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CONSORTIUM AGREEMENT 631-056/12
To Grant Agreement nr 2011 23 02

for

**PARENT Joint Action –
Cross border Patient Registries Initiative**

PARENT Consortium Agreement

THIS CONSORTIUM AGREEMENT is based upon the Grant Agreement nr. 2011 23 02 for the Action entitled "Cross border Patient Registries Initiative – PARENT and is made on 17 September 2012, hereinafter referred to as "effective date".

BETWEEN:

- (1) National Institute of Public Health of the Republic of Slovenia (NIPH, the Coordinator)
- (2) National Institute of Health and Welfare (THL) – established in Finland
- (3) Národné centrum zdravotníckych informácií (NCZI) – established in Slovakia
- (4) Ministry of Health, the Elderly & Community Care (MHEC) – established in Malta
- (5) National Institute for Quality- and Organizational Development in Healthcare and Medicines (GYEMSZI) – established in Hungary
- (6) Direcção geral de Saúde (DGS) – established in Portugal
- (7) Ministry of Health (MdS) – established in Italy
- (8) CENTRO SUPERIOR DE INVESTIGACIÓN EN SALUD PÚBLICA (CSISP/DGSP) – established in Spain
- (9) National Institute of Public Health (HZJZ) – established in Croatia
- (10) Ministry of Health (MZ) – established in Slovenia
- (11) National and Kapodistrian University of Athens (NKUA) – established in Greece

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Hereinafter, jointly or individually, referred to as "Parties" or "Party"
relating to the Action entitled "Cross border Patient Registries Initiative"
in short

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hereinafter referred to as "the Action".

The Action shall run for 36 months from 2 May 2012 ("the starting date of the Action").

WHEREAS:

The Parties, having considerable experience in the field concerned, have submitted a proposal for the Action to the Executive Agency for Health and Consumers

The Parties have entered into the Grant Agreement

The Parties wish to specify or supplement, among themselves the provisions of the Grant Agreement.

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

Section 1: Definitions

Words beginning with a capital letter shall have the meaning defined either herein or in the Grant Agreement including its Annexes without the need to replicate said terms herein.

Consortium Agreement means the present agreement.

Coordinator is the National Institute of Public Health of the Republic of Slovenia.

Executive Agency is the Executive Agency for Health and Consumers (hereinafter EAHC) acting under powers delegated by the Commission of the European Union (hereinafter EC).

Grant Agreement means the Grant Agreement No. 2011 23 02 (including its Annexes) between the Commission and the Consortium for the undertaking by the Parties of the Action. Grant Agreement also means, as applicable, any Grant Agreement amendment.

Party or Parties means a party or the parties to this Consortium Agreement also identified as the parties to the Grant Agreement (also referred to in the Grant Agreement as Associated Partners).

Stakeholder or Stakeholders means an organisation or body external to the list of Parties as identified in the Action's Grant Agreement and external to the list of Collaborating Partners for which a meaningful reason exists to be engaged in the Action for the purpose of providing input to the Action or share the Action's results.

Foreground means the results, including information, materials and knowledge, generated within the Action, whether or not they can be protected. It includes intellectual property rights (IPRs, such as rights resulting from copyright protection, related rights, design rights, patent

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rights), similar forms of protections (e.g. sui generis right for databases) and unprotected know-how (e.g. confidential material). Thus, foreground includes the tangible (e.g. prototypes, source code) and intangible (IPR) results of a project. Results generated outside the Action (i.e. before, after or in parallel with the Action) do not constitute foreground.

Background is information and knowledge (including inventions, databases, etc.) held by the participants prior to their accession to the Grant Agreement, as well as any IPRs, which are needed for carrying out the project or for using foreground. Regarding IPRs for which an application shall be filed, only those IPRs are included, for which the application was filed before the accession of the participant to the Grant Agreement.

Section 2: Purpose

The contracting Parties of this Consortium Agreement are determined to realise the Action under the precondition of approved funding of EAHC and assured by the Grant Agreement.

This Consortium Agreement is a legal agreement between its signatories.

