than 4000 rare diseases coded with Orphanet for 270000 patients. The team is also responsible for enchancing locally the RD coding plan in HIS.

Key Staff

- Rémy Choquet will lead the task 1 in the WP5. He has a PhD in medical informatics. His specific interests are knowledge engineering, from terminologies to ontologies. He is the operational director of the national databank for rare diseases and leads the interoperability framework work to enable data collection at national scale of comparable data to enable RD epidemiology studies for all RD. His peripheral view over databases for rare diseases and his experience with the national registry project will help in setting the right strategy to gather at EU level comparable data for rare diseases.
- Céline Angin will coordinate the work during the JA. She worked several years at Orphanet as a project manager for communication purposes. She has a master in biology applied to communication. She has project management skills for multi stakeholder projects. Her experience both at Orphanet for 5 years and the BNDMR team for more than a year will facilitate the coordination work for the 1 task of the WP5.

11 France - European Organisation of rare Diseases (EURORDIS) - Yann Le Cam

Participant' institution

EURORDIS, the European Organisation for Rare Diseases, is a patient-driven pan-European alliance of rare diseases patient organisations representing the voice of an estimated 30 million living with a rare disease in Europe and their families. EURORDIS has (as of November 2014) 646 member organisations, in 60 countries, 26 of which are EU Member States. EURORDIS has been involved in the elaboration of policies related to RDs thereby participating to the establishment of the current regulatory environment and policy framework. EURORDIS has 4 representatives and 4 alternates sitting at the Commission Expert Group on Rare Diseases.

Key Staff

- Yann Le Cam, Chief Executive Officer: Yann is a co-founder of EURORDIS (1996-1997) and joined as CEO in 2001. Yann has dedicated 20 years of professional and personal commitment to health and medical research NGOs in France, in Europe and in the United States in the fields of cancer, HIV/AIDS and rare Diseases. He served as COMP's Vice-Chairman from 2000 to 2006. He is a member of the Commission Expert Group on Rare Diseases and other Commission Working groups.
- Patrice Régnier, Finance & Support Services Unit Director: Patrice holds a degree in Management from the "Ecole Supérieure de Commerce" of Paris, specialised in finance applied to non-profit associations. Professional experience includes: Four years in Management Auditing for Généthon (the premier French gene therapies research and applications centre for rare diseases), 10 years in EURORDIS to manage finances, human resources, information technology, office operations and legal affairs.
- Valentina Bottarelli, EU Public Affairs Senior Advisor: Valentina is European Public Affairs Senior Advisor at EURORDIS, where she works in the Brussels' office to help raise awareness on rare diseases in the EU policy agenda. She coordinates EURORDIS' contribution to the EUROPLAN project and to WP4 of the Joint Action Working for Rare Diseases, supporting aimed to support EU Member States in developing national plans for rare diseases. Valentina holds a MA in European Politics and Administration from the College of Europe, Bruges, and has extensive experience in the area of EU policies and programmes, having worked as a senior consultant on public affairs and communications.
- Matt Johnson, Healthcare and Research Director: Matt holds a Master of Arts in Production Design from University College London. He has been working in the field of RDs for more than x years, and has 14 years of experience in National Health Service, England. He was been the responsible commissioner for health services nationally for RDs, across 50 Centres of Expertise for rare cancers, genetic conditions, rare paediatric conditions, transplants and highly specialised mental health conditions. Matt is currently responsible for supporting the development of Centres of Expertise, European Reference Networks, RD Connect.

- Ariane Weinman, EU Public Affairs Manager: Ariane holds a Master of Arts in International Policy Studies. She has been working in the field of rare diseases for more than 10 years, and has over 15 years of experience of managing projects in the field of medical and biological sciences (Federation of Paris Public Hospitals, Scientific Department of the French Embassy in China). Ariane is currently involved in the EUCERD Joint Action 2012-2015, in the Work Package dedicated to national planning for rare diseases.
- Raquel Castro, Social Policy Manager: Raquel holds a Bachelor of Arts in Communication and Multimedia as well as a post graduate degree in Project Management at the Lisbon School of Economics and Management. She has over 6 years of experience in field of rare diseases. She is currently involved in the EUCERD Joint Action 2012-2015 Work Package dedicated to 'Provision of Specialised Social Services and Integration of Rare Diseases into social services and policies' and was formerly the coordinator of the Portuguese national help line for Rare Diseases.

12 Germany - Medizinische Hochschule Hannover (MHH) - Joerg Schmidtke

Participant' institution

Hannover Medical School is one of the top ranking medical faculties in Germany. It is the host of Orphanet Germany since 2002. It is involved in the German National Action Plan for Rare Diseases. It runs a Center for Rare Diseases as one of the first of this type of research and patient care oriented set-ups in Germany.

Key Staff

- Prof. Joerg Schmidtke is a professor and medical specialist of human genetics. He holds a university degree in medicine and has 42 years of professional experience in research and patient care. He was coordinator of Orphanet Germany since 2002. He was Director of the Institute of Human Genetics of Hannover Medical School from 1990-2014. He is currently Director of the Rare Disease Center of Hannover Medical School.
- Dr. Kathrin Rommel is a biologist with a doctorate in human genetics. She is working as an information scientist for Orphanet Germany since 2002.

13 Germany - Deutsches Institut für Medizinische Dokumentation und Information (DIMDI) - Stefanie Weber

Participant' institution

DIMDI is the publisher of official medical classifications and provides additional terminologies and standards that are important for health telematics. DIMDI develops and operates database-supported information systems for drugs, medical devices and health care data and is responsible for a program of health technology assessment (HTA).

Key Staff

The DIMDI classification team comprises of 7 Medical doctors with expertise in medical informatics as well as classifications and terminologies, one computer scientist specialized in medicine, a health information manager and a clerical assistant. The classification team is part of the medical information department with approx. 50 employees from all fields of biosciences.

14 Hungary - Országos Tisztifőorvosi Hivatal (OCMO) - Melinda Csáky-Szunyogh

Participant' institution

National Public Health and Medical Officers' Service (NPHMOS) is composed of the Office of the Chief Medical Officer (OCMO) and national institutes under the leadership of OCMO. It is a central independent budgetary authority, led by the Chief Medical Officer (CMO). The Rare Disease- Centre, -Joint Action and the Hungarian Congenital Abnormalities Registry have been relocated to the OCMO. The RD field is the priority under our strategies and we follow the Hungarian National Plan for Rare Diseases.

Key Staff

- Melinda Csáky-Szunyogh is coordinator of the Hungarian Congenital Abnormalities Registry (HCAR), in Budapest since 2008. She graduated in the Semmelweis University, Budapest in 1998. In 2004 she received an MSc degree in Healthcare Management. Since 2000 she is the Hungarian Case-Control Surveillance of Congenital Abnormalities program international contact. Since March 2015 she works at Department of Public Health, Strategic Planning and Epidemiology at OCMO. Numbers of her publications are more than 70 and as a member of several national and international scientific societies represent the case of congenital anomalies. Her research area is the cardiovascular epidemiology of congenital malformations.

- Anita Szilágyi works at Department of Public Health, Strategic Planning and Epidemiology at OCMO. Since 2013 she works as an epidemiologist in the Hungarian Congenital Abnormalities Registry. She graduated in 2012 in Hungary as a public health expert. She holds a master's degree in health policy planning.

15 Hungary - Semmelweis Egyetem (SE) - Molnar Maria Judit

Participant' institution

The Semmelweis Rare Diseases Network, a biobank of detailed clinical & lab data at SU, coordinated by IGMRD with expertise in core activities – diagnostics & treatment, research and education, the institute continuously expands the participation in policy development, exchange of knowledge, professional international collaborations, and representation of academie in decision making processes. SU owns the newest NGS technologies for detecting rare disorders.

Key Staff

The Institute of Genomic Medicine and Rare Disorders (IGMRD) is led by the SU Vice-Rector for Scientific Affairs with M.D., PhD, Med. Habil. and D.Sc., 25+ years of professional experience in neurology, psychiatry and clinical genetics (special focus rare diseases), participation in 10 research grant projects. The team responsible for the scientific implementation will consist of 4 research fellows/3postdocs/2specialists/1professor with experience in patient care, registry building, myopathology, molecular biology, clinical genomics and bioinformatics. A project management team of 2 people with excellent English communication skills, having 10 years of managerial experience in international projects will support the management and technical issues. A dedicated financial manager with professional experience of project accounting will be responsible for the financial questions. A professional Innovation Centre will provide support for the project management.

16 Ireland - Health Service Executive (HSE) - Tony O'Brien, Prof Eileen Treacy

Participant' institution

HSE Ireland, has the capacity to deliver on the suggested Work Packages to include WP4 (Objective 4), and WP2 (Dissemination and Organisation of RD Workshop). This will be provided by the established National Rare Diseases Clinical Programme (NCPRD) (Clinical Lead Prof. Eileen Treacy/Country Co-ordinator), with the support of the NCPRD Programme Manager and NCPRD Working and Advisory Groups in collaboration with our national RD Alliance. The work for WP4 will be provided by an experienced Information Scientist (Msc in Genetics).

Key Staff

The country Co-ordinator Prof. Eileen Treacy, MD, FRCPC, FRCPI, FCCMG, National Clinical Lead for the Irish Rare Diseases Clinical Programme, (NCPRD) has specific training and substantial experience in Clinical Genetics, Inborn Errors of Metabolism and Rare Diseases, obtained at McGill University, Montreal, Canada, Murdoch Institute, Melbourne, Australia and Necker Enfants Malades Hospital, Paris. As outlined in our Rare Diseases National Plan, we will be supported by the NCPRD Programme Manager, Ms. Dervela Gray, who has an MBA, has substantial project management skills and is a physiotherapist; with also support from the NCPRD Clinical Advisory Group and colleagues at the National Centre for Medical Genetics. The Project Manager/ Information Scientist will have an MSc in Clinical Genetics and extensive clinical experience in genetic counselling/project management. The IT/administrative supports will be provided by the Host Institution.

17 Italy - Ospedale Pediatrico Bambino Gesù (OPBG) - Bruno Dallapiccola

Participant' institution

The Bambino Gesù Paediatric Hospital (OPBG) is Italy's main Institute for Research and Health Care in Paediatric. It is widely recognized as referral centre for all paediatrics specialties and particularly for genetic and rare diseases. Since 2010 ORPHANET-Italia has been headquartered at OPBG, who contributes updating and implanting new data insights and providing information on rare diseases. Recent research activities within OPBG led to the identification of the gene behind 9 rare paediatric diseases.

Key Staff

Bruno Dallapiccola, Prof, MD, (M) : A specialist in medical genetics, one of the Italy's major experts in genetics and in the care and management of patients with rare diseases, with long lasting leading experience in ORPHANET and ORPHANET ITALIA. He will be supported by a health care manager with more than 20 years of experience in the definition of guidelines for rare diseases and a university degree in medicine and surgery, previously involved in ORPHANET, who will act as supervisor. Moreover the staff will be composed by a genetist with a university degree in medicine, currently involved in rare diseases diagnosis and research within OPBG, acting as information

scientist. A project manager, with a strong background in the management of website contents and scientific articles, will act as editorial assistant during the project.

18 Italy - Regione del Veneto (VR-IIBRD) - Paola Facchin

Participant' institution

Since 2002, Veneto Region established a care network of labelled RD Centres and appointed our Coordinating Center to create and implement an area-based Registry, designed as an information system to support this network and the care pathways of RD patients. From Veneto, it has been extended to other 8 Italian Regions (25 mill inhs). It monitors 3,000 RD entities (Orpha and ICD-coded), and records data on 80,000 RD patients and it is used by more than 5,000 professionals.

Key Staff

- Three epidemiologists with a university degree in medicine, a fellowship in Community medicine/Public Heath and/or a PhD in Epidemiology and at least 5 years of professional experience in RD epidemiology and RD coding and classification;
- A bioinformatic engineer with a university degree in informatics, at least 5 years of experience in ICT tools development, relational DB and web-based systems;
- A biostatisticians with a university degree in statistics, a PhD in Epidemiology and at least 5 year of professional experience in RD epidemiology ;
- A project technical assistant with a university degree and at least 3 years of professional experience in managing research projects and a high command of English.

19 Latvia - Center For Disease Prevention and control of Latvia SPKC) - Jana Lepiksone

Participant' institution

The Center for Disease Prevention and Control of Latvia has experience as a partner in several international projects, including Joint Actions and especially the previous JA Orphanet, where the Center participated as an associated partner. Our staff has long-year experience in international collaboration, statistics, data analysis, scientific work as well as maintenance and development of national registers in the public health sector.

Key Staff

- The country coordinator is a specialist with a master's degree in social science and 14 years of professional experience in health care organisation, statistics and registries at national level and at least 2 years of experience as a country coordinator in the previous Joint Action Orphanet, having also a high command of English.
- The information scientist is a public health analyst with a university degree in public health or medicine and at least 2 years of professional experience in public health or healthcare organisations, having also a high command of English.

20 Lithuania - Vilnius University Hospital Santariskiu Klinikos (VULSK) - Elena Jurevičiene

Participant' institution

Vilnius University Hospital Santariškių Klinikos was designated for participation in the Rare Diseases Joint Action activities under the Third EU program 2014-2020 by Ministry of Health of the Republic of Lithuania. The Institution has participated in Orphanet Joint Action since 2010. Vilnius University Hospital is a partner of several international projects (FP6, FP7, JA-Chrodis, INTERREG IIIB, IVC, Telemedicine networking etc.).

Key Staff

A pulmonologist with a university degree in medicine and at least 15 years of professional experience in pulmonology and pulmonary hypertension. A clinical geneticist with a university degree in medicine and PhD degree in genetic counselling of rare diseases and at least 20 years of professional experience in clinical genetics. A clinical geneticist with a university degree in medicine and at least 3 years of professional experience in clinical genetics, Orphanet national team information scientist at least 4 years. A cardiologist with a university degree in medicine and PhD degree in Pulmonary hypertension centre and at least 15 years of professional experience in cardiology and pulmonary hypertension. A children nephrologist with a university degree in medicine and PhD degree in Children rare diseases centre and at least 20 years of professional experience in children nephrology. All of them have high skills in English.

21 Netherlands - Leids Universitair Medisch Centrum (LUMC) - Gertjan B. Van Ommen

Participant' institution

Leiden University Medical Center (LUMC) is a high-ranking university medical center for research, education and patient care, employing 7000 people (http://hospitals.webometrics.info/en/Ranking_Europe). Orphanet NL is in the Dept. of Human Genetics, which has as main track record neurogenetics, lipid disorders and cancer. Coordinator Prof van Ommen's fields cover genome research, diagnostic technology, therapy development and societal aspects of genetics. He has been involved in Orphanet since 2008.

Key Staff

- Prof. Gertjan van Ommen, PhD; Orphanet country coordinator since 2011, specialised in neuromuscular diseases and biobanking. His main aim is to help improving diagnosis, therapy and prevention of rare and common diseases. He is founding member of BBMRI, the European Biobanking and Biomolecular Research Infrastructure, and heads the Dutch BBMRI-NL. He is Editor-in-chief of the European Journal of Human Genetics, past president of HUGO (1998-2000) and of the European and Dutch Societies of Human Genetics, board member of the American Society of Human Genetics (ASHG) and treasurer of the Public Population Project in Genomics and Society (P3G).
- Petra van Overveld, PhD in human genetics; programme and project management of large national and EU projects, involved in Orphanet since 2008 as project manager.
- Judith Carlier – de Leeuw van Weenen, PhD in endocrinology; information scientist Orphanet since 2011.

22 Norway - Norwegian Directorate of Health, HDIR - Bodil Stokke

Participant' institution

The Norwegian Directorate of Health is an executive agency and competent authority subordinate to the Norwegian Ministry of Health and Care Services. The political frameworks to which the Directorate is subject are the political platform of the government in office at any time and resolutions of the government and of Parliament. The political values conveyed by the annual national budget and the instructions in the annual letter of allocation from the Ministry of Health and Care Services are determinative.

Key Staff

- Senior adviser/Nutritionist, Genetic counselor and Sosial worker Bodil Stokke will use about 20 % of her work on Joint Action – EU wide rare diseases information databases; WP 5 Steering, maintaining and promoting the adoption of Orphacodes across MS and WP6 - Thematic Priorities of Expert Group and integation with other relevant initiatives. Stokke has been working with Rare diseases in Norway since 1989.
- Co-partner in HDIR will bee Senior adviser Jim Jianhua Yang who are responsable for national statistique og coding in Norway.

23 Norway - Norwegian National Advisory Unit For Rare Diseases (NKSD) - Lena Lande Wekre

Participant' institution

NKSD is a national service that unifies all resource centers for Rare Disorders in Norway.

Key Staff

Lena Lande Wekre (Special Advisor, MD, PhD) will use about 20% of her work on Joint Action /Orphanet – to coordinate this work in Norway. Collaborating partners will be the central staff in NKSD, and people representing the 9 Centres of Expertise for Rare Disorders (governed by NKSD) in Norway. The people working at the centers are medical doctors, nurses, social workers, physiotherapists, psychologists, occupational therapists, special teachers etc. working in multidisiplinary teams.

24 Poland - Instytut „Pomnik - Centrum Zdrowia Dziecka" (IPCZD) - Malgorzata Krajewska-Walasek; Krystyna Chrzanowska

Participant' institution

The Children's Memorial Health Institute is one of the biggest highly specialized pediatric hospitals treating children in Poland, mainly with rare diseases, from all country regions. Also a research institute working on innovations in pediatric medicine and implementation of international and national research projects in the field of rare diseases.

Key Staff

- Professors Małgorzata Krajewska-Walasek and Krystyna Chrzanowska : Clinical geneticists and pediatricians with decades of experience in rare diseases, mainly in clinical (dysmorphological) and molecular diagnostics, disseminating knowledge about rare diseases among physicians and patients, above 3 years of experience in managing Joint Actions at EU level, having also a high command of English.
- Dorota Karczmarewicz: Doctor of Veterinary Medicine with above 5 years of experience, working as an Information Scientist for Orphanet, having also a high command of English.

25 Portugal - Directorate-General of Health (DGS) - Alexandre Diniz

Participant' institution

The Directorate-General of Health (DGS) is a central service of the Portuguese Ministry of Health, responsible for the regulation, guidance and coordination of all activities related to health promotion and disease prevention. It further defines the technical conditions for an adequate provision of quality healthcare. It is also responsible for the planning of national health policies, besides ensuring the implementation of the National Health Plan. DGS coordinates the new Integrated Strategy for Rare Diseases 2014-2020.

Key Staff

- Project Leader and Coordinator: University degree in medicine, Director of the Department of Quality in Health (Directorate-General of Health), represents the Ministry of Health in various EU Committees and national inter-ministerial Commissions, 6 years of professional experience in managing + supervising the planning + programming of national policy for Quality in health system.
- Chief Technical Officer: Doctor's degree in International Health with specialty in Policy Analyses, Head of the Division of Quality Management from the Department of Quality in Health.
- Project Manager: Hospital Manager, candidate for a Doctor's degree in Information and Decision Systems.
- Scientific Expert: University degree in medicine, PhD in Genetics, Fellow in Medical Genetics at John Hopkins Hosp., Baltimore, USA, Full Professor of Medical Genetics, Research leader, Director of ORPHANET – Portugal.

26 Romania - University of Medicine and Pharmacy"GR.T.Popa"Iasi ORPHANET Center (UMF Gr. T. Popa) - Cristina Rusu

Participant' institution

The team from « Gr T Popa » University of Medicine and Pharmacy has attended many scientific meetings and trainings in the field of RD, having the ability to update and expand the encyclopedia of RD, the directory of expert services, to make the database sustainable, to support the stakeholders in introducing Orphacodes in daily practice and to support the Commission Expert group on RD and the implementation of its recommendations in Romania.

Key Staff

- Country coordinator: Professor (Medical Genetics Department, UMF Iasi), consultant in Medical Genetics and Pediatrics, head of the Medical Genetics Unit (Children's Hospital, Iasi), member of the National Committee of RD (commission of the Health Ministry that supports the achievement of the National Plan on RD in Romania) ; coordinator of Orphanet Romania in the last 5 years ;
- Information scientist 1: Senior lecturer (Medical Genetics Department, UMF Iasi), consultant in Medical Genetics, specialist in Endocrinology, information scientist Orphanet Romania since 2004 ;
- Information scientist 2: Lecturer (Medical Genetics Department, UMF Iasi), specialist in Medical Genetics, information scientist of Orphanet Romania since 2004.

27 Slovakia - Faculty of Medicine in Bratislava (CUMS) - Laszlo Kovacs

Participant' institution

Comenius University Medical School is the oldest and largest medical faculty in Slovakia. Its Department of Pediatrics is traditionally a leader in evaluating and treating patients with rare diseases from the whole country. In addition, it is involved in clinical and genetic reaserch in collaboration with other domestic and international centers. From 2010 the Slovak Orphanet Team is also resides on the Pediatric Department of the Comenius University Medical School.

Key Staff

The members of the Slovak Orphanet Team are:

- László Kovács, MD, DrSc, MPH, Professor of Pediatrics and Chairman – leading pediatrician and clinical geneticist with university degree of Doctor of Science and more than 30 years of professional experience in evaluation and treatment of patients with rare diaseses.
- Gabriela Nagyová, MD, Information Scientist. She is in training as clinical geneticist and is a PhD student in this field.
- Anna Hlavatá, MD, PhD., Team Manager – experienced pediatrician with a PhD degree working more than 20 years in the field of rare diaseases.

Prof. Kovács and Dr. Hlavatá are members of the Rare Diseases Working Group of the Ministry of Health of the Slovak Republic. All three team member are are involved in scientific, technical and managerial implementation of the action in Slovakia from 2010.

28 Slovenia - University Medical Centre Ljubljana (UKC Ljubljana) - Borut Peterlin

Participant' institution

The University Medical Center Ljubljana is the leading medical institution in Slovenia, providing medical services at the secondary and tertiary level, as well as educational and research activities. The Clinical Institute for Medical Genetics is a national authority in the clinical and laboratory diagnosis of rare and inherited diseases with extensive experience in genetic counselling, laboratory diagnostics, high-quality research and in leading and participating in many research projects, at the national and international level (FP5, FP6, FP7, DG Sanco).

Key Staff

- Prof. Borut Peterlin, MD, PhD, Clinical geneticist and Neurologist, heads the Clinical Institute of Medical Genetics, UMCL, which is a reference center for medical genetics in Slovenia. He is a member of EUCERD and Public Professional and Policy Committee at the European Society of Human Genetics (ESHG) as well as previous member of SCHER at DG Sanco and a board member of European Society of Human Genetics. He heads the Center for undiagnosed rare diseases at UMCL and has more that 25 years of experience in the field of rare and genetic diseases.
- Assit. Prof. Luca Lovrecic, MD, PhD, Clinical geneticist in training and Head of Laboratory for molecular cytogenetics. She has morethan 10 years of experinece in diagnosis of genetic diseases.
- Aleš Maver, MD, Head of Center for Mendelian Genomics, in charge of clinical next generaiton sequencing facility with 4 years of experience in NGS. All three, BP, LL and AM have been involved with previous Orphanet joint actions – BP and LL are national validators, LL and AM have been trained as information scientist for Orphanet.

All three are in charge of National web page.

29 Spain - Centro de Investigación Biomédica en red (CIBER) - Francesc Palau

Participant' institution

The Centre for Biomedical Network Research (CIBER) is a consortium depending on the Carlos III Health Institute (Economy and Competitiveness Ministry). The CIBER in the Thematic Area of Rare Diseases (CIBERER) is the reference centre in Spain for research into RD. Its main aim is to coordinate and further basic, clinical and epidemiological, as well as to foster translational research in RD. CIBERER consists of a team of over 700 professionals and integrates 62 research groups.

Key Staff

- Francesc Palau, MD, PhD: Specialist in paediatrics and medical genetics. CIBERER's Scientific Director and leader of the Programme in Rare and Genetic Diseases at the Principe Felipe Research Centre (CIPF). Scientific coordinator of the RD Strategy of the NHS, national coordinator of the Orphanet-Spain team and the leader of the Work Package 7 in the EUCERD Joint Action (EJA).
- Virginia Corrochano: PhD in Biology. CIBERER Biobank Coordinator, Orphanet-Spain and WP7 EJA project manager.
- Beatriz Gómez: BSc in Nursing and BA in Journalism. CIBERER's and WP7 EJA project manager.
- Ingrid Mendes: BSc in Biology. CIBERER's Scientific Manager. Asst. to CIBERER´s Scientific Director.
- Mª Elena Mateo: Bsc in Information Science, with 5 years of experience as Orphanet-Spain information scientist.

30 Sweden - Karolinska University Hospital (KS) - Magnus Nordenskjold

Participant' institution

The participant institution, the Department of Clinical Genetics at the Karolinska University Hospital, has an extensive and long experience in the field of genetic and rare diseases including diagnostics, genetics, healthcare and research. All personnel involved in this project has a solid background in the field and have been engaged in the former Orphanet Joint Action project in a direct or indirect manner and already contributed to the development of this consortium.

Key Staff

- Senior Physician, Clinical Geneticist, Professor in Medical Genetics, research group leader in rare and genetic diseases and head of the Department of Clinical Genetics.
- PhD in Physiology with long experience in Rare Disease related projects including project coordination of Orphanet – Sweden and research activities in rare diseases.
- Senior Physician, Pediatric Oncologist, Professor in Pediatric Hematology and Oncology, Research group leader in rare pediatric diseases and Director of the Research and Education at Karolinska.
- Associate Professor in Chemical Biology, Orphanet information scientist and involved in rare disease research and coordination tasks within the Centre for Rare Diseases – Karolinska.
- Senior Physician, Clinical Geneticist, Associate Professor in Medical Genetics, highly active and long experience in the field of rare disease research and project leader of the Centre for Rare Disease.

31 United Kingdom - University of Newcastle (UNEW) - Kate Bushby

Participant' institution

Newcastle University has an excellent pedigree in research and teaching with a strong interdisciplinary research base. In the UK it ranks in the top 5 for both hospital- and laboratory-based clinical subjects, with two-thirds of its outputs classified as world-leading or internationally excellent in the areas of ageing, chronic disease, genetics and stem cells. Based in an expert centre for neuromuscular disorders, the UNEW team led the TREAT-NMD network of excellence and retains its strategic and managerial role in the TREAT-NMD Alliance, whilst coordinating numerous neuromuscular-related projects and studies. The team has cemented its position in the broader field of rare diseases as exemplified by coordination of the EUCERD JA and RD-Connect. Whilst also highly active at the national and global levels, the Muscle Team at UNEW has participated in EU grants worth a total of approximately €73 Million and is able to contribute scientific, managerial and policy-based expertise in the field of rare diseases.

Key Staff

- Prof. Kate Bushby : Professor of Neuromuscular Genetics with over 200 publications, and current Coordinator of EUCERD Joint Action: Working for Rare Diseases; Deputy Director of MRC Centre for Neuromuscular Diseases; member of Commission Expert Group on Rare Diseases (one of 4 Independent Experts); formerly Vice-Chair of EUCERD; former Coordinator of TREAT-NMD Network of Excellence (FP6);
- Dr Stephen Lynn: Project Manager of EUCERD JA and TREAT-NMD, with a scientific background (PhD) and over 11 years of experience in healthcare and research policy

32 United Kingdom - UK department of Health (UK PHE) - Sarah Stevens

Participant' institution

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through advocacy, partnerships, world-class science, knowledge and intelligence, and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

The other associated partners are colleagues across the other home nations of Northern Ireland, Scotland and Wales. All 4 UK countries will work together to achieve the goals of ORPHANET UK.

Key Staff

- The information scientist has a background in biology with a university degree in veterinary medicine and a masters in global public health and policy.
- The country coordinator for the UK is a Consultant in Public Health, who following over 10 years in the National Health Service is now leading the development of a national congenital anomaly and rare disease registration service.

33 France – The National Directorate for Health - Direction Générale de la Santé (DGS FR) - Patrice Dosquet

Participant' institution

The National Directorate for Health (Direction Générale de la Santé – DGS) is one of the General Directorates of the French Ministry of Health, currently called "Ministry of Social Affairs, Health and Women's Rights". In particular, the DGS is responsible for proposing, planning, implementing and following public health policies with the objective to improve general population health, enhance the quality and security of healthcare and reduce health inequalities. The DGS participates to the discussions and deliberations concerning public health policies in European and international official bodies (WHO, etc.). The INSERM operates under the joint authority of the French Ministry of Research and the French Ministry of Health through the DGS. The DGS participates actively to the implementation and funding of the French National Plans for Rare Diseases, and directly to the funding of Orphanet activities in France.

Key Staff

Patrice Dosquet is a medical doctor, medical specialist in nephrology, with a master degree in Immunology. Since more than 20 years, he has been working in medical evaluation, clinical practice guidelines development, quality of care and certification of hospitals, in particular as a member of the French National Authority for Health. Since 2011, he has been working in DGS as project leader for the 2nd French National Plan for Rare Diseases in close relation with all the stakeholders of the Plan. In particular, he is following the Orphanet's activities in relation with the INSERM and the Orphanet's team. He is the French representative in the EC expert group for rare diseases, as previously within EUCERD.

34 Italy: Istituto Superiore di Sanità (ISS) - Domenica Taruscio

The Istituto Superiore di Sanità is the leading technical and scientific public institution of the Italian National Health Service. ISS activities include research, control, training and consultation in the interest of public health protection. Established in 1934, it is composed of 7 Departments and 8 National Centres. It employs about 1900 staff, 400 fellows and 300 volunteers (www.iss.it).

The Italian National Centre for Rare Diseases (Centro Nazionale Malattie Rare, CNMR; www.iss.it/cnmr) was established to promote and develop experimental research and public health actions, as well as to provide technical-scientific expertise & information on rare diseases (RD) and orphan drugs for the prevention, treatment and surveillance of RD. CNMR holds a strategic institutional position at national and international level in RD. CNMR activities include: primary and secondary prevention of RD and congenital anomalies; new-born screening; experimental research on selected RDs; management of RD National Registry and disease-specific registries; institutional national external quality assurance program for genetic laboratories (http://www.iss.it/tege/index.php?lang=1&anno=2015&tipo=27); development, implementation & dissemination of RD guidelines and best practices; implementation of Evidence-based Medicine and Narrative Based Medicine in RD; quality of life of RD patients; continuing education and training programs for health professionals and patient associations. Institutional information (by Helpline 800-896949 and website www.iss.it/cnmr) and communication (ISS Bulletin "Rare diseases and orphan drugs"). It represents Italy at the COMP-EMA and participate to the Advice Scientific WG-EMA since 2001. CNMR-ISS signed the bilateral (IT-USA) scientific agreement with NIH-Office for Rare Diseases-NCATS since 2003. CNMR coordinates/has national, EU & international projects: EUROPLAN (www.europlanproject.eu); EPIRARE (www.epirare.eu); Rare-Bestpractices (www.rarebestpractices.eu); IT-USA projects on RDs; Tender" EU Tender "Neonatal Screening Practices in Europe" (http://ec.europa.eu/health/rare_diseases/screening/index_en.htm). *The Italian National Centre for Rare Diseases: where research and public health translate into action. (www.ncbi.nlm.nih.gov/pmc/articles/PMC4044801/pdf/blt-12-s591.pdf)*

Key Staff

- Domenica TARUSCIO, MD, Director of the National Centre for Rare Diseases-ISS. In this position, her efforts are directed mainly to tackle RD from science to society. She published 104 scientific publications (PubMed: www.ncbi.nlm.nih.gov/pubmed/?term=taruscio+d), several Reports and other documents.
  She is/has been the Italian Representative at the COMP-EMA (2000-2009); member of several Working Groups and Committes, including: EU Expert Group on RD, EUCERD & RD Task Force; IRDiRC Interdisciplnary Committee; OECD Genetic Testing Working Group; European Molecular Genetics Quality Network Management Board; Eurogentest Advisory board. Scientific coordinator of the Italian Quality Assurance Scheme for genetic testing since 2001. Scientific coordinator of several projects, including: EU-funded projects NEPHIRD (Network of Public Health Institutions on Rare Diseases); EUROPLAN (www.europlanproject.eu); EU Tender "Neonatal

Screening Practices in Europe" (http://ec.europa.eu/health/rare_diseases/screening/index_en.htm); EPIRARE (www.epirare.eu); RARE-Bestpractices (www.rarebestpractices.eu); WP Leader "Registries and natural history" of RD-Connect. Past President and Member of ICORD Board (http://icord.se). Director of the International Summer Schools "Rare disease and Orphan drugs registries" and "Health care guidelines". In the RD-Action, she will coordinate the ISS team activities.

- Claudio FRANK, MD, Neurologist, Senior Researcher, Director of the Unit "Orphan Drugs" of the National Center for Rare Diseases (ISS). He is or has been involved in national and international projects on RD (e.g. Principal Investigator, Research Project Italy-USA: "Mechanisms of Neuronal Death in Niemann-Pick C Disease: from Molecules to Clinic; Chief of the Research Unit ISS in the Finalized Research Project 2009, funded by Ministry of Public Health: "Role of protein misfolding in the pathogenesis of Niemann-Pick type C disease: a possible therapeutic target"). Concerning the "sustainable health systems for rare diseases" task, he will contribute on the health systems features, with attention to access to orphan drugs and health care.
- Rita FERRELLI, MD, Researcher experienced in networking RD public health policy makers, in health systems equity and sustainability and in human resources training. She is or has been involved in the coordination and management of several national and international public health projects and health professionals training courses. Concerning the "sustainable health systems for rare diseases" task, she will contribute on the health systems sustainability, equity and resilience as well as on the dissemination activities in WP2.
- Marco SALVATORE, Biologist, specialized in molecular Genetics and Cytogenetics, Researcher at the National Center for Rare Diseases (ISS). He is involved in national and international project (i.e. involved in RD Connect; External Quality Assessment Schemes for genetic test of rare diseases); in the management of the specific national pathology disease registry (Italian Cystic Fibrosis Registry) and of the first Italian project for external quality assessment of sweat test for cystic fibrosis; he attended as deputy Member the Management Board of the European Molecular Genetics Quality Network (2004 to 2015). Concerning the "sustainable health systems for rare diseases" task, he will contribute on the health information systems, including registries.
- Stefano DIEMOZ, Administrative assistant with experience in administrative management of national and international projects, in office operations as well as technical organization of workshops and conferences. He will contribute on the administrative issues.
- a researcher experienced in networking RD public health policy makers (e.g. EUROPLAN project and WP4 of the Joint Action Working for Rare Diseases) as well as RD other stakeholders in national and international projects. The researcher will contribute to the literature review and the networking concerning the "sustainable health systems for rare diseases" task, as well as on the dissemination activities in WP2.
- two MD, as specific experts in public health; they will contribute to the literature review, studies of health system features, with particular attention to sustainability, equity and resilience.

9.4 Financial management

The financial management of the action will be conducted as follows:
2 months prior the compilation of the interim financial reports (M12 and M24) and of the final report (M36) all the associated partners will be asked to send in their financial documents and the budget template filled-in for their institution with clear instructions (first quality control level). Upon reception, the finance officer will further quality control the documents in order to make sure they comply with the Grant regulations and with the original budget agreement. If necessary the finance officer will revise them in agreement with the associated partners. Finally the financial officer will provide all collected documents to the Gestion Ressources Extérieures (GRE) office of the Inserm (DR6) which will compile these documents in order to provide the Chafea with a consolidated budget (third round of quality control). The GRE is also in charge of managing the payments of the partners.

The financial officer will inform the partners upon each payment in order to ensure the reception of such payment. He will be also be available for day-to-day support for administrative and budget issues of the partners and transmission to the Commission. He works in close collaboration with the project manager and the project coordinator so that in case of problems or particular issues or amendments to be done to the contract the steering committee will be informed timely.

The same kind of monitoring has proven to be effective in the previously managed action and it will be conducted by the finance officer Corentin Fort (finance officer of the contract Orphanet Europe Joint action 201002206 and Eucerd Joint action 2011 22 01) in collaboration with the Inserm GRE office, which is experienced in handling the finances of European contracts.

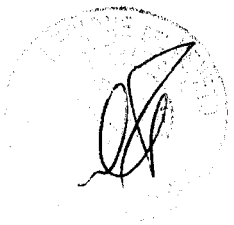
10. BUDGET

10.1 Content description and justification

Budget was agreed by associated partners and WP leaders through conference calls and mail discussions. It was decided to attribute 32.87% of the budget to the core Orphanet database (including scientific content, consortium coordination, IT infrastructure, training and quality control), 32.52% to Orphanet consortium partners (covering national coordination and data collection); 15.4% to Policy activities, 5% to Codification issues and overall 13% to horizontal WPs (coordination, dissemination and evaluation). This distribution was based on the number of PMs needed to accomplish the work foreseen in each WP, and to allow participants to attend the meetings and workshops. Some nominated partners agreed on being collaborating partners instead of beneficiaries: in WP4, when more than one institution was nominated to conduct Orphanet activities in the same country, some partners decided to have all the budget managed by one of the institutions while others participate as collaborating partners. In workpackages in which the work will be done through workshops and meetings, participating institutions were consulted and agreed to have the budget centralised at the WP/tasks leaders level, in order to optimise the allocated resources and to ease managing funding and administrative issues (WPs 2, 5, 6).

As far as the budget breakdown was conducted amongst Orphanet consortium partners (participating countries), it was calculated on the basis of: the size of the country population as an indicator of the foreseen amount of expert resources to be collected, the FTE needed to cover this data collection (based on the experience of previous Orphanet actions) and the daily costs of a master-degree information scientist (data obtained from the country coordinators of the former Orphanet JA). Additional funding was foreseen for those teams taking on Orphanet encyclopaedia activities starting M18.
Some exceptions to these rules were applied in order to balance inequalities between countries due to differences in countries incomes (Germany budget was decreased in favor of Poland, Portugal and Hungary). Adjustments were done when countries could not contribute to match the EC contribution.

10.3 Detailed budget tables



Allegato A alla Dgr

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Applicant Number	1
Short Name	INSERM

(A) Direct personnel costs

Persons (position)	Total Person-Month	Costs (€) of (A)
	WP1	
Financial officer (Fort)	9	29 330,25 €
Project manager (Mailella)	19	72 000,00 €
ORPHANET Scientific Director (Rath)	9	56 925,00 €
	WP2	
Orphanews writer (Unni)	28	108 500,00 €
	WP4	
ORPHANET Scientific Director (Rath)	3	18 975,00 €
Bioinformatician (Demarest)	24	73 000,00 €
Networks and systems engineer (Gerard)	28	145 786,67 €
Chief technical officer (Hanauer)	28	141 400,00 €
Disease & classification team manag. (Olry)	33	140 360,00 €
Public official-Database manager (Urbero)	28	221 760,00 €
Communication & valorisation officer (Rodwell)	32	118 400,00 €
Client project manager (Serriere)	32	160 000,00 €
Inf. scientist for epidemiology (Marpil)	28	122 500,00 €
Inf scient. for Literature survey (Hohn)	24	89 000,00 €
Encyclopaedia manager (Bala)	21	96 500,00 €
Medical writer (Tsili)	12	49 310,25 €
Medical writer (Varin)	24	86 000,00 €
Project manager (Mailella)	17	68 000,00 €
Medical writer (Barr)	24	79 000,00 €
Medical writer (Newton)	36	142 500,00 €
Data curator (Gonthier)	36	140 000,00 €
Medical writer (Jara)	36	160 000,00 €
Intl. expert resources manager (Arles)	36	128 000,00 €
Quality manager (Gueydan)	36	140 000,00 €
Developer (Chandelle)	36	96 000,00 €
Nomenclature officer (Janmaat)	28	120 000,00 €
	WP5	
Disease & classification team manag. (Olry)	3	12 760,00 €
	Total Costs (€) of (A)	2 816 007,17 €

Justification

The project coordinator is the intermediary for all communication with Chafea and DG sanco. Assisted by the project manager when needed he will organise the kick-off meeting, ensure setting up of effective governance for the JA, prepare a detailed workplan, ensure monitoring of the activities and of the overall quality of the implementation also adressing compliance with milestones and workplan. The project coordinator is also responsible for coordination of the Orphanet consortium ensuring overall scientific validity of the different Orphanet activities (RD nomenclature and classification, developmentt of tools, directory of expert resources, RD Encyclopaedia). He is also involved in evaluation activities and in developing a sustainability plan...
The project manager will assist the project coordinator in the previously described activities and also ensure communication and information exchange amongst JA participants organising the annual meetings, the steeering committee meetings, the conference calls amongst partners and making available reports. The project manager will also edit an internal newsletter for the consortium and will administrate the internal and external JA websites. He is also responsible for coordination of the Orphanet consortium (editing of an internal newsletter, organising the management board meetings, editing the annual user survey and administrating the internal website). **The financial officer** will be in charge of all the administrative and financial daily issues of the partners and will be in charge of the consolidated budget of the JA. The Orphanews editor will manage the editorial workflow from the sources surveying to editing the articles.
The information scientist for literature survey is in charge of monitoring more than 50 core journals and to perform regular pubmed queries to detect newly described disorders (5 to 10/month) and new facts on already known disorders and to capture relevant articles on RD. **The nomenclature officer** is in charge of integrating newly described disordes to the existing RD classification and to adapt the nomenclature and classification in accordance to the most recent literature as well as of managing the contributions from the community and the curation process. **The scientific curator** is in charge of annotating RD with their related genes and assessing the role of genes in the aetiology of RD (literature survey, expert feedback and cross-referencing of genetic databases). **The disease database manager** will manage the scientif team and will ensureoiverall scientific validity of the nomenclature, RD indexation and curation. **The chief editorial officer** is in charge of managing the **8 scientific writers** who produce and update RD abstracts according to a well established procedure including peer review from experts. **The IT manager, the bio-informatician, the developper, networks and system engineer, a DB manager**, CTO, CPM are in charge of developping the IT tools necessary for the Orphanet database as well as for the development of the web Orphanet knowledge management platform. **The expert ressources data manager** is in charge of day to day support to the Orphanet information scientists in 39 countries, of data registration follow up and of organising annual trainings and at distance trainings for the consortium information scientists. The Expert ressources data manager is also responsible of testing the tools developed by the IT team and of collaborating to the updates of the technical procedures. **The quality manager** is in charge of establishing and maintaining quality assurance and of implementing quality control measures to ensure internal coherence, transversal consistency and completeness in the database (both scientific and expert ressources data). **The valorisation and communication officer** will overwiev the production of ORS reports in order to provide compiled pieces of information required to support CEGRD activities. The **information scientist for epidemiology** is in charge of daily survey of the scientifc literature in order to index the rare disordes with newly described epidemiological data. **Please note that INSERM will cover any additional audit charges if needed.**

(B) Direct costs of sub-contracting

Costs (€)	Tasks subcontracted
0,00 €	
0,00 €	
Total Costs (€) of (B) 0,00 €	

Justification for resorting to subcontracting
CHAFEA Confirmed that audits may be required, in accordance with Financial Regulation under RAP article 207 §3. Please note that INSERM will cover any

(C) Other direct costs

	Costs (€)	Justification
(C.1) Travel	36 328,00 €	**WP1** 3 Consortium 2 days Meetings - Travel and Subs collaborative partners - 15 PAX
	11 760,00 €	**WP4** 2 2 days trainings - Travel and Subs collaborative partners - 7 PAX
	Costs (€)	**Justification**
(C.2) Equipment	0,00 €	N/A
	0,00 €	
	Costs (€)	**Justification**
(C.3) Other goods and services	12 060,00 €	**WP1** Catering 3 Consortium 2-day Meetings - 67 PAX (1 dinner, 4 coffee breaks, 2 lunches)
	2 800,00 €	**WP4** Catering 2 2 days trainings - 33 PAX (1 dinner, 3 coffee breaks, 2 lunches)
	0,00 €	
Total Costs (€) of (C)	62 948,00 €	

(D) Indirect Costs (Max. 7% on A, B and C)	201 470,86 €
Total estimated eligible costs	3 079 626,03 €
Total requested EC contribution (60% max)	1 847 775,62 €

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Applicant Number	2		
Short Name	MUW		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Orphanet country coordinator, WP 3 leader (Voigtländer)	3,00	20 075,00 €
	Orphanet Information scientist (Unterberger)	19,84	129 000,00 €
	Orphanet Information scientist (Unterberger)	13,16	85 600,00 €
	WP 3 IT support (NN)	1,00	5 133,33 €
	WP 3 Information Scientist (NN)	6,00	38 765,07 €
			0,00 €
		Total Costs (€) of (A)	278 573,40 €
	Justification		
	Orphanet country coordinator, WP3 leader (Voigtländer) : Management of the Orphanet country team, responsible for all tasks related to the function of a country coordinator. Management of WP3 including data analysis and elaboration of the task-related individual evaluation reports. **Orphanet information scientist (Unterberger):** Collection, pre-validation and data entry of all relevant country-specific data into the Orphanet database. Continuous searching for new services or other new data relevant for Orphanet. Elaboration of country-adapted assessment forms for quality assessments of specialised clinical and laboratory services. Assistance in the dissemination of information about Orphanet. **WP3 IT support (Jurkowich):** IT support to WP 3 regarding the development and management of the online partner survey as well as other task-specific survey tools (like, for instance, surveys to assess WS achievements). **WP3 information scientist (Rashidian):** Support of the WP leader in the accomplishment of WP3 (assistance in the elaboration of JA task-specific questionnaires, in the collection, preparation and analysis of data related to JA task-specific indicators and in the elaboration of the individual evaluation reports for the different tasks of the JA).		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	2 700,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	1 800,00 €	Two 2-day WP 4 Training (Paris)	
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
Total Costs (€) of (C)	4 500,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**19 815,14 €**		
Total estimated eligible costs	**302 888,54 €**		
Total requested EC contribution (60% max)	**126 079,00 €**		

Applicant Number	3		
Short Name	SPF		
	Persons (position)	**Total Person-Month**	**Costs (€) of (A)**
	Pol Gerits (Advisor to the DG)	1,5	16 000,00 €
	I. Mertens (Head of the data management unit)	1	14 167,00 €
	S. Van Den Bogaert (Head of the organisation of healthcare unit)	1	6 139,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	36 306,00 €
	Justification		
	Pol Gerits will partipate in WP4 more participate he will participate to the subtask validation of data by health authorities and he will doing the coordination of the JA at the level of his organisation. **Dr. I. Mertens** will participate in WP 5. She will participate to workshops organized in the framework of WP5 (Task 5.1, 5.2, 5.3, 5.4) in order to explore the different ways how orphacodes could be implement in the health information system in Belgium. **Dr. S. Van den Bogaert** will participate actively to the workshops organized in the framework of WP6 (Task 6.1, 6.2) and she will give information concerning the state of the art of the implementation of national plan of rare diseases in Belgium (Task 6.3).		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	4 000,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	0,00 €		
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	4 000,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**2 821,42 €**		
Total estimated eligible costs	**43 127,42 €**		
Total requested EC contribution (60% max)	**25 876,45 €**		

Applicant Number	4		
Short Name	WIV-ISP		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Information scientist (Montse Urbina Paz)	9	58 033,79 €
	Information scientist (Annelies Mallezie)	9	51 728,15 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	109 761,93 €
	Justification		
	Information scientist, Montse Urbina Paz, will participate in WP4 and WP5, more exactly for WP4: responsible for the registration and update of certain Belgian expert activities (genetic testing services, clinical trials ...), attend trainings; contribute to internal newsletter. This collaborator is also involved in implementation of ORPHA-codes in information systems at country level and will continue to participate in this domain at the European level in WP5. **Information scientist, Annelies Mallezie** will participate in WP4 activities : responsible for the registration and update of certain Belgian expert activities (biochemical testing services, research projects...), attend trainings, contribute to internal newsletter, perform QC tasks as requested by the coordinator.		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	4 000,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	1 600,00 €	Two 2-day WP 4 Training (Paris)	
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	5 600,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**8 075,34 €**		
Total estimated eligible costs	**123 437,27 €**		
Total requested EC contribution (60% max)	**74 062,36 €**		

Applicant Number	5		
Short Name	BAPES		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Elena Eneva (Information scientist)	24	9 641,00 €
	Alexander Geshev (Technical assistant)	25	5 021,35 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	14 662,35 €
	Justification		
	Information scientist role: Identification of the sources of information in the country, collection of the information about expert services according to the SOPs, validation of the collected data, publication of the data and communication with the coordinating team **Elena Eneva**, MSc is trained psychologist with experience in project management. She is active in the rare disease community in Bulgarian, being a board member of DEBRA Bulgaria and member of the National Alliance of people with rare diseases. Ms. Eneva will take over the position of Information Scientist, serving as a liaison for the rare disease stakeholders in Bulgaria. **Alexander Geshev**, BSc will provide technical support to the tasks implemented by the National Coordinator and the Information Scientist.		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	3 000,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	2 070,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	5 070,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**1 381,26 €**		
Total estimated eligible costs	**21 113,61 €**		
Total requested EC contribution (60% max)	**12 668,00 €**		

Applicant Number	6		
Short Name	HSRB		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Information scientist (Kladar)	18	18 736,58 €
	Activity Coordinator (Kreso)	12	10 871,88 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	29 608,46 €
	Justification		
	Anja Kladar, as Information Scientist will be in charge of gathering the information and their entering in the database. **Tihana Kreso, as Activity Coordinator**, will be in in charge for preparation and organization off all educative and promotional activities and coordinations between the stakeholders. Country coordinator role: Governance of the project at national level, including liaison with learned societies, health authorities and patient organisations. Responsible for data quality management.Participation in the Orphanet management board. Information scientist role: Identification of the sources of information in the country, collection of the information about expert services according to the SOPs, validation of the collected data, publication of the data and communication with the coordinating team		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	4 200,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	2 976,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	7 176,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**2 574,91 €**		
Total estimated eligible costs	**39 359,37 €**		
Total requested EC contribution (60% max)	**23 615,62 €**		

Applicant Number	7		
Short Name	NKCVO		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	country coordinator (public official)	3,8	16 285,00 €
	information scientist (non-public)	8	21 617,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	37 902,00 €
	Justification		
	Country coordinator role: Governance of the project at national level, including liaison with learned societies, health authorities and patient organisations. Responsible for data quality management.Participation in the Orphanet management board. **Information scientist role:** Identification of the sources of information in the country, collection of the information about expert services according to the SOPs, validation of the collected data, publication of the data and communication with the coordinating team		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	3 000,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	1 750,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	4 750,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**2 985,64 €**		
Total estimated eligible costs	**45 637,64 €**		
Total requested EC contribution (60% max)	**27 382,58 €**		

Applicant Number	8		
Short Name	UTARTU		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Project lead (Vallo)	1	4 740,00 €
	Senior Information Scientist (Rita)	5	9 425,00 €
	Information Scientist (Sille)	8,4	8 971,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	23 136,00 €
	Justification		
	Prof. Vallo Tillmann, MD, PhD, will be the **national co-ordinator** of the project in Estonia. He will be also responible for the writing of the periodic reports and the financial tasks. **Dr. Rita Teek**, MD, PhD, will be the **Senior Information Scientist** responsible for answering and solving all clinical questions and problems within this project. Her expertise in medical genetics will be highy appreciated. **Mrs Sille Vahtra, Information Scientist**, will be responsible for technical data management and the project's daily management. Country coordinator role: Governance of the project at national level, including liaison with learned societies, health authorities and patient organisations. Responsible for data quality management.Participation in the Orphanet management board.		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	2 700,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	1 500,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0.00		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	4 200,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**1 913,52 €**		
Total estimated eligible costs	**29 249,52 €**		
Total requested EC contribution (60% max)	**17 549,71 €**		

Applicant Number	9		
Short Name	Rinnekoti		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Information scientist	14,2	60 240,75 €
	Country coordinator	5,3	49 287,89 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	109 528,64 €
	Justification		
	Country coordinator role: Governance of the project at national level, including liaison with learned societies, health authorities and patient organisations. Responsible for data quality management.Participation in the Orphanet management board. **Information scientist role:** Identification of the sources of information in the country, collection of the information about expert services according to the SOPs, validation of the collected data, publication of the data and communication with the coordinating team		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	2 970,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	1 735,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	4 705,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	7 996,36 €		
Total estimated eligible costs	122 230,00 €		
Total requested EC contribution (60% max)	55 003,50 €		

Applicant Number	10		
Short Name	APHP (BNDMR)		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Health information manager scientific director	3	17 100,00 €
	Health information & project manager	12	60 000,00 €
	Coordination	4	14 000,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	91 100,00 €
	Justification		
	To build the necessary framework to enable homogeneous coding of RD diagnostic at EU level, the right tools and guidelines are necessary. Our institution will be mainly involved in the first task of the WP5 by interviewing each MS and drafting the necessary documents to help in attaining this objective. A clear methodology will have to be set in order to build the necessary guidelines and methodologies based on existing morbidity systems and systems based on ORPHA codes. To manage the work during the 3 years of the project, a health information manager scientific director is required. To interview MS, follow and draft the EU recommandations for coding RD in clinical practice, a project manager with specific technical knowledge is required for the 1st year of the project. To support and help in coordinating the 3 years of the project, a coordinating set of tasks is also required.		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	6 705,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	0,00 €		
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	6 705,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**6 846,35 €**		
Total estimated eligible costs	**104 651,35 €**		
Total requested EC contribution (60% max)	**62 790,81 €**		

Applicant Number	11		
Short Name	EURORDIS		
(A) Direct personnel costs	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Social Policy Manager - Raquel Castro	10,1	56 594,83 €
	Healthcare and Research Infrastructure Director - Matt Johnson	15,9	116 051,72 €
	Public Affairs Director - Valentina Bottarelli	14,5	95 000,00 €
	Public Affairs Manager - Ariane Weinman	14,5	80 000,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	347 646,55 €
	Justification		
	The Public Affairs Director will oversee the implementation and delivery of WP2 outputs, in liaison with the WP co-leader. She will facilitate communication and exchanges amongst partners involved in WP2.She will liaise with other WP leaders, notably WP1 and WP6, and will reports to the EC and the CEGRD. She will be responsible to ensure that the WP2 EURORDIS-specific tasks (notably task 2.5 and task 2.4; the latter is managed by staff which is allocated to the EURORDIS OG FPA) are performed and delivered according to the workplan. She will liaise with other EURORDIS staff responsible involved in the JA and ensure that their respective activities are coordinated. With the assistance of **the Public Affairs Manager**, she will develop the content of national workshops and ensures that it reflects the CEGRD policies and relevant technical and policy developments in the area of RDs so to respond to their main objective i.e. to promote the dissemination at national level of those policies and recommendations. She will establish a call for expression of interest addressed to EURORDIS' National Alliances in view of the organisation of national workshops in their respective countries, and set up the terms of the agreement with the successful candidates leading to the signature of Memoranda of Understanding with them. She will supervise the workshop organisations to make sure that they comply with the common features of national workshop as detailed in the JA workplan: close relations with supporting national authorities; participation of all relevant national stakeholders; patient organisation role in the Programme committee; use of the content and format provided by EURORDIS. **The Public Affairs Manager** will assist the Public Affairs Director in the previously described activities and also ensure communication and information exchange with EURORDIS staff and JA partners. She will be the main day-to-day EURORDIS contact of the JA leader as she is based at the Rare Disease Platform in Paris. She will be in charge of the launch of the call for expression of interest to National Alliances, the signatures of the Memoranda of Understanding with the successful candidate Alliances. She will have the day-to-day responsibility for monitoring the national workshops' organisation and will be the main contact person of the National Alliances in charge of organising these national workshops, ensuring a regular information flow with them. She will supervise EURORDIS expenditures within WP2 and will liaise regularly with VB the PA Director and the EURORDIS Finance Team to make sure that EURORDIS respects its budgetary commitments. **The Social Policy Manager** will continue to support the development of policies within the thematic area of integration of RDs into Social Policies, namely in respect to the finalisation and the adoption of the CEGRD recommendations in the social field. Raquel will build on her experience gathered with a similar role in WP6 EUCERD Joint Action. She will liaise with WP 6 project coordinator and Thematic Coordinator in particular, to ensure that the work within the field of social policies is developed within WP6/EUCERD Joint Action. With the support of relevant EURORDIS staff, Raquel will engage in patient consultations and participatory activities (e.g. seminars, ad hoc meetings of the EURORDIS Social Policy Advisory Group or other patient representatives) aimed to let patients' preferences emerge in the field of RD integration into social policies. She will continue to track the implementation of National Plans/Strategies on RD and the measures in the social field that are gradually adopted in Member States and consolidate this information in dissemination material. **The Healthcare and Research Infr. Director** will support UNEW, WP6 leader, throughout the different stages of the ongoing systematic review cycle on the following thematic areas: ERNs for RDs, CoE and health care pathways. He will liaise with the WP 6 leader and the Thematic Coordinator in particular, to ensure that the work within the field of RD centres of expertise, healthcare pathways and ERNs is developed within WP6 of the Joint Action, in line with patient needs and experience. In liaison with the WP6 leader and the Thematic Coordinator, he will feed this information to the CEGRD members. **The Healthcare & Research Director** will establish communication and exchanges with EURORDIS members, by providing regular updates to the WP6 leader and producing relevant reports and updates. With the support of EURORDIS staff, he will oversee the collection (via surveys, consultations, participatory activities) of RD patient experience of care within and across a number of RD ERNs.		
(B) Direct costs of subcontracting	**Costs (€)**	**Tasks subcontracted**	
	10 000,00 €	**WP2** Translation of 30 6 pages reports	
	11 000,00 €	**WP2** Pre-projection of slides	
	2 000,00 €	**WP2** Photographer	
	14 000,00 €	**WP2** Interpreters	
Total Costs (€) of (B)	37 000,00 €		
	Justification for resorting to subcontracting		
	Reports in the context of National Plans need to be translated in English, Pre-projection of slides is a service which is provided in the context of ECRD, as well as Photographer and Interpreters.		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	2 000,00 €	**WP1** Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	9 000,00 €	**WP6** Attendance of 2 PAX to 9 Preparation / follow-up Thematic Priorities meetings	
	0,00 €	**WP6** Attendance of 4 PAX to 9 Thematic Workshops - EUR18000 on UNEW budget for Patient Rep.	
	30 000,00 €	**WP2** Attendance of 2 PAX to 30 conferences	
	35 000,00 €	**WP2** 70 speakers of ECRD2016	
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	169 000,00 €	**WP2** ECRD 2016 Renting of venue incl. Technicians and Catering	
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	245 000,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**0,00 €**	Indirect costs are not allowed because beneficiary already has an Operating Grant on the same period.	
Total estimated eligible costs	**629 646,55 €**		
Total requested EC contribution (60%	**377 787,93 €**		

Applicant Number	12		
Short Name	MHH		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Information scientist	25,7	174 350,46 €
	Coordinator	10,5	109 416,30 €
	Secretariate	6	23 946,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	357 712,76 €
	Justification		
	An experienced information scientist is needed to perform the tasks outlined in the proposal. The position is intended to be filled with **Dr. Kathrin Rommel** who has over 12 years of experience related to rare disease databasing (Identification of the sources of information in the country, collection of the information about expert services according to the SOPs, validation of the collected data, publication of the data and communication with the coordinating team). - **Prof. Schmidtke** will act as the country coordinator. The role will be : the governance of the project at national level, including liaison with learned societies, health authorities and patient organisations; the data quality management. - **Ms. H. Wrede** will give secretarial support.		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	2 600,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	1 215,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	3 815,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**21 806,94 €**		
Total estimated eligible costs	**333 334,70 €**		
Total requested EC contribution (60% max)	**200 000,00 €**		

Applicant Number	13		
Short Name	DIMDI		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Health Information Manager	18	85 920,00 €
	Scientific officer (public official)	12	64 497,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	150 417,00 €
	Justification		
	The Health information manager will fullfill the following tasks: - Coordination of the work in DIMDI, administrative tasks for project lead of WP 5 - Editorial function for coding guidelines and collection of input from German experts on coding guidelines - Technical development of master file and coordination of feedback from member state countries **The scientific officer** will fullfill the following tasks: - Design of master file according to initial feedback from countries and coding guideline development - Compilation of preexisting content for master file and preparation of masterfile with content from countries for testing phase - Development of recommendations for future maintenance of master file, coding guidelines and feedback mechanism for countries		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	6 705,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	0,00 €		
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	6 705,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**10 998,54 €**		
Total estimated eligible costs	**168 120,54 €**		
Total requested EC contribution (60% max)	**100 872,32 €**		

Applicant Number	14		
Short Name	OCMO		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Melinda Csáky-Szunyogh	4	4 374,72 €
	Anita Szilágyi	7	5 472,11 €
		Total Costs (€) of (A)	9 846,83 €
	Justification		
	Roles of **Country coordinator**: These include organisation of the governance of the project at national level, including liaison with learned societies, health authorities and patient organisations, and the build-up of the Orphanet team if applicable. The country coordinator is responsible for data quality management about expert resources in the country. The country coordinator acts as the national contact point for the health authorities on rare diseases. He/she is a professional well established in the field of rare/genetic diseases, with a strong interest for public health and research issues. The country coordinator participates in the Orphanet management board, edits the national web pages of Orphanet, contributes to the dissemination of national initiatives in the field of RD via OrphaNews and the OrphaNetwork internal newsletter, and he/she participates to the annual meeting (prior to which he/she should brief the National representative of the SC if any). **Roles of Assistant**: Continuous assistance to Country coordinator in communication, documentation		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	3 000,00 €	Regional co-ordination of data upload	
	0,00 €		
Total Costs (€) of (B)	3 000,00 €		
	Justification for resorting to subcontracting		
	Regional co-ordination will provide greater efficiency in gathering and uploading information on experts, institutions, patient organizations		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	4 280,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and	**Costs (€)**	**Justification**	
	0,00 €		
Total Costs (€) of (C)	4 280,00 €		
(D) Indirect Costs (Max. 7%	**1 198,88 €**		
Total estimated eligible costs	**18 325,71 €**		
Total requested EC	**10 995,42 €**		

Applicant Number	15		
Short Name	SE		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Information scientist	8,15	11 200,00 €
	Project manager	3,08	8 000,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	19 200,00 €
	Justification		
	Semmelweis University (SU) is going to employ an information scientist and a project manager : **The information scientist** is responsible for the contact with the Hungarian expert services, collection and validation of the data. **The project manager** coordinates and facilitates the work of the information scientist and prepares the accounts and documentation towards the EU.		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	1 050,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	1 050,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**1 417,50 €**		
Total estimated eligible costs	**21 667,50 €**		
Total requested EC contribution (60% max)	**13 000,50 €**		

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Applicant Number	16		
Short Name	HSE		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Information Scientist	36	191 952,00 €
	Country co-ordinator	0	0,00 €
	medical writer	15	95 976,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
	Total Costs (€) of (A)		287 928,00 €
	Justification		
	Ireland has not directly participated in the previous two Joint Actions in Rare Diseases but has published a National Rare Disease Plan in 2014. The **Information Scientist** will be employed to gather and advance information regarding expertise on rare diseases in Ireland, assisting in the designation of Centres of Expertise in Ireland, assisting our NCP and uploading all relevant information onto the Orphanet portal. The Orphanet site is currently inactive in Ireland and will require extensive validation of national sites. Ireland has a high incidence of specific rare diseases (ascertained by newborn screening) as outlined in our National Plan. Medical **writer** produce and update RD abstracts according to a well established procedure including peer review from experts, coordinated at central level		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	2 400,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017	
	1 500,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	3 900,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**13 709,64 €**		
Total estimated eligible costs	**305 537,64 €**		
Total requested EC contribution (60% max)	**164 090,10 €**		

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Applicant Number	17		
Short Name	OPBG		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Information scientist	36	46 584,00 €
	Information scientist	18	23 292,00 €
	Editorial assistant	18	23 274,00 €
	Project Coordinator	2	30 000,00 €
	Supervisor	3	27 900,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	151 050,00 €
	Justification		
	Project coordinator role: Governance of the project at national level, including liaison with learned societies, health authorities and patient organisations. Responsible for data quality management.Participation in the Orphanet management board. He will be supported by a health care manager with more than 20 years of experience in the definition of guidelines for rare diseases and a university degree in medicine and surgery, previously involved in ORPHANET, who will act as supervisor **Information scientist role:** identification of the sources of information in the country, collection of the information about expert services according to the SOPs, validation of the collected data, publication of the data and communication with the coordinating team. 54PM is needed and this was calculated based on the size of the country population as an indicator of the foreseen amount of expert resources to be collected. **The Editorial Assistant** role : Help with dissemination and communication material.		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	2 970,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	1 780,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	4 750,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**10 906,00 €**		
Total estimated eligible costs	**166 706,00 €**		
Total requested EC contribution (60% max)	**97 900,00 €**		

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Applicant Number	18		
Short Name	VR-IiBRD		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Epidemiologist, MD, scientific director	4	23 333,20 €
	Yunior epidemiologist, MD	12	45 000,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	68 333,20 €
	Justification		
	The Epidemiologist, MD, scientific director, will fulfill the following tasks: - coordination of the work of Veneto Region; - design of the file for the integration of ICD and orpha-code classifications; - administrative tasks for the Veneto Region Unit. **The Junior epidemiologist**, MD, will fulfill the following task: - compilation of contents for the relational database integrating ICD and orpha tables.		
(B) Direct costs of subcontracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	6 700,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	15 000,00 €	1 WP5 final workshop in Padua (19 participants)	
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	21 700,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**6 302,32 €**		
Total estimated eligible costs	**96 335,52 €**		
Total requested EC contribution (60% max)	**57 801,31 €**		

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Applicant Number	19		
Short Name	SPKC		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Information scientist	7,2	9 482,00 €
	Country coordinator	3,6	6 959,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	16 441,00 €
	Justification		
	Country coordinator role: Governance of the project at national level, including liaison with learned societies, health authorities and patient organisations. Responsible for data quality management.Participation in the Orphanet management board. **Information scientist role:** Identification of the sources of information in the country, collection of the information about expert services according to the SOPs, validation of the collected data, publication of the data and communication with the coordinating team;		
(B) Direct costs of sub contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	2 970,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	1 735,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	4 705,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	1 480,22 €		
Total estimated eligible costs	22 626,22 €		
Total requested EC contribution (60% max)	13 575,73 €		

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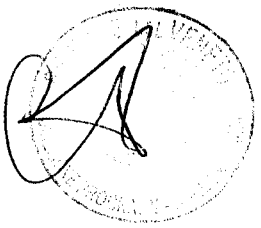
Applicant Number	20		
Short Name	VULSK		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Country coordinator (E.Jurevičienė)	4,5	3 780,00 €
	Project manager (A.Utkus)	4,5	2 210,00 €
	Information scientist (B.Burnytė)	9	2 580,00 €
	Bioinformatician (R.Puronaitė)	4,5	1 310,00 €
	Information scientist (L. Gumbienė)	1,125	472,00 €
	Information scientist (R. Čerkauskienė)	2,25	945,00 €
	Assitant	4,5	800,00 €
		Total Costs (€) of (A)	12 097,00 €
	Justification		
	The country coordinator is responsible for data quality management about expert resources in the country. The country coordinator participates in the Orphanet management board and Joint Action, acts as the national contact point for the health authorities on rare diseases. **The financial officer** is required for budget planning and support, fund distribution, document preparation ongoing budget tracking. **The manager** coordinates Information scientists' activities in accordance with the strategy established by the country coordinator, performs validation of the collected data and communicates with the coordinating team. **The information scientists** identify the sources of information in the country, collects the information about expert services according to the SOPs, validates the collected data according to the workflow established by the country coordinator, publicates the data and communicates with the coordinating team. **A bioinformatician** is required, able to work with large datasets and able to handle different data formats related to rare diseases. Work includes management of Orphanet data, performing statistical analysis on rare disease data.		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	5 000,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	2 490,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €	N/A	
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	7 490,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**1 371,09 €**		
Total estimated eligible costs	**20 958,09 €**		
Total requested EC contribution (60% max)	**12 574,85 €**		



Applicant Number	21		
Short Name	LUMC		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	J. Carlier-de Leeuw van Weenen - Researcher	21	124 168,00 €
	P. van Overveld - Ass. Professor	2	16 646,26 €
	medical writer	14	82 778,67 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	223 592,93 €
	Justification		
	Petra van Overveld will be in charge of the following tasks in WP4: - Daily coordination of RD-ACTION project for National coordinator Prof. van Ommen; - Daily supervisor of information scientist Judith Carlier; - Point of contact for Netherlands Federation of University Medical Centres (Nederlandse Federatie van Universitair Medische Centra; NFU) representing the eight cooperating University Medical Centres in the Netherlands. NFU has been commissioned by the Ministry to designate the nationally recognized expert centers in the Netherlands, together with Orphanet-NL and the Dutch Genetic Alliance VSOP. The first list of centres has been selected and is expected to be published by the end of June. Orphanet-NL will maintain the source database of these centres; - Point of contact for other organizations working on rare diseases in the Netherlands, like the Dutch Genetic Alliance VSOP, National Institute for Public Health and the Environment (RIVM) and Erfocentrum; - Coordination of legal and financial documents required for the project; - Writing scientific reports; - Attending conference calls and annual meetings organised by the Orphanet management team and by Dutch organizations involved in rare diseases; - Enter information into the Orphanet database in close collaboration with the information scientist; - Validation of database information added by the information scientist. - Point of contact for all Dutch parties in the Netherlands that work on coding and registration of rare diseases, like Netherlands Federation of University Medical Centres (Nederlandse Federatie van Universitair Medische Centra; NFU) and National Institute for Public Health and the Environment (RIVM) (for WP5) **Judith Carlier – de Leeuw van Weenen**, information scientist Orphanet since 2011 will be in charge of the identification of the sources of information in the country, collection of the information about expert services according to the SOPs, validation of the collected data, publication of the data and communication with the coordinating team. To distribute the encyclopaedia activities across national Orphanet teams the Orphanet management team has proposed Orphanet-NL to recruit a **medical writer** in charge of writing definitions and short summaries for the Orphanet encyclopaedia in English. He/she will receive a monthly list of diseases from the Orphanet editorial manager, check the recent literature and enter definitions and short abstracts in the database. The medical writer will be appointed by Orphanet-NL in close consultation with its partner Erfocentrum, which is already using the Orphanet texts for their Government-sponsored website on hereditary diseases www.erfelijkheid.nl.		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	0,00 €	Travel costs will be paid from other budgets	
	0,00 €		
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	0,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	15 651,50 €		
Total estimated eligible costs	239 244,43 €		
Total requested EC contribution (60% max)	143 546,66 €		

Applicant Number	22		
Short Name	HDIR		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Bodi Stokke Country Coordinator	0,20	1 744,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	1 744,00 €
	Justification		
	We will not seek for EC co-funding for the working days		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	0,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	122,08 €		
Total estimated eligible costs	1 866,08 €		
Total requested EC contribution (60% max)	0,00 €		

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Applicant Number	23		
Short Name	NKSD		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Information scientist (Wekre)	3,6	25 800,00 €
	National coordinator (Wekre)	3,6	25 800,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	51 600,00 €
	Justification		
	Country coordinator role: Governance of the project at national level, including liaison with learned societies, health authorities and patient organisations. Responsible for data quality management.Participation in the Orphanet management board. **Information scientist role:** Identification of the sources of information in the country, collection of the information about expert services according to the SOPs, validation of the collected data, publication of the data and communication with the coordinating team		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	2 520,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	1 680,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	470,00 €	Catering and consumables, Consortiums and Meetings	
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	4 670,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	3 938,90 €		
Total estimated eligible costs	60 208,90 €		
Total requested EC contribution (60% max)	36 125,34 €		

Applicant Number	24		
Short Name	IPCZD		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Country Coordinator (Malgorzata Krajewska-Walasek)	3,2	15 840,00 €
	Project manager (Krystyna Chrzanowska)	2,5	11 250,00 €
	Information Scientist (Dorota Karczmarewicz and persons to be recruited)	28	43 400,00 €
	Translation (persons to be recruited)	18	36 000,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	106 490,00 €
	Justification		
	The collection on expert services: expert centers, medical laboratories, patient organisations, clinical trials, research projects, patient or mutation registries will be performed by information scientists. IS will identify expert services releated to rare diseases in Poland, contact the professional and invite him/her to register their activities in Orphanet, then if the data is relevant, add the submitted data to the database. Country Coordinators will evaluate and validate whether the submitted data comply with the Orphanet standards. Professors **Malgorzata** Krajewska-Walasek and Krystyna Chrzanowska have already successfully collaborated as coordinators in the former JA project. As Country Coordinators they will not only evaluate and validate whether the submitted data comply with the Orphanet standards, but in addition they will be responsible for the maintenance, updating and expansion of the rare diseases database in Poland, as well as cooperation with patients and Polish MS representatives. The aim of the above-mentioned activities is to reflect healthcare pathways of rare disorders at national level and to disseminate information about the importance of Orphanet database among physicians and patients. Translations: The person/persons could be responsible for the translation component of the project, among others for: the regular update of the RD nomenclature and classification and translation of the new RD definitions, the indexation and annotation of RD, expanding and updating the encyclopedia of RD, the update of existing abstracts and the translation of new ones and other newly produced textual information for each RD, etc. The most important activity of translators will be associated with launching the Orphanet international website in Polish, because the financial support of our Ministry of Health will be mainly allocated to this aim. It will be necessary to complete all the last updates to put the translations in the production phase i.e. the translation of the HPO terms and non-medical content which are now being updated.		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	2 800,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	1 700,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	4 500,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**7 769,30 €**		
Total estimated eligible costs	**118 759,30 €**		
Total requested EC contribution (60% max)			

Applicant Number	25		
Short Name	DGS		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Director of the Quality Department (J. A. Diniz)	1,08	5 093,27 €
	Chief technical officer (Anabela Coelho)	2,4	5 827,90 €
	Information scientist	36	43 253,28 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	54 174,45 €
	Justification		
	J. A. Diniz is the project leader and the strategic coordinator; The role will be : the governance of the project at national level, including liaison with learned societies, health authorities and patient organisations. Responsible for data quality management.Participation in the Orphanet management board. **A. Coelho** is the executive leader and will operationalize the activities of the JA in Portugal. **Information scientist** will Identify the sources of information in the country, collect the information about expert services according to the SOPs, validate the collected data, publish the data and communication with the coordinating team.		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	3 287,00 €	3 Consortium: 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	1 735,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
Total Costs (€) of (C)	5 022,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**4 143,75 €**		
Total estimated eligible costs	**63 340,20 €**		
Total requested EC contribution (60% max)	**38 004,12 €**		

Applicant Number	26		
Short Name	UMF Gr.T.Popa		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Country coordinator: Rusu Cristina	11,8	17 661,00 €
	Information scientist 1: Braha Elena Emanuela	9,0	8 119,00 €
	Information scientist 2: Panzaru Monica Cristina	11,7	8 119,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	33 899,00 €
	Country coordinator role: Governance of the project at national level, including liaison with learned societies, health authorities and patient organisations. Responsible for data quality management.Participation in the Orphanet management board. **Information scientist role:** Identification of the sources of information in the country, collection of the information about expert services according to the SOPs, validation of the collected data, publication of the data and communication with the coordinating team		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	4 465,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	2 900,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	7 365,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**2 888,48 €**		
Total estimated eligible costs	**44 152,48 €**		
Total requested EC contribution (60% max)	**26 491,49 €**		

Applicant Number	27		
Short Name	CUMS		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Country Coordinator (Kovács)	13	15910,92
	Information Scientist (Nagyová)	13	8666,67
	Project Manager (Hlavatá)	13	8666,67
	medical writer	18	34388
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	67 632,25 €
	Justification		
	The members of the Slovak Orphanet Team are: **László Kovács, MD, DrSc, MPH,** Professor of Pediatrics and Chairman – leading pediatrician and clinical geneticist with university degree of Doctor of Science and more than 30 years of professional experience in evaluation and treatment of patients with rare diaseses. The role will be : Governance of the project at national level, including liaison with learned societies, health authorities and patient organisations. Responsible for data quality management. Participation in the Orphanet management board. **Gabriela Nagyová, MD,** Information Scientist. She is in training as clinical geneticist and is a PhD student in this field. The role will be : Identification of the sources of information in the country, collection of the information about expert services according to the SOPs, validation of the collected data, publication of the data and communication with the coordinating team. **Anna Hlavatá, MD, PhD., Project Manager** – experienced pediatrician with a PhD degree working more than 20 years in the field of rare diaseases. Prof. Kovács and Dr. Hlavatá are members of the Rare Diseases Working Group of the Ministry of Health of the Slovak Republic. All three team member are are involved in scientific, technical and managerial implementation of the action in Slovakia from 2010. **Medical writer** produce and update RD abstracts according to a well established procedure including peer review from experts, coordinated at central level		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	6 700,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	3 600,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	10 300,00 €		
(D) Indirect Costs (Max. 7% on	**3 200,00 €**		
Total estimated eligible costs	**81 132,25 €**		
Total requested EC	**48 500,00 €**		

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Applicant Number	28		
Short Name	UKC		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	National coordinator (Peterlin B)	4,16	22 131,20 €
	Information scientist (Lovrecic L)	4,16	11 523,20 €
	Information scientist (Maver A)	4,16	6 614,40 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	40 268,80 €
	Justification		
	Country coordinator role: Governance of the project at national level, including liaison with learned societies, health authorities and patient organisations. Responsible for data quality management.Participation in the Orphanet management board. **Information scientist role:** Identification of the sources of information in the country, collection of the information about expert services according to the SOPs, validation of the collected data, publication of the data and communication with the coordinating team		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	5 941,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	1 980,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	7 921,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**3 373,29 €**		
Total estimated eligible costs	**51 563,09 €**		
Total requested EC contribution (60% max)	**30 937,85 €**		

Applicant Number	29		
Short Name	CIBER		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Documentalist 1 (ME Mateo)	36	88 865,64 €
	Project Manager 1 (V Corrochano)	7,2	23 446,80 €
	Project Manager 2 (B Gómez)	3,6	10 612,12 €
	Documentalist 2 (to be hired)	36	66 247,56 €
	Assistant to CIBERER Scientific Direction (I Mendes)	3,6	11 723,40 €
		Total Costs (€) of (A)	200 895,52 €
	Justification		
	The tasks to be developed by **Documentalist 1** (ME. Mateo) and **Documentalist 2** (to be hired in replacement of M Arles) are all those related to giving continuity to Orphanet-Spain activities: 1. Updating the Orphanet database related to clinical and scientific activity on RD by identifying/tracking significant sources of information and detecting/selecting/assessing the activities taking place; 2. Translating the contents of the Orphanet site; 3. Disseminating and giving visibility to the Orphanet database and RD resources, managing and editing the Orpha-Spain site or contributing to Orphanews Europe. V. Corrochano has been the **project Manager** for Orphanet-Spain since 2010. She supervises and provides support to the documentalists and is in charge of tasks such as planning, organizing, and controlling resources of the team in order to achieve specific goals or solve daily problems. In addition to its contribution to WP4, CIBER will also participate in WP6 developing tasks related to its participation in the EUCERD Joint Action where CIBER led a WP on 'Improving access to higher-quality healthcare'. The areas where CIBER has proposed the coordinators to participate are Centres of Expertise and healthcare pathways and Genetic testing, Next Generation Sequencing and Genetic Counseling. B. Gomez will be the **project manager** 2 in charge of managing the tasks assigned to CIBER in this part of the project. I. Mendes, **Assistant to the CIBERER's Scientific Direction**, will provide support to Dr. F. Palau, country coordinator for Orphanet-Spain since 2010, during the development of the project.		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	3 000,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris).	
	2 000,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	5 000,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**14 412,69 €**		
Total estimated eligible costs	**220 308,20 €**		
Total requested EC contribution (60% max)	**94 506,40 €**		

Applicant Number	30		
Short Name	KS		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Country coordinator	0,40	2 686,00 €
	Information Scientist	19,44	130 578,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	133 264,00 €
	Justification		
	According to the structure and the the setup of the work flow of previous Joint Action Orphanet Consortium, there is a declared need of one project cooridinator and at least one information scientist. This is to ensure a successful performance of the WP-task including inventory of national resources and collection of relevant information, validation, registration in the Orphanet database and also continous networking and communication with national and international partners and the coordinating Orphanet team.	
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	2 970,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	1 735,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	4 705,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**9 657,83 €**		
Total estimated eligible costs	**147 626,83 €**		
Total requested EC contribution (60% max)	**88 576,10 €**		

Applicant Number	31
Short Name	UNEW

(A) Direct personnel costs

Persons (position)	Total Person-Month	Costs (€) of (A)
WP1		
WP Leader/Policy Lead (K. Bushby)	2	28 613,34 €
WP6 Project Manager (S.Lynn)	1	6 747,50 €
WP2		
WP Leader/Policy Lead (K. Bushby)	1	14 306,67 €
Senior Policy Researcher (A Atalaia)	5	33 997,09 €
WP6 Project Manager (S.Lynn)	8	53 980,01 €
Thematic Coordinator (V Hedley)	12	51 320,92 €
WP4		
Senior Policy Researcher (A Atalaia)	2	13 598,84 €
WP6 Project Manager (S.Lynn)	2	13 495,00 €
WP6		
WP Leader/Policy Lead (K. Bushby)	7,15	102 292,70 €
WP6 Project Manager (S.Lynn)	12,2	82 319,51 €
Senior Policy Researcher (A Atalaia)	16,2	110 150,55 €
Thematic Coordinator (V.Hedley)	17	72 704,63 €
Senior Policy Researcher (T. Evangelista)	23,2	160 170,74 €
Project Assistant	36	117 639,43 €
Financial Support	1,45	5 910,29 €
Total Costs (€) of (A)		667 247,22 €

Justification

The **WP leader** will contribute overarching expertise from the RD field, both clinical and research. She will additionally assume overall responsibility for delivery of high quality WP outputs and report directly to the EC and the CEGRD. **Project Manager** will have day-to-day responsibility for the WP and its interaction with other WPs (in particular
WP5). He will ensure closer communication with the national Orphanet teams and is responsible for reporting. He is also deeply involved in the integration work. The Project Manager will oversee the other members of the UNEW Policy development team in the generation of the key outputs of this WP: information and integration activities, recommendations and the State of the Art Document. **Thematic Coordinator** will maintain an overview of progress across all topics and support the Consultative Group to ensure integration of project/initiative representatives and facilitate input. He/She will assume responsibility for specific named thematic areas. This role will invoive close collaboration with the other WPs of the JA, especially the dissemination activities planned in WP2 (particularly the National Conferences, to ensure the relevance of WP6 outputs by understanding the needs of the MS). The TC will also play a key role in integrating initiatives (esp. the more 'external' groups). 'Assuming responsibility' for policy outputs means ultimately responsibility for establishing current practices and thereafter ensuring efficient horizon-scanning. It also involves identifying ongoing and new initiatives outside of the usual RD field (some of these PM have been allocated into WP2 insofar as they relate to dissemination). What this will mean in practice is that the UNEW policy researchers and policy coordinators will be the first point of contact for all issues relating to their respective specialist topics, with responsibility to work with the interested APs and ensure that workshops/conference calls/drafting group meetings (e.g. at CEGD) relating to these thematic priorities are planned and executed appropriately. This will entail conducting a large amount of background research; working with APs to draft working documents for the workshops (and between workshops, as appropriate); drafting workshop reports and disseminating the key messages of these; preparing presentations for the CEGRD; leading on the revision of the thematic documents following CEGRD review and feedback, etc.. They will also need to create dissemination tools related to their topics – e.g. Recommendation PwPs, webinars, peer-reviewed journal articles and policy factsheets.
One **Policy Researcher** will lead the State of the Art work and assume overarching responsibility for at least 2 thematic areas (see above). The second **Policy Researcher** will have overarching responsibility for the remaining thematic areas, and will also support the national workshops/conferences of WP2. He /She will work a little with INSERM re. the conception and elaboration of the Orphanet reports.
The FT **Project Assistant** will spend 11 PM supporting the State of the Art resource. 18 PM will be spent on the organisation of the 8 workshops, as all pre- and post-workshop arrangements will be the responsibility of UNEW. This post is needed to provide administrative support to the policy team, including invitations, reimbursements, travel arrangements, venue bookings and catering. The PA will also support the team here with the reporting, with generation of the Deliverables, and general administrative support. Finally, 1.8 days are foreseen across the project to allow the University Finance team to support UNEW participation in the new Joint Action.

(B) Direct costs of sub-contracting

Costs (€)	Tasks subcontracted
3 000,00 €	Audit
Total Costs (€) of (B) 3 000,00 €	

Justification for resorting to subcontracting

CHAFEA Confirmed that audits may be required, in accordance with Financial Regulation under RAP article 207 §3. 3000 Euros is the University's mandatory charge

(C) Other direct costs

	Costs (€)	Justification
(C.1) Travel and Subsistence	149 000,00 €	WP6: 8 x Workshops x 2 days each: Travel and Subs for 25 PAX each time
	50 000,00 €	Travel and subsistence budget to integrate JA policy work with relevant initiatives
	6 705,00 €	WP6 3 Consortium 2 days Meetings - Travel and Subs for 3 PAX each time
(C.2) Equipment	**Costs (€)**	**Justification**
	7 324,00 €	3 Computers for use across the team, each based on 36M depreciation and 100% use for the project
(C.3) Other goods and services	**Costs (€)**	**Justification**
	11 000,00 €	Other costs for 8 x 2-day workshops (catering, room and equipment rental)
	4 366,00 €	Office Stationary and supplies. It is the usual accounting practice of the Beneficiary to consider these costs as direct costs
Total Costs (€) of (C)	228 395,00 €	

(D) Indirect Costs (Max. 7% on A, B and C)	76 904,96 €
Total estimated eligible costs	1 175 547,17 €
Total requested EC contribution (60% max)	**716 045,97 €**

Applicant Number	32		
Short Name	UK PHE		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Information Scientist/ Project lead (SEO Grade)	36	162 429,00 €
	Country Coordinator (Grade 6 0.05 WTE)	1,8	14 070,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	176 499,00 €
	Justification		
	Posts are required to: Identify the sources of information in the UK (36PM are needed for the information scientist and this was calculated based on the size of the country population as an indicator of the foreseen amount of expert resources to be collected) **Country coordinator role:** Governance of the project at national level, including liaison with learned societies, health authorities and patient organisations. Responsible for data quality management.Participation in the Orphanet management board. **Information scientist role:** -Collect the information about: expert centers, diagnostic tests, patient organisations, clinical trials, patient registries, mutation registries/biobanks, research projects/platforms. According to the Orphanet Standard Operating Procedures SOPs and using the backoffice of the online registration tool - Validate the collected data - Publish the validated data in Orphanet either using the editing tool (MAJOR)		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	1 920,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	1 920,00 €	Two 2-day WP 4 Training (Paris)	
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	8 227,00 €	10% for new office set up within PHE includes desk, computer and other office equipment	
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	12 067,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**13 199,62 €**		
Total estimated eligible costs	**201 765,62 €**		
Total requested EC contribution (60% max)	**121 059,37 €**		

Applicant Number	33		
Short Name	DGS FR		
(A) Direct personnel costs (including Public officials)	**Persons (position)**	**Total Person-Month**	**Costs (€) of (A)**
	Project manager	3	12 000,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
			0,00 €
		Total Costs (€) of (A)	12 000,00 €
	Justification		
	The task of DGS in the JA will be fully integrated in the follow up by the project manager of the French National Plan for Rare Diseases. So, the DGS does not ask for fundings from the JA for this activity. The total duration of the work is estimated at three months at least on the total duration of the JA		
(B) Direct costs of sub-contracting	**Costs (€)**	**Tasks subcontracted**	
	0,00 €		
Total Costs (€) of (B)	0,00 €		
	0,00 €		
	Justification for resorting to subcontracting		
(C) Other direct costs			
(C.1) Travel	**Costs (€)**	**Justification**	
	1 600,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)	
	0,00 €		
	0,00 €		
	0,00 €		
(C.2) Equipment	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
(C.3) Other goods and services	**Costs (€)**	**Justification**	
	0,00 €		
	0,00 €		
	0,00 €		
Total Costs (€) of (C)	1 600,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	**952,00 €**		
Total estimated eligible costs	**14 552,00 €**		
Total requested EC contribution (60% max)	**0,00 €**	*Shall not exceed amount allocated (see separate excel doc with Budget allocation)*	

Applicant Number	34
Short Name	ISS

(A) Direct personnel costs (including Public officials)

Persons (position)	Total Person-Month	Costs (€) of (A)
Domenica TARUSCIO, Professor	1	9 449,92 €
Claudio FRANK, Senior Researcher	6	41 009,10 €
Rita FERRELLI, Researcher	5,2	23 061,12 €
Marco SALVATORE, Researcher	6	23 256,18 €
Stefano DIEMOZ, Administrative staff	6	25 410,00 €
To be identified , Researcher	11,8	45 765,00 €
		0,00 €
		0,00 €
	Total Costs (€) of (A)	167 951,32 €

Justification

In the RD-Action, **Domenica TARUSCIO** will coordinate and orient the ISS team activities.
Claudio FRANK will contribute on the health systems features, with special attention to access to care. He will be a coordinator of the Working groups on specific topics such as prevention, diagnosis, treatment of RDs, to provide Evidence-Based and useful Recommendations in order to reduce health inequalities and promote measures for sustainability of National strategies on RDs. He will also contribute to do literature review, consensus building and production of policy briefs and he will carry out, in collaboration with TBI researcher an analysis of the health situation.
Rita FERRELLI will contribute on the health systems sustainability, equity and resilience as well as on the dissemination activities in WP2. She will be the coordinator of Working groups with representatives from EU Member States to share and better define the scope and the objects of study. She will carry out, in collaboration with TBI researcher an analysis of the political situation, and will contribute to produce final report on health systems resilience for RDs.
Marco SALVATORE will contribute on the health information systems, including registries. He will carry out, in collaboration with TBI researcher, an analysis of epidemiological data on RDs (starting from the existing sources e.g. Orphanet, Registries, etc). He will be the coordinator of a European network (consisting of partners from EU member States) to reduce health inequalities and to promote measures for sustainability of National strategies for RDs. He will also contribute to do literature review, consensus building and production of policy briefs.
Stefano DIEMOZ will contribute on the administrative issues.
The **researcher** will contribute on the literature review and the networking concerning the "sustainable health systems for rare diseases" task, as well as on the dissemination activities in WP2. He will be responsible for scientific secretary of the Project workshops; He will carry out, in collaboration with C. Frank, M. Salvatore and R. Ferrelli, an analysis of the context in which the contemporary health care systems of the different EU Member States are unfolding, through: analysis of epidemiological data on RDs (starting from the existing sources e.g. Orphanet, Registries, etc.), analysis of the political situation, analysis of the health situation. He will support other colleagues in the management of the activities of the work groups and will produce the final report of the project.

(B) Direct costs of sub-contracting

Costs (€)	Tasks subcontracted
0,00 €	
0,00 €	
Total Costs (€) of (B) 0,00 €	

Justification for resorting to subcontracting

(C) Other direct costs

(C.1) Travel

Costs (€)	Justification
4 470,00 €	Three consortium 2-day meetings (2015 Luxembourg, 2016 Edinburgh, 2017 Paris)
0,00 €	
0,00 €	
0,00 €	

(C.2) Equipment

Costs (€)	Justification
0,00 €	
0,00 €	

(C.3) Other goods and services

Costs (€)	Justification
14 000,00 €	Travel expensens for 28 participants from Member States to the 1st Workshop
14 000,00 €	Travel expensens for 28 participants from Member States to the 2nd Workshop
14 000,00 €	Travel expensens for 28 participants from Member States to the **Final Conference**

Total Costs (€) of (C) 46 470,00 €

(D) Indirect Costs (Max. 7% on A, B and C)	**15 009,49 €**	
Total estimated eligible costs	**229 430,81 €**	
Total requested EC contribution (60% max)	**90 000,00 €**	*Shall not exceed amount allocated (see separate excel doc with Budget allocation)*

11. PREVIOUS AND CURRENT GRANTS RELEVANT TO THE PROGRAMME

Orphanet Europe Joint action 20102206

Eucerd Joint action 2011 22 01

12. CURRENT APPLICATIONS RELEVANT TO THE PROGRAMME

The coordinator has no other current applications relevant to the Third EU Health Programme.

13. EXCEPTIONAL UTILITY

Not applicable.

14. COLLABORATING STAKEHOLDERS

Institution	Contact person	Country
Austrian Health Institute (GÖG)	Joy Ladurner	Austria
Ministry of Health	Victor Atanasov	Bulgaria
Medical University Sofia	Aleksey Alekseev	Bulgaria
Croatian institute of Public Health (HZJZ)	Tomislav Benjak	Croatia
Ministry of Health (MoH CY)	Violetta Christophidou-Anastasiadou	Cyprus
Robert Koch Institut (RKI)	Anton Aebischer	Germany
Universitatsklinikum Frankfurt (UKF)	Thomas OF Wagner	Germany
Fehlbildungsmonitoring Sachsen-Anhalt an der Medizinischen Fakultät der Otto-von Guericke-Universität Magdeburg	Med. Anke Rissmann	Germany
Institute for Research of Regulatory policies (INERP)	Panagiotis Karkatsoulis	Greece
PTE (Pécsi Tudományegyetem)	Melegh Bela	Hungary
Landspitali University Hospital Ragnar	Ragnar Bjarnason & Olafur Baldursson	Iceland
Directorate of Health (Ministry of Health)	Yolande Wagener	Luxembourg
Ministry for Energy and Health (MEH)	Neville Calleja	Malta
Poznan University of Medical Sciences	Jacek Wysocki&Anna Latos-Bielenska	Poland
Instituto de Salud Carlos III	Manuel Posada De La Paz	Spain
Fundación para la Investigación Sanitaria y Biomédica de la Comunidad Valenciana (FISABIO-Salud Pública)	Óscar Zurriaga Llorens	Spain
Center of medical genetics and primary health	Hovhannesyan Kristine	Armenia
Office population Health Genomics, dept oh Health Gvmt of WA	Hugh dawkins	Australia
Garvan Institute of Medical Research	Tudor Groza	Australia
University hospital of Aarhus	Ostergard John	Denmark
Foundation for Genetic and Rare Diseases (GeRaD)	Tamari rukhadze	Georgia

Institute for Rare Diseases, Institute of Medical Genetics The Chaim Sheba Medical center	annick Rotschild	Israel
Institut national d'hygiène, dpt of medical genetics	Sefiani Abdelaziz	Morocco
Mc Gill University	Paul Lasko	Québec/Canada
Belgrade University	Dragica Radojkovic	Serbia
CMU Institute of Medical Genetic	D'Amato Sizonenko Loredana	Switzerland
Service de Cytogénétique et de Biologie de la Reproduction, CHU Farhat HACHED Sousse	Dorra H'Mida	Tunisia
University of Istanbul	Ozbeck Ugur	Turkey
Institute of Health Information and Statistics of the Czech Republic	Miroslav Zvolský, M.D.	Czech Republic

ESTIMATED BUDGET FOR THE ACTION (page 1 of 4)

	Estimated eligible[1] costs (per budget category)					EU contribution			Action's estimated receipts		
	A Direct personnel costs	B Direct costs of subcontracting	C Other direct costs	D Indirect costs[2]	Total costs	Reimbursement rate %	Maximum EU contribution[3]	Maximum grant amount[4]	Income generated by the action	Financial contributions given by third parties to the beneficiary	Action's total receipts
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract and seconded persons		C.1 Travel C.2 Equipment C.3 Other goods and services								
Cost form[5]	Actual	Actual	Actual	Flat-rate 7%[6]							
	a	b	c	d = 0.07×(a+b+c)	e = a+b+c+d	f	g= e×f	h	k	l	m=k+l
1 INSERM	2816007.17	0.00	62148.00	201470.86	3079626.03			1424429.00	0.00	0.00	0.00
2 MUW	278853.40	0.00	4500.00	19815.14	303888.54			126079.00	0.00	0.00	0.00
3 SPF	36306.00	0.00	4000.00	2821.42	43127.42			25876.00	0.00	0.00	0.00
4 WIV-ISP	109762.00	0.00	5600.00	8075.34	123437.34			74062.00	0.00	0.00	0.00
5 BAPES	14662.35	0.00	5070.00	1381.26	21113.61			12668.00	0.00	0.00	0.00
6 HSRB	29608.00	0.00	7176.00	2574.88	39358.88			23615.00	0.00	0.00	0.00
7 NKCVO	37962.00	0.00	4750.00	2985.64	45697.64			27382.00	0.00	0.00	0.00
8 UTARTU	23136.00	0.00	4200.00	1913.52	29249.52			17549.00	0.00	0.00	0.00
9 RINNEKOTI	109528.00	0.00	4705.00	7996.31	122229.31			55003.00	0.00	0.00	0.00
10 APHP	91100.00	0.00	6705.00	6846.35	104651.35			62790.00	0.00	0.00	0.00
11 EURORDIS	347646.55	37000.00	245000.00	0.00	629646.55			377787.00	0.00	0.00	0.00
12 MHH	307712.00	0.00	3815.00	21806.89	333333.89			200000.00	0.00	0.00	0.00
13 DIMDI	159417.00	0.00	6705.00	10998.54	168120.54			100872.00	0.00	0.00	0.00
14 OCMO	9846.83	3000.00	4280.00	1198.88	18325.71			10995.00	0.00	0.00	0.00
15 SE	19260.00	0.00	1050.00	1417.50	21687.50			13000.00	0.00	0.00	0.00

ESTIMATED BUDGET FOR THE ACTION (page 2 of 4)

	Estimated eligible[1] costs (per budget category)					EU contribution			Action's estimated receipts		
	A. Direct personnel costs	B. Direct costs of subcontracting	C. Other direct costs	D. Indirect costs[2]	Total costs	Reimbursement rate %	Maximum EU contribution[3]	Maximum grant amount[4]	Income generated by the action	Financial contributions given by third parties to the beneficiary	Action's total receipts
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract and seconded persons		C.1 Travel C.2 Equipment C.3 Other goods and services								
Cost form[5]	Actual	Actual	Actual	Flat-rate 7%[6]							
	a	b	c	d = 0.07 x (a+b+c)	e = a+b+c+d	f	g = e x f	h	k	l	m = k+l
16. HSE	287928.00	0.00	3900.00	13709.64	305537.64			164090.00	0.00	0.00	0.00
17. OPBG	151050.00	0.00	4750.00	10906.00	166706.00			97900.00	0.00	0.00	0.00
18. VR-IBRD	68333.20	0.00	21705.00	6302.67	96340.87			57801.00	0.00	0.00	0.00
19. SPKC	16441.00	0.00	4705.00	1480.22	22626.22			13575.00	0.00	0.00	0.00
20. VULSK	12097.00	0.00	7490.00	1371.09	20958.09			12574.00	0.00	0.00	0.00
21. LUMC	223592.93	0.00	0.00	15651.51	239244.44			143546.00	0.00	0.00	0.00
22. HDIR	1744.00	0.00	0.00	122.08	1866.08			0.00	0.00	0.00	0.00
23. NKSD	51680.00	0.00	4670.00	3938.90	60208.90			36125.00	0.00	0.00	0.00
24. IPCZD	106490.00	0.00	4500.00	7769.30	118759.30			48145.00	0.00	0.00	0.00
25. DGS	54174.45	0.00	5022.00	4143.75	63340.20			38004.00	0.00	0.00	0.00
26. UMF	33599.00	0.00	7365.00	2888.48	44152.48			26491.00	0.00	0.00	0.00
27. CUMS	67632.25	0.00	10300.00	3200.00	81132.25			48500.00	0.00	0.00	0.00
28. UKCL	40268.80	0.00	7921.00	3373.29	51563.09			30937.00	0.00	0.00	0.00
29. CIBER	260895.52	0.00	5000.00	14412.69	280308.21			94506.00	0.00	0.00	0.00
30. KS	133264.00	0.00	4705.00	9657.83	147626.83			88576.00	0.00	0.00	0.00

ESTIMATED BUDGET FOR THE ACTION (page 3 of 4)

	Estimated eligible[1] costs (per budget category)					EU contribution			Action's estimated receipts		
	A. Direct personnel costs	B. Direct costs of subcontracting	C. Other direct costs	D. Indirect costs[2]	Total costs	Reimbursement rate %	Maximum EU contribution[3]	Maximum grant amount[4]	Income generated by the action	Financial contributions given by third parties to the beneficiary	Action's total receipts
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract and seconded persons		C.1 Travel C.2 Equipment C.3 Other goods and services								
Cost form[5]	Actual	Actual	Actual	Flat-rate 7%[6]							
	a	b	c	d = 0.07 × (a+b+c)	e = a+b+c+d	f	g = e - f	h	k	l	m = k+l
31. UNEW	867247.00	3000.00	228395.00	76904.94	1175546.94			716045.00	0.00	0.00	0.00
32. UK PHE	176429.00	0.00	12067.00	13199.62	201765.62			121059.00	0.00	0.00	0.00
33. DGS FR	12000.00	0.00	1600.00	952.00	14552.00			0.00	0.00	0.00	0.00
34. ISS	167951.32	0.00	46470.00	15009.49	229430.81			90000.00	0.00	0.00	0.00
Total consortium	7054514.77	43000.00	750269.00	496296.03	8344079.80	60.00	5006447.86	4329979.00	0.00	0.00	0.00

ESTIMATED BUDGET FOR THE ACTION (page 4 of 4)

(1) See Article 6 for the eligibility conditions
(2) The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme). A beneficiary that receives an operating grant during the action's duration cannot claim any indirect costs for the year(s)/reporting period(s) covered by the operating grant
(3) This is the theoretical amount of the 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 Agency decided to grant for the action) (see Article 5.1)
(4) The 'maximum grant amount' is the maximum grant amount decided by the Agency. It normally corresponds to the requested grant, but may be lower
(5) See Article 5 for the cost forms
(6) flat rate - 7% of eligible direct costs
(7) The reimbursement rate is applied at consortium level only (i.e. to the total costs). The reimbursement rate is normally 60% (or 80% in cases of exceptional utility)

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ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

MEDIZINISCHE UNIVERSITAET WIEN (MUW), established in SPITALGASSE 23, WIEN 1090, Austria, ATU57469858, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('2')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Susanne FRIEDL with ECAS id nfriesus signed in the Participant Portal on 06/08/2015 at 09:39:02 (transaction id SigId-5119-MKibmeyMJTGezrh6ZWaGZtYXizNVGUhzcU3zTJwl8U8rbckzq2L3FZYEU f7qc4N7zzUtA8XqWsnrvKjPjelsyGzw-PHslUMVSXYCH3xcLZM8UuW-mqmPfuoRzfXPaUzT7zzersVyP04J1t12a99UdgxCGpS9). Timestamp by third party at Thu Aug 06 10:39:08 CEST 2015

Allegato A alla Dgr

n del

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

SERVICE PUBLIC FEDERAL SANTE PUBLIQUE, SECURITE DE LA CHAINE ALIMENTAIRE ET ENVIRONNEMENT (SPF), N/A, established in SQUARE VICTOR HORTA 40 BUR 1D 1G, BRUSSELS 1060, Belgium, N/A, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('3')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Els EEMAN with ECAS id neemanel signed in the Participant Portal on 06/08/2015 at 09:07:47 (transaction id SigId:5092-4qZQqf2ICuFtyjOBErShzzYztctzVA97egBll3VXc0grcU9LzzHizI42GFRhnU7voAZLpzm9GlFZyUXB40zd6GADG-PHsiUMVSXYCH3xcLZM8UuW-M3pVJhTf5HByjmH3mx7pyUpK8mSDrEP4nFazN4W4Ozy0). Timestamp by third party at Thu Aug 06 10:07:51 CEST 2015

Allegato A alla Dgr

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ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

INSTITUT SCIENTIFIQUE DE SANTE PUBLIQUE (WIV-ISP), 0254014195, established in Rue Juliette Wytsman 14, BRUXELLES 1050, Belgium, BE0254014195, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('4')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Johan PEETERS with ECAS id npeejoha signed in the Participant Portal on 06/08/2015 at 09:17:22 (transaction id SigId-5101-rUZ2WhyURrOK6ipGAxlKwyDCzJxswQzXTW2bQM51b0XsYjOFzzvbh8lP4Y2NoOs5Y9YHwixTzLo7DdSetKPzLqWm-PHsiUMVSXYCH3xcLZM8UuW-szj3ZzchrvbGYmWr2cZa62hazNF8TgchanMk7tzjRZpo). Timestamp by third party at Thu Aug 06 10:17:26 CEST 2015

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ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

BULGARIAN ASSOCIATION FOR PROMOTION OF EDUCATION AND SCIENCE (BAPES) BG16, 115782273, established in BRATYA SVESHTAROVI STR 4, PLOVDIV 4017, Bulgaria, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('5')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Rumen STEFANOV with ECAS id nstefrum signed in the Participant Portal on 08/08/2015 at 12:14:56 (transaction id SigId-167-6iRonrzzgKsrUmhFvNtyBJyzNEQIcsZ9IP3xeLikzyhSHVsm4ntTFKM8HY6FbcVJt0qNCEf7V30HzkC9MaZj5ZA-Jj71zxYb8yrmkuWnR3zgLC-dg0RK6hM5ea3zrizGsy2IZW0xCa0uYUj7V5orWP5yx1G). Timestamp by third party at Sat Aug 08 13:15:01 CEST 2015

Allegato A alla Dgr

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ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

HRVATSKI SAVEZ ZA RIJETKE BOLESTI (HSRB) HR1, 21002274, established in Ivanicgradska 38, Zagreb 10000, Croatia, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('6')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Anja KLADAR with ECAS id nkladaan signed in the Participant Portal on 06/08/2015 at 11:21:00 (transaction id SigId-5248-P7oSXwVR3sFqpY7V15sEk7QPR7IJVRzZ3VFLjnsh7wZnWHzyd2KU2i1oWNJY9Dirtt7kyjAfsnq0FPxGMXXR4Y-PHsIUMVSXYCH3xcLZM8UuW-ru39zUoKT7ISi2jJuzx7LVpLKZorzd1Kl4HBmIlAloy). Timestamp by third party at
Thu Aug 06 12:21:05 CEST 2015

Allegato A alla Dgr

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ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

FAKULTNI NEMOCNICE V MOTOLE (NKCVO), 00064203 , established in V UVALU 84, PRAHA 5 150 06 , Czech Republic, CZ00064203, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('7')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission').*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Anna SEDIVA with ECAS id nsedivaa signed in the Participant Portal on 06/08/2015 at 13:17:06 (transaction id SigId-5329-Sw1vpzhkDJcfjfMot7Dkhb8wkD49Kr6ENAnjtqCAB4BRycX1OFVfIOLCt4SNogGKjhKow4XdgaaRsUiCnPv6uK-PHslUMVSXYCH3xcLZM8UuW-q9488y7WrGDsNebrwpOscVVr4v5qXZoFh1BHT9ybBZ0). Timestamp by third party at Thu Aug 06 14:17:11 CEST 2015

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n (3)

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

TARTU ULIKOOL (UTARTU), 74001073, established in ULIKOOLI 18, TARTU 50090, Estonia, EE100030417, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('8')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Marco KIRM with ECAS id nkirmkma signed in the Participant Portal on 11/08/2015 at 13:15:55 (transaction id SigId-1105-TLhmk0DpNYLzKLhTqQmwpckTEKzPzMJdAuzjNT6wdZI5HUzedOQCzIURWzWvyLD6IP9biQTOJKPVSdQGfACI1mLu-Jj71zxYb8yrmkuWnR3zgLC-FrEViKciRnQRafhFrAC3zInuZeOALJAtp7zQ6rdWba3W). Timestamp by third party at
Tue Aug 11 14:16:00 CEST 2015

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ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

RINNEKOTI SAATIO (RINNEKOTI) FI1, 02019768, established in RINNEKODINTIE 10, ESPOO 02980, Finland, FI02019768, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('9')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission').*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Akif ARIFULLA with ECAS id narifuak signed in the Participant Portal on 06/08/2015 at 11:26:12 (transaction id SigId-5251-DaxKGzROtNPtta0ZxzN1Drc88u8Og67pqbra5zxnEFzZ8ld4hlEe1u1fpxTqE8bHiYZqSOpH9Cvg1HoAYw62SEC-PHslUMVSXYCH3xcLZM8UuW-miVk4AxzzYpKYYOiE993ujM7uwyzqFnPEeBdvpY5EIL4). Timestamp by third party at Thu Aug 06 12:26:16 CEST 2015

Allegato A alla Dgr

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ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS (APHP), 42132660400012, established in 3 Avenue Victoria, PARIS 75004, France, FR95267500452, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('10')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Florence FAVREL-FEUILLADE with ECAS id nfavrflo signed in the Participant Portal on 14/08/2015 at 16:29:55 (transaction id SigId-2582-PhyKza80HA4XQyjAPwHZS5KEnNNjjL60o23JKabSlqSizvpSwRzf7Azz Oa0EJgUVLiWhfPWPi0bdZYbfB5IUWCn-Jj71zxYb8yrmkuWnR3zgLC-36ZdzU5xFqizzrW6h7VCahf3TsKzzTetyh2sfrVdKlzei). Timestamp by third party at
Fri Aug 14 17:30:29 CEST 2015

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ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

EURORDIS - EUROPEAN ORGANISATION FOR RARE DISEASES ASSOCIATION (EURORDIS) FR3, 413459066/129742P, established in RUE DIDOT 96, Paris 75014, France, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('11')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Yann LE CAM with ECAS id ncamyann signed in the Participant Portal on 06/08/2015 at 15:21:06 (transaction id SigId-5426-WzSWmxgAzYOR5AT9yXvzbOZ6rRsySB8yzxN7s0Rf7oMmVZGqwWb6XvRYUcf2zbq5Z8y2Pet9wN1nnDED6i4XGa-PHsIUMVSXYCH3xcLZM8UuW-n0YPqvUh6szKt8QJ1lzITalCf3xfKaMGoSF8zgNiC4dK). Timestamp by third party at Thu Aug 06 16:21:11 CEST 2015

Allegato A alla Dgr

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ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

MEDIZINISCHE HOCHSCHULE HANNOVER (MHH), Not applicable, established in Carl-Neuberg-Strasse 1, HANNOVER 30625, Germany, DE115650503, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('12')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Katrin DINKLA with ECAS id ndinklka signed in the Participant Portal on 07/08/2015 at 07:54:21 (transaction id SigId-5525-2FzgobELybNnQlJNpAgzpzMlKQ4cPVFja7v6hyw0DEPV85TOsoxpeIrAuJGUPYUxkV0gOaJFjiVQlftzlBLm6im-PHslUMVSXYCH3xcLZM8UuW-USRR8qa42YbHiQbWiNwF4ghER63d4Fp8nzn2xdml4dzW). Timestamp by third party at Fri Aug 07 08:54:26 CEST 2015

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Allegato A alla Dgr

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ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

DEUTSCHES INSTITUT FUR MEDIZINISCHE DOKUMENTATION UND INFORMATION (DIMDI) (DIMDI), established in WAISENHAUSGASSE 36-38A, KOLN 50676, Germany, DE123052538, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('13')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Weber STEFANIE with ECAS id nstefweb signed in the Participant Portal on 12/08/2015 at 13:18:39 (transaction id SigId-1684-xPO2TJse6zmgetVcSH0739oMNRVOTLP8w3GtD88nhWKQ9eEXjlNR!04UEwPzs4IRtsvpO9dqEmB7Ef74rsQa2y-Jj71zxYb8yrmkuWnR3zgLC-7JHshAoAeixe9SIFZUFaw25PXOLbQmwczeuwJ9alQ9). Timestamp by third party at Wed Aug 12 14:18:44 CEST 2015

Allegato A alla Dgr

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ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

ORSZAGOS TISZTIFOORVOSI HIVATAL (OCMO), 329530, established in ALBERT FLORIAN UT 2-6., BUDAPEST 1097, Hungary, HU15329530, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('14')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Judit PALLER with ECAS id npalleju signed in the Participant Portal on 13/08/2015 at 12:49:35 (transaction id SigId-2124-L9QNc94nnL8dmbHZH3xFQhIFAryTqiYQ0zV3OCxrXwqQd1rRtJwPiDvVyjzn3LiUWNutCToW2affjXF6Tze1zzM-Jj71zxYb8yrmkuWnR3zgLC-YpKXx1TmnUnxYzZw0bQ2fCm8k7N9sZ4nMwPZoeev09d).
Timestamp by third party at
Thu Aug 13 13:49:56 CEST 2015

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Allegato A alla Dgr

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ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

SEMMELWEIS EGYETEM (SE) HU13, FI62576, established in ULLOI UTCA 26, BUDAPEST 1085, Hungary, HU15329808, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('15')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission').*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

György BAGDY with ECAS id nbagdgyo signed in the Participant Portal on 02/09/2015 at 09:12:09 (transaction id SigId-1421-jzPCzfXbl79Q9zVEPRBPdOgXl1VLotmsRKfFtmtaNDQjOkBRbt16WEKlW8u3Kk0P3Wi3kMtn8Fuee3w8qFMqUWW-Jj71zxYb8yrNX0dhnHa7Ki-ZR9OtRUW3NPqQY9P7PByc04ru8XknpK9qHJtk2mtA3u). Timestamp by third party at
Wed Sep 02 10:12:34 CEST 2015

Grant Agreement number: 677024 — RD-ACTION — HP-JA-2014
Associated with document Ref. Ares(2015)3186279 - 29/07/2015

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

HEALTH SERVICE EXECUTIVE HSE (HSE), established in LIMETREE AVENUE 2ND FLO OAK HOUSE, NAAS, Ireland, IE66093541, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('16')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

DARA PURCELL with ECAS id npurceda signed in the Participant Portal on 06/08/2015 at 09:42.21 (transaction id SigId-5124-j6CuDiBqcOhT37jh6SDVqf4VodMPjxMmAzWTd2efovSGqjWLviVKObdkDwfpZ5niVqZFfSbfZPRQhUpvxA2bnu-PHslUMVSXYCH3xcLZM8UuW-Sh4fzH1oxyg4OcxlWmzh5czOlWFdA19yEbenuQOZKHRW).
Timestamp by third party at
Thu Aug 06 10:42.27 CEST 2015

Allegato A alla Dgr

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ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

OSPEDALE PEDIATRICO BAMBINO GESU (OPBG), -, established in PIAZZA SANT ONOFRIO 4, ROMA 00165, Italy, VAT exemption, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('17')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission').*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Bruno DALLAPICCOLA with ECAS id ndalbrun signed in the Participant Portal on 18/08/2015 at 13:58:06 (transaction id SigId-3611-0fnApeVsgCTnlibKL2oxmZZzjSi3Rvkel4FiiNMsSszzRsrlG3zxzG1uMsa7wzT6hi3EWc8E6jU5u4yMR5Yg2Cqm-Jj71zxYb8yrmkuWnR3zgLC-zLhjU0cYWpJQkeaUlThV7fxzzRyJWCi0nSghpfKO3hce). Timestamp by third party at Tue Aug 18 14:58:38 CEST 2015

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ACCESSION FORM FOR BENEFICIARIES

REGIONE DEL VENETO (VR-IIBRD), established in Palazzo Balbi - Dorsoduro 3901, VENEZIA 30123, Italy, IT02392630279, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('18')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Facchin PAOLA with ECAS id npaolfac signed in the Participant Portal on 06/08/2015 at 10:31:07 (transaction id SigId-5193-hAvnLHBqdju8IXBiRIIva18zaMZDza0C3McdPZTwITDHGKrofs5aSwrFyr2O0CopeOumWDN5ELzHutx08zzp4zt0-PHsiUMVSXYCH3xcLZM8UuW-p3pj4XzogBzhzNkVtKR14zvE4tS9vzhQ8uajTtqpb9s). Timestamp by third party at Thu Aug 06 11:31:11 CEST 2015

Allegato A alla Dgr

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ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

SLIMIBU PROFILAKSES UN KONTROLES CENTRS (SPKC), 90009756700, established in Duntes 22, Riga LV1005, Latvia, 90009756700, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('19')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission').*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Inga ŠMATE with ECAS id nsmatein signed in the Participant Portal on 07/08/2015 at 09:17:08 (transaction id Sigid-5564-1ilF5NzsjEfoKV58xlfCRCmlsrttPo8hYPiN3DfVGND8OF7NNuEbUUuzi KRpZFiMq1Lu2jRNpKi06V4ombUNFo-PHslUMVSXYCH3xcLZM8UuW-7n4Q1AyzhDA8Hq7YKPBzXiKdkhd1M8G8Aqzdzvrp PzwLW).
Timestamp by third party at
Fri Aug 07 10:17:15 CEST 2015

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ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

VIESOJI ISTAIGA VILNIAUS UNIVERSITETO LIGONINES SANTARISKIU KLINIKOS (VULSK) LT3, 124364561, established in SANTARISKIU G 2, VILNIUS 08661, Lithuania, LT243645610, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('20')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Elena JUREVIIEN with ECAS id njurevel signed in the Participant Portal on 13/08/2015 at 10:29:48 (transaction id SIgId-2015-cel2MnFwF7exzLrP6BGSUTafplh4HUWDeEal3rLsTrhWYjUcWEXQ1zx b5Qvvzpizx1ZZtjNowfzZeJG179yhxHzG-Jj71zxYb8yrmkuWnR3zgLC-riqlbHPYaFHKTQPVEPPv2zfmYmG5GwiPZdilmKzkGZXm).
Timestamp by third party at
Thu Aug 13 11:30:07 CEST 2015

Allegato A alla Dgr

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ACCESSION FORM FOR BENEFICIARIES

ACADEMISCH ZIEKENHUIS LEIDEN (LUMC), 27366422, established in ALBINUSDREEF 2, LEIDEN 2333 ZA, Netherlands, NL003566213B01, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('21')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission').*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Guillaine DE BLECOURT with ECAS id nblecogu signed in the Participant Portal on 17/08/2015 at 12:03:25 (transaction id SigId-3043-xpyn7jzVJ6ZhhpX4iFa70GE6JHPuBIRZbVYnrdHOvAT3dhnh6ttUnrjw7A09PGkIdI3stQiB8M6sur5LsMWnZm-Jj71zxYb8yrmkuWnR3zgLC-x1HyYSDe7Ku8lUzztfEUBZOXJvf8el7EC6RcnknWuVEm). Timestamp by third party at Mon Aug 17 13:03:48 CEST 2015

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

HELSEDIREKTORATE (HDIR), 983544622, established in UNIVERSITETSGATA 2, OSLO 0164, Norway, NO983544622 , ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('22')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Anne-Stina NORDMO with ECAS id nnoannes signed in the Participant Portal on 25/08/2015 at 16:54:00 (transaction id SigId-1021-CwfMoBJF3TpjKTq6lZl8A4ZpOiV6rDwB5bFSCsJRQUEJ0zMmfbzzH1XNIUi2c0wpba3Jo210XLVodyTajMdxUwG-PHslUMVSXYCCnd35MgqX9u-gf9hrN4aznese2EkkSOpw4lAEnc9SF1O3nYb1Cs7MHN). Timestamp by third party at Tue Aug 25 17:54:35 CEST 2015

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

OSLO UNIVERSITETSSYKEHUS HF (NKSD), 993467049, established in KIRKEVEIEN 166 TARNBYGGET, OSLO 0450, Norway, NO993467049MVA, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('23')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission').*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Peder Heyerdahl UTNE with ECAS id nutneped signed in the Participant Portal on 06/08/2015 at 09:16:10 (transaction id SigId-5099-LxeUrA0u1YT3RQidWQrqzVUxwVVcllLyJaXvDNJSxlZAWl4Tr1ylEr8vEiKc7rWpacyi1TtHWbQitjnEfB2zlw-PHslUMVSXYCH3xcLZM8UuW-VbqJw2ptWvUEFfE32qo5Kzzazb84UrEnhzuBPXAJxsLM). Timestamp by third party at Thu Aug 06 10:18:17 CEST 2015

Allegato A alla Dgr

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ACCESSION FORM FOR BENEFICIARIES

INSTYTUT POMNIK CENTRUM ZDROWIA DZIECKA (IPCZD), 0000092381/000557961, established in Aleja Dzieci Polskich 20, WARSZAWA 04730, Poland, PL9521143675, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('24')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Magorzata SYCZEWSKA with ECAS id nsyczema signed in the Participant Portal on 11/08/2015 at 12:58:03 (transaction id SigId-1093-uQBozvJDgzo1Id9iatzyxIBIozLufOiORvtLFTuLKmx6SUqUVzd3RBLeX XfC0dbG7m83dwTaQAZB0QxM87LuBXo-jj71zxYb8yrmkuWnR3zgLC-PFqenE2fzvnRiUBIEvzPuLSWWGlih8ezgkrKcepSbLju). Timestamp by third party at
Tue Aug 11 13:58:08 CEST 2015

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

MINISTERIO DA SAUDE - REPUBLICA PORTUGUESA (DGS), Decreto-Lei n.° 212/2006, de 27 de Outubro , established in Av. João Crisóstomo, 9, LISBOA 1049-062 , Portugal, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('25')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission').*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Paulo NOGUEIRA with ECAS id nnogupau signed in the Participant Portal on 07/08/2015 at 00:31:15 (transaction id SigId-5492-x5OrGKZfFte8y79EOzwM7Fp0zd0McbT6BW8JmbCgKYzVNh4klGuQ78Q85ZYv6IiOrIkzbo9WhzKBC5oMSDb6CdT-PHsiUMVSXYCH3xcLZM8UuW-pFot6D6Eh75fscF1BzHTwaQSOOYRD0XM5GFMFPZUis9). Timestamp by third party at Fri Aug 07 01:31:21 CEST 2015

Allegato A alla Dgr
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ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

UNIVERSITATEA DE MEDICINA SI FARMACIE GRIGORE T.POPA IASI (UMF), CF4701100, established in STRADA UNIVERSITATII 16, IASI 700115, Romania, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('26')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Drago PIEPTU with ECAS id npieptdr signed in the Participant Portal on 11/08/2015 at 13:14:39 (transaction id SigId-1103-xTu02TroxRloadvOOoOkfilh3LtlFsvalwcu0omyN5EL0CHDjWX9nFhx EZl0UKbRObzsCMNLfqFfNoS9mhQQy-Jj71zxYb8yrmkuWnR3zgLC-lEgmRXiXLqukOHQpzwaABziY7fZLZ3sTezZCwBdywlmC). Timestamp by third party at Tue Aug 11 14:14:44 CEST 2015

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ACCESSION FORM FOR BENEFICIARIES

UNIVERZITA KOMENSKEHO V BRATISLAVE (CUMS), 00397865, established in SAFARIKOVO NAM 6, Bratislava 1 81499, Slovakia, SK2020845332, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('27')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Michal RIES with ECAS id mrimihal signed in the Participant Portal on 06/08/2015 at 09:28:59 (transaction id SigId-5109-BFOzuq7jIswqgDL7M6YerkKLGqsN2tzvLc3RKyaFYchRRmMoZjBIWAmswT9JzI0EBEUYycema1BR2jSwnMQhcXG-PHsIUMVSXYCH3xcLZM8UuW-oAzinFaglhEStDUA7KpbidIzJEqU2jSGzlvv0CmWnwJG). Timestamp by third party at Thu Aug 06 10:29:03 CEST 2015

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ACCESSION FORM FOR BENEFICIARIES

UNIVERZITETNI KLINICNI CENTER LJUBLJANA (UKCL), 5057272, established in ZALOSKA CESTA 002, LJUBLJANA 1000, Slovenia, SI52111776, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('28')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission').*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Simon VRHUNEC with ECAS id nvrhunsi signed in the Participant Portal on 07/08/2015 at 15:01:49 (transaction id SigId-71-qcb1v03m38QVS6JzTyJ5e4bVQoa3QzPIeyLDrQ6LZD23pWb1jwkYqsbi6zUfETQujKsxPYLzsXQ7iQZbmwbfO8S-Jj71zxYb8yrmkuWnR3zgLC-imqsiketuKYzSpQ8pT2kspwoFiADTnXnSeRqWcCKPBo). Timestamp by third party at Fri Aug 07 16:01:55 CEST 2015

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ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

CENTRO DE INVESTIGACION BIOMEDICA EN RED (CIBER) ES7, established in CALLE MONFORTE DE LEMOS 5, MADRID 28029, Spain, ESG85296226, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('29')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission').*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Manuel SANCHEZ with ECAS id nsancaia signed in the Participant Portal on 06/08/2015 at 09:16:05 (transaction id SigId-5098-mRzzqL1JDngh6LtzfYsF04nAEJn547OyZAt7vbKcW9YbsHf87ztCzosN0pCZ0hnCACXqLiJNnQ7CztAcZeG9oDJ0-PHsltJMVSXYCH3xcLZM8UuW-LigmCbOhjqifOj2U55zW7cjWrKRHgXzGJZPzzhufkG6S). Timestamp by third party at
Thu Aug 06 10:16:09 CEST 2015

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

STOCKHOLMS LAENS LANDSTING (KS), 2321000016, established in Hantverkargatan 45, STOCKHOLM 104 22, Sweden, SE232100001601, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('30')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission').*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Magnus NORDENSKJÖLD with ECAS id nnormagn signed in the Participant Portal on 07/08/2015 at 10:44:28 (transaction id SigId-5636-6AupE83I7XI85ArQp1TJa22WKSIiGa5lWlr1ckKQ2vAqgkxthzLjQtaRzzvU9nDRXjiwYfYTMYGR4ROG1VpKB1m-PHsIUMVSXYCH3xcLZM8UuW-hYNw2VVVjlufY1DQoSTaeyilnt2hm1xNQ1FJChzSqjv). Timestamp by third party at
Fri Aug 07 11:44:33 CEST 2015

Allegato A alla Dgr

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ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

UNIVERSITY OF NEWCASTLE UPON TYNE (UNEW), established in KINGS GATE, NEWCASTLE UPON TYNE NE1 7RU, United Kingdom, GB499672470, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('31')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission').*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Rory DEANE with ECAS id ndeanero signed in the Participant Portal on 06/08/2015 at 16:53:19 (transaction id SigId-5465-i36t71gW5w3P6TE0SO7zZcoXHaXzVuSKiDJpoSUSfhpffGKr8Fdhmzjlg HL2yzbD0uXYKSNEzXsFnwHZdHtkZEx-PHslUMVSXYCH3xcLZM8UuW-n75Ck98ze2v8KWu2zLzr2n14QmDEbbVUWlRjila5iDT8). Timestamp by third party at Thu Aug 06 17:53:23 CEST 2015

Allegato A alla Dgr

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ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

Department of Health (UK PHE), -, established in Quarry House, Quarry Hill, Leeds LS2 7UE, United Kingdom, 888815064, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('32')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Bernie HANNIGAN with ECAS id nhannber signed in the Participant Portal on 06/08/2015 at 11:06:56 (transaction id SigId-5232-FieBZyVvw3qnzHUADkdk1HxXQ0qevmx3NfZUdJN7YZCNBVoX0SbVNab JPtXdHOnY9nJYpHN4j8nG4M3wUzOHC-PHsIUMVSXYCH3xcLZM8UuW-08cmZ5XfVXo5Yi6F:fUDBzUN8FiQUCV58RSWFNzUTsqW). Timestamp by third party at Thu Aug 06 12:07:01 CEST 2015

Allegato A alla Dgr

n del

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

Ministere des Affaires Sociales et de la Sante (DGS FR), N/A, established in AVENUE Duquesne 14, PARIS CEDEX 75350, France, N/A, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('33')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission').*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Philippe CERTIN with ECAS id ncertiph signed in the Participant Portal on 17/08/2015 at 09:10:24 (transaction id SigId-2821-1MOZ5j3zLdhoDxZRDmAwULqvtiQRJks23qJOFmpHfit80vTbrOb4Z1jziPa3JV7TFzzGIZlWH9CkDM2JlKlaRQq-Jj71zxYb8yrmkuWnR3zgLC-iCH8zSzvjJ53PVHXagzho0hrYfsvBjpVuutXAAeexniO). Timestamp by third party at
Mon Aug 17 10:10:48 CEST 2015

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

ISTITUTO SUPERIORE DI SANITA (ISS), 80211730587, established in Viale Regina Elena 299, ROMA 00161, Italy, IT03657731000, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary ('34')

in Grant Agreement No 677024 ('the Agreement')

between INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) **and** *the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the power delegated by the European Commission ('the Commission'),*

for the action entitled 'Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases (RD-ACTION)'.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

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

Del Favero ANGELO with ECAS id nangdelf signed in the Participant Portal on 07/08/2015 at 07:52:00 (transaction id SigId-5524-tzmoFF2zYvlZM3NbnAzuDY8s4FRzKZ1eWAqFAc0jzrppzrMoaDagG9tAjeogQ3zM3vBD2DUlJFslSTFoZyOFfqyO-PHslUMVSXYCH3xcLZM8UuW-LJmLx5uVpSAEzaZ7MK7Nm8WzwuWDDkUhkbaYAm2y6zYu).
Timestamp by third party at
Fri Aug 07 08:52:04 CEST 2015

ⓘ print format A4 landscape

MODEL ANNEX 4 CHAFEA MGA — MULTI

FINANCIAL STATEMENT FOR *[BENEFICIARY [name]/AFFILIATED ENTITY [name]]* FOR REPORTING PERIOD [reporting period]

	Eligible [1] costs (per budget category)					Receipts			EU contribution
	A. Direct personnel costs	B. Direct costs of subcontracting	C. Other direct costs	D. Indirect costs [2]	Total costs	Income generated by the action	Financial contributions given by third parties to the beneficiaries	Total receipts	Requested EU contribution [3]
	A.1 Employees A.2 Natural persons under direct contract and seconded persons		C.1 Travel C.2 Equipment C.3 Other goods and services						
Cost form [4]	Actual	Actual	Actual	Flat-rate [5] 7%					
	a	b	c	d = 0,07 * (a + b + c)	e = a + b + c + d	f	g	h = f + g	i
[short name beneficiary/affiliated entity]									

The beneficiary/affiliated entity hereby confirms that:
The information provided is complete, reliable and true.
The costs declared are eligible (see Article 6).
The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 12, 13 and 17).
For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

ⓘ Please declare all eligible costs, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account lateron, in order to replace other costs that are found to be ineligible.

[1] See Article 6 for the eligibility conditions

[2] The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme); see Article 6.2.D. If you have received an operating grant during this reporting period, you cannot claim any indirect costs

[3] You may request up to 100% of the total cost declared. The reimbursement rate mentioned in Article 5.2 applies only at consortium level (and will only be checked by the Agency at the payment of the balance)

[4] See Article 5 for the cost forms

[5] Flat rate : 7% of eligible direct costs

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ANNEX 4 CHAFEA MGA — MULTI: Details

A. Direct personnel costs

A.1 Employees

Name/Function	No of hours worked for the project	Hourly rate	Total costs
	(a)	(b)	(c) = (a) * (b)
		Total for A.1 Employees	

A.2 Natural persons under direct contract and seconded persons

Name/Function	No of hours worked for the project	Hourly rate	Total costs
	(a)	(b)	(c) = (a) * (b)
		Total for A.2 Natural persons under direct contract and seconded persons	
		Total for A. Direct personnel costs	

B. Direct costs of subcontracting

Invoice Number	Subcontractor and Description of task	Price
	Total for B. Direct costs of subcontracting	

C. Other direct costs

C.1 Travel

Description (Name of person travelling, meeting as referenced in the technical report, place of the meeting)	Travel cost	No of days	Daily rate	Total costs
	(a)	(b)	(c)	(d) = (a) + ((b) * (c))
			Total for C.1 Travel	

C.2 Equipment

Invoice Number	Description of the equipment	Purchase price	Date of purchase	Depreciation method (36 or 60 month)	Number of month of depreciation allocated to the project	% of use for the purpose of the project	Total costs
		(a)	(b)	(c)	(d)	(e)	(f) = (d)/(c) * (e) * (a)
						Total for C.2 Equipment	

C.3 Other goods and services

Invoice Number	Description of service or good	Purchase price
	Total for C.3 Other goods and services	
	Total for C. Other direct costs	

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REGIONE DEL VENETO

ANNEX 5

MODEL OF 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

TABLE OF CONTENTS

Terms of Reference for an Independent Certificate on Financial Statements and Report on Findings on costs declared under a Grant Agreement financed under the Health and Consumer Programmes 2014-2020

This document sets out the '**Terms of Reference (ToR)**' under which

[insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to issue an Independent Certificate on the Financial Statements' ('CFS') referred to in Articles 15.3 and 15.4 of the Agreement based on the compulsory reporting template stipulated by the Agency, and

to produce an independent Report of findings ('the Report') concerning the Financial Statement(s)[1] drawn up by the *[Beneficiary] [Affiliated Entity]* for the [Health] / [Consumer] Programme 2014-2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'),

The Agreement has been concluded under the [Health] / [Consumer] Programme 2014-2020 between the Beneficiary and *Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission').*

The *Agency* is mentioned as a signatory of the Agreement with the Beneficiary only. The Agency is not a party to this engagement.

1.1 Subject of the engagement

The coordinator must submit to the Agency the final report within 60 days following the end of the each reporting period which should include, amongst other documents, a CFS for each beneficiary (and linked affiliated entity), for which the total contribution in the form of reimbursement of actual costs as referred to in Article 5.2 of the Agreement is at least EUR 750.000, and which requests a reimbursement in that form of EUR 325 000 or more, as reimbursement of actual costs calculated on the basis of its usual cost accounting practices. The CFS must cover the reporting period of the beneficiary (or linked Affiliated Entity) concerned by the payment.

The Beneficiary must submit to the coordinator the CFS for itself and for its linked Affiliated Entity, if the CFS must be included in the interim and final reports according to Articles 15.3 and 15.4 of the Agreement.

The CFS is composed of the following documents:

[1] By which costs under the Agreement are declared (see template 'Model Financial Statements' in Annex 4 to the Grant Agreement).

- The Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Affiliated Entity]* and the Auditor;
- the Auditor's Certificate on Financial Statements and Independent Report of 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 checks (laid down in the Annex I to the Report) to be performed by the Auditor, and the standard findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the interim and final report according to Articles 15.3 and 15.4 of the Agreement, the request for interim payment or payment of the balance to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the Agency, the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 17 of the Agreement.

1.2 Responsibilities

The *[Beneficiary] [Linked Affiliated Entity]:*

- 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 Affiliated Entity'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 checks.;
- accepts that the Auditor cannot carry out the checks unless he/she is given full access to the *[Beneficiary's] [Linked Affiliated Entity'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 Affiliated Officer 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*]*.

The Auditor:

- must be independent from the Beneficiary *[and the Linked Affiliated Entity]*, in particular, it must not have been involved in preparing the *[Beneficiary's] [Linked Affiliated Entity's]* Financial Statement(s);
- must plan work so that the checks may be carried out and the Findings may be assessed;
- must adhere to the checks laid down in Annex I to the Report 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 Affiliated Entity]*.

The Agency sets out the list of checks to be carried out by the Auditor which is defined in detail in the Annex I to the Report. The Auditor has to examine the Financial Statements and verify the supporting documentation in order to provide a reasonable assurance on their correctness.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[2]:

- 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 checks, the 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 Affiliated Entity]*, 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.

Under Article 17 of the Agreement, 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 declared from *the European Union* 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 Agency, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The CFS must be provided together with the request for the interim and balance payment, if required according to Articles 15.3 and 15.4 of the Agreement.

1.6 Other terms

[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.

[*The [Beneficiary] [Linked Affiliated Entity] 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 Affiliated Entity]*]
[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 Affiliated Entity]*

Independent certificate on the financial statements declared under grant agreements signed under the Health and Consumer Programmes 2014-2020

(To be submitted by each beneficiary if the maximum grant amount in the form of reimbursement of 'actual costs' is at least EUR 750 000 and if it requests a reimbursement of actual costs of at least EUR 325 000 (see Articles 15.3 and 15.4)
To be drawn up and signed by an approved auditor or, in case of public bodies, by a competent and independent public officer (and printed on their letterhead).)

To
[name of contact person(s)], [Position]
[[*Beneficiary's*] [*Linked Affiliated Entity'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 Affiliated Entity ('the Linked Affiliated Entity), Affiliated Entity 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],

have carried out an audit relating to the provisions of the Terms of Reference, the costs declared in the Financial Statement(s)[3] of the *[Beneficiary] [Linked Affiliated Entity]*, the documents provided in their support , to which this Certificate is attached, and which is to be presented to Agency together with the request for payment under the grant agreement [insert grant agreement reference: number, title of the action and acronym] ('the Agreement'), for the following period (s) covered by Agreement [insert period(s) covered by the Financial Statements].

The audit and subsequent checks were carried out solely to assist Agency in evaluating whether the*[Beneficiary][Linked Affiliated Entity's]* costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The Agency will draw its own conclusions from the Report and any additional information it may require.

The above mentioned Financial Statement(s) of the *[Beneficiary] [Linked Affiliated Entity]*, their supporting documentation and accounting records were examined in accordance with

[3] By which the Beneficiary declares costs under the Agreement (see template 'Financial Statement' in Annex 4 to the Agreement).

the upon-agreed checks , as detailed in Annex I to the Report, in order to provide Agency with the following reasonable assurance:

- the amount of the total eligible costs (*[insert amount in number]* (*[insert amount in words*[4]*]*)) declared in the attached Financial Statement(s) of the *[Beneficiary] [Linked Affiliated Entity]* is complying with the following cumulative conditions, as defined in the Article 6.1 of the Agreement:
  - ✓ they are actual and recorded in the *[Beneficiary's] [Linked Affiliated Entity's]*accounts at the date of the establishment of this audit certificate;
  - ✓ they have been incurred during the periods covered by the Financial Statement(s) concerned by this audit certificate;

    [they also include the eligible costs incurred in drawing up the final reports referred to in Article 15 of the Agreement, which may be incurred up to two calendar months after the end of the action;]
  - ✓ they are determined in accordance with the beneficiary's accounting standards applicable in the country where the *[Beneficiary] [Linked Affiliated Entity]*is established, and with the beneficiary's usual cost accounting practices;
  - ✓ they comply with the national law on taxes, labour and social security applicable in the country where the *[Beneficiary] [Linked Affiliated Entity]*is established;
  - ✓ they are exclusive of any non-eligible costs identified below which are established in Article 6.4 of the above mentioned agreement with the Agency:
    - return on capital;
    - debt and debt service charges;
    - provisions for future losses or debts;
    - interest owed;
    - doubtful debts;
    - currency exchange losses;
    - bank costs charged by the beneficiary's bank for transfers from the Agency;
    - deductible VAT;
    - costs incurred during suspension of the implementation of the action;
    - excessive or reckless expenditure;
    - contributions in kind provided by third-parties;
    - costs declared under another EU or Euratom grant, in particular, indirect costs if beneficiary is already receiving an operating grant financed by EU or Euratom in the same period.
  - ✓ [they are claimed according to the EUR conversion rate as defined in the Article 15.5 of the Agreement;
- as declared in the Financial Statement(s) of the *[Beneficiary] [Linked Affiliated Entity*] and only for the request of payment of the balance, the total amount of receipts for the total period covered by this(those) Financial Statement(s) is equal to (*[insert amount in number]* (*[insert amount in words*[5]*]*) ;

[4] In EUR.

[5] In EUR.

- accounting procedures used in the recording of eligible costs and receipts respect the accounting rules of the State in which the beneficiary is established and permit the direct reconciliation between the costs and receipts incurred for the implementation of the project covered by the Agreement and the overall statement of accounts relating to the beneficiary's overall business activity[6];
- based on our audit, we can conclude that the financial management of the grant was carried out in an acceptable manner and in compliance with the requirements of *[grant agreement reference: title, acronym, number]*
- our company [organisation – for competent public officers] is qualified to deliver this audit certificate in full compliance with the Articles 15.3 and 15.4 of the agreement;

  [Relevant information establishing this qualification is included with this audit certificate;][7]

The list of Findings, Exceptions and Further remarks, if any, is presented in the Report annexed to this Certificate.

The Certificate on Financial Statement(s) and Report was prepared solely for the confidential use of the *[Beneficiary] [Linked Affiliated Entity]* and the Agency, and only to be submitted to the Agency in connection with the requirements set out in Articles 15.3 and 15.4 of the Agreement. The Certificate and Report may not be used by the *[Beneficiary] [Linked Affiliated Entity]* or by the Agency for any other purpose, nor may it be distributed to any other parties. The Agency may only disclose these documents to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

Both Certificate and Report relate only to the Financial Statement(s) submitted to the Agency by the *[Beneficiary] [Linked Affiliated Entity]* for the Agreement. Therefore, they do not extend to any other of the [*Beneficiary's*] [*Linked Affiliated Entity's*] Financial Statement(s).

There was no conflict of interest[8] between the Auditor and the Beneficiary *[and Linked Affiliated Entity]* in establishing these documents. As declared in the Financial Statement(s) the total fee paid to the Auditor for providing the Report was EUR _____ (including EUR_____ of deductible VAT).

.

[legal name of the Auditor]
[name and function of an authorised representative]

---

[6] Article 6.1.

[7] If the auditor is not known internationally or for a competent public officer whose competence to provide an audit certificate has not been attested to by its national authorities.

[8] 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.

[dd Month yyyy]
Signature of the Auditor

Report of Findings on costs declared under grant agreement signed under Health and Consumer Programmes 2014-2020

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 check(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 check(s) are not applicable;

ii) if the condition set to apply certain check(s) are not met the related Finding(s) and those check(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the check 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 check(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

The *[Beneficiary] [Linked Affiliated Entity]* provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested checks and evaluate the Findings.

Explanation (to be removed from the Report):

- *If the Auditor was not able to successfully complete a procedure requested,. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the audit must be indicated below.*
- *If the Auditor cannot corroborate a standard finding after having carried out the corresponding audit, it must state, 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 daily costs was different from the one accepted by the Agency. The differences were as follows: ...*
3. *After carrying out the agreed checks 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: ....*

ANNEX I to the Report on Findings: Agreed-upon checks to be performed and standard findings to be confirmed by the Auditor

The Agency reserves the right to i) provide the auditor with additional guidance regarding the checks 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 checks, by notifying the Beneficiary in writing. The list of checks to be carried out by the auditor in order to confirm the standard findings is laid down in the table below.

If this certificate relates to a Linked Affiliated Entity, any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Affiliated Entity'.

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 finding' and, therefore, there is no exception to be reported.
- 'E' stands for 'exception' and means that the Auditor carried out the checks but cannot confirm the 'standard finding', or that the Auditor was not able to carry out a specific check (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 check(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 check(s) are not applicable; ii) if the condition set to apply certain checks(s) are not met then the related Finding(s) and checks(s) are not applicable. For instance, if no additional remuneration is paid, the related Finding(s) and check(s) for additional remuneration are not applicable.

Ref	Checks	Standard finding	Result (C / E /N.A)
A	**ACTUAL PERSONNEL COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE**		
	The Auditor draws the full list of persons (including *employees and natural persons working under a direct contract)* whose costs were declared in the Financial Statement(s) in order to carry out the checks indicated in the consecutive points of this section A. (The Auditor sampled _____ people out of the total of _____ people.		

Ref	Checks	Standard finding	Result (C / E /N.A)
A.1	**PERSONNEL COSTS** For the persons declared by the beneficiary or Linked Affiliated Entity in the Financial Statement, and working under an employment contract or equivalent act (general procedures for individual actual personnel costs) To confirm standard findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: ○ a list of the persons declared by Beneficiary or Linked Affiliated Entity 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; ○ 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 the declared personnel, in particular their employment contracts or equivalent; ○ 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.	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.	
		2) Personnel costs were recorded in the Beneficiary's accounts/payroll system.	
		3) Costs were adequately supported and reconciled with the accounts and payroll records.	
		4) Personnel costs did not contain any ineligible elements.	
		5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.	

Ref	Checks	Standard finding	Result (C / E /N.A)
	Further procedures if 'additional remuneration' is paid To confirm standard factual findings 6-8 listed in the next column, the Auditor: ○ 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.). *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., THIS CAN BE CHARGED AS ELIGIBLE COST TO THE ACTION.*	6) The Beneficiary paying "additional remuneration" was a non-profit legal entity.	
		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.	
		8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used.	
	<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> To confirm standard factual findings 9-13 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary:	9) The natural persons reported to the Beneficiary (worked under the Beneficiary's instructions).	
		10) They worked on the Beneficiary's premises (unless otherwise agreed with the	

Ref	Checks	Standard finding	Result (C / E /N.A)
	○ the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary; ○ 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.).	Beneficiary).	
		11) The results of work carried out belong to the Beneficiary.	
		12) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		13) The costs were supported by audit evidence and registered in the accounts.	
A.2	**PRODUCTIVE HOURS** To confirm standard factual findings 14-19 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: ○ 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.	14) The Beneficiary applied method [*choose one option and delete the others*] [**A**: 1720 hours] [**B**: the 'total number of hours worked'] [**C**: 'annual productive hours' used correspond to usual accounting practices]	
	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	15) Productive hours were calculated annually.	

Ref	Checks	Standard finding	Result (C / E /N.A)
	workable hours. 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. *BENEFICIARY'S PRODUCTIVE HOURS' FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS:* *A. 1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)* *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).* *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*	16) For employees not working full-time the full-time equivalent (FTE) ratio was correctly applied.	
		If the Beneficiary applied method B. 17) The calculation of the number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary.	
		If the Beneficiary applied method C. 18) The calculation of the number of 'standard annual workable hours' was verifiable based on the documents provided by the Beneficiary.	

Ref	Checks	Standard finding	Result (C / E /N.A)
	COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS. *'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.*	19) 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'.	
A.3	**TIME RECORDING SYSTEM** 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: ○ 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) ;	20) All persons recorded their time dedicated to the action on a **daily/ weekly/ monthly** basis using a **paper/computer-based** system. (*delete the answers that are not applicable)*	
		21) Their time-records were authorised at least monthly by the project manager or other superior.	
		22) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.	

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Ref	Checks	Standard finding	Result (C / E /N.A)
	○ the hours charged to the action matched those in the time recording system. *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).*	23) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.	
	<u>If the persons are working exclusively for the action and without time records</u> 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.	24) The exclusive dedication is supported by a declaration signed by the Beneficiary's and by any other evidence gathered.	
B	**COSTS OF SUBCONTRACTING**		
B.1	**The Auditor obtained the detail/breakdown of subcontracting costs and sampled _____ 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*). To confirm standard factual findings 25-29 listed in the next column, the Auditor reviewed the following for the items included in the sample: ○ the use of subcontractors was foreseen in Annex 1of grant agreement; ○ subcontracting costs were declared in the subcontracting category of the Financial Statement;	25) The use of claimed subcontracting costs was foreseen in Annex 1 to the Agreement and costs were declared in the Financial Statements under the subcontracting category.	
		26) There were documents of requests to different providers, different offers and assessment of the offers before selection of	

Ref	Checks	Standard finding	Result (C / E /N.A)
	○ 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). In particular, 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..	the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Agency will analyse this information to evaluate whether these costs might be accepted as eligible)*	
	For the items included in the sample the Auditor also verified that: ○ the subcontracts were not awarded to other Beneficiaries in the consortium; ○ there were signed agreements between the Beneficiary and the subcontractor; ○ there was evidence that the services were provided by subcontractor;	27) The subcontracts were not awarded to other Beneficiaries of the consortium.	
		28) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.	
		29) There was evidence that the services were provided by the	

Ref	Checks	Standard finding	Result (C / E /N.A)
		subcontractors.	
C	**OTHER ACTUAL DIRECT COSTS**		
C.1	**COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES** **The Auditor sampled _____ 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 the highest*). The Auditor inspected the sample and verified that: ○ 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.	30) Costs were incurred, approved and reimbursed in line with the Beneficiary's usual policy for travels.	
		31) There was a link between the trip and the action.	
		32) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting.	
		33) No ineligible costs or excessive or reckless expenditure was declared.	
C.2	**DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required*	34) Procurement rules, principles and guides were followed.	

Ref	Checks	Standard finding	Result (C / E /N.A)
	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). For "equipment, infrastructure or other assets" selected in the sample the Auditor verified that: ○ 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); 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). The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.4 GA).	35) There was a link between the grant agreement and the asset charged to the action.	
		36) The asset charged to the action was traceable to the accounting records and the underlying documents.	
		37) 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.	
		38) The amount charged corresponded to the actual usage for the action.	
		39) No ineligible costs or excessive or reckless expenditure were declared.	
C.3	**COSTS OF OTHER GOODS AND SERVICES** **The Auditor sampled _____ 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,*	43) Contracts for works or services did not cover tasks described in Annex 1to the Grant Agreement.	

Ref	Checks	Standard finding	Result (C / E /N.A)
	or 10% of the total, whichever number is highest). For the purchase of goods, works or services included in the sample the Auditor verified that: ○ the contracts did not cover tasks described in Annex 1; ○ 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 6.4 GA). In addition, the Auditor verified that these goods and services were acquired in conformity with the Beneficiary's internal guidelines and procedures, in particular: ○ 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. For the items included in the sample the Auditor also verified that: ○ 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	44) Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment. 45) The costs were charged in line with the Beneficiary's accounting policy and were adequately supported. 46) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups. 47) 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.	

Ref	Checks	Standard finding	Result (C / E /N.A)
	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); *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 AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.*	*(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Agency will analyse this information to evaluate whether these costs might be accepted as eligible)*	
D	**USE OF EXCHANGE RATES**		
D.1	a) For Beneficiaries with accounts established in a currency other than euros **The Auditor sampled _____ 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)*: *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.* *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*	48) 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.	

Ref	Checks	Standard finding	Result (C / E /N.A)
	PUBLISHED ON ITS WEBSITE (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.		
	b) For Beneficiaries with accounts established in euros **The Auditor sampled _____ 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)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY'S USUAL ACCOUNTING PRACTICES.*	49) The Beneficiary applied its usual accounting practices.	

[legal name of the audit firm]
[name and function of an authorised representative]

[dd Month yyyy]
<Signature of the Auditor

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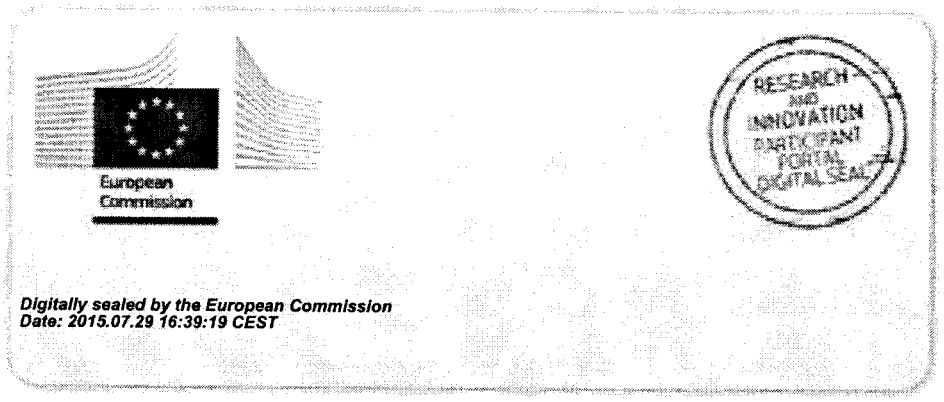

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