The purpose of this Consortium Agreement is to specify with respect to the Action the relationship among the Parties, in particular concerning the organisation of the work between the Parties, the management of the Action and the rights and obligations of the Parties concerning inter alia liability, access rights and dispute resolution.

The work to be accomplished, including the deliverables and their timing, the contribution by each Party (personell structure, Work Package Leadership, subcontracting responsibility), and the maximum expected effort by each Party, is set out in Annexes of the Grant Agreement.

This Consortium Agreement shall not conflict with the provisions in the Grant Agreement. Any provision in this Consortium Agreement shall be valid to manage the relations between the Parties of the Action, but can not change the way the relation between the EC and the Action's Parties are described in the Grant Agreement.

Section 3: Entry into force, duration, termination and amendments

3.1 Entry into force

This Consortium Agreement shall come into force at the date of its signature by the Parties, but shall have retroactive effect from 2 May 2012 (the starting date of the Action).

A new Party enters the Consortium upon signature of the accession document (see Annex 1) by the by a duly authorised representative of the new Party and the Coordinator.

The Coordinator shall give proper advice to other Parties before signing the accession document in order to share the decision.

3.2 Duration and termination

This Consortium Agreement shall continue in full force and effect until complete fulfilment of all obligations undertaken by the Parties under the Grant Agreement and under this Consortium Agreement.

However, this Consortium Agreement or the participation of one or more Parties to it may be terminated in accordance with the terms of this Consortium Agreement and General Conditions – Legal and Administrative Provisions of the Grant Agreement (Article II.11).

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If EAHC terminates the Grant Agreement or a Party's participation in the Grant Agreement, this Consortium Agreement shall automatically terminate in respect of the affected Party/ies, subject to the provisions surviving the expiration or termination under Art. 3.3 of this Consortium Agreement.

3.3 Survival of rights and obligations

The provisions relating to access rights and confidentiality, as well as for liability, applicable law and settlement of disputes shall survive the expiration or termination of this Consortium Agreement for a period of 2 years.

Termination shall not affect any rights or obligations of a Party leaving the Consortium incurred prior to the date of termination, unless otherwise agreed between the Action and the leaving Party. This includes the obligation to provide all input, deliverables and documents for the period of its participation.

3.4 Changes to this Consortium Agreement

In case the circumstances require changes to the Consortium Agreement, an amendment shall be added upon agreement of all Parties.

Section 4: Responsibilities of Parties

4.1 General principles

Each Party shall undertake to take part in the efficient implementation of the Action, and to cooperate, perform and fulfil, promptly and on time, all of its obligations under the Grant Agreement and this Consortium Agreement as may be reasonably required from it and in a manner of good faith.

Each Party shall undertake to notify promptly, in accordance with the governance structure of the Action, any significant information, fact, problem or delay likely to affect the action, as well as a suggested contingency plan to remedy it.

Each Party shall promptly provide all information reasonably required by the Coordinator to carry out its tasks.

Each Party shall take reasonable measures to ensure the accuracy of any information or materials it supplies to the Coordinator and/or other Parties.

In case of interdependence of Work Packages or activities across Work Packages (as in case of Work Package 4 and 6), Parties acting as respective Work Package Leaders are responsible to prepare a plan of interdependent activities and provide contingency management in addition to the work plan as laid out in the Annexes to the Grant Agreement.

4.2 Breach

In the event the Coordinator or the Action's governing bodies identifies a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement (e.g. producing poor quality work), the Coordinator shall give written notice to such Party requiring that such breach be remedied within 30 calendar days.

If such breach is substantial or is not remedied within that period or is not capable of remedy, the Coordinator shall inform the Joint Action Executive Committee (hereinafter the ExCo) to

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deliberate and decide, and the Plenary Assembly (hereinafter the PA) to review and confirm decisions made by the ExCo.

4.3 Financial penalties

By virtue of the Financial Regulation applicable to the general budget of the European Union, any one or several of the beneficiaries declared to be in grave breach of their obligations under the Grant Agreement (Article II.12) shall be liable to financial penalties of between 2% and 10% of the value of their share of the grant in question, with due regard to the principle of proportionality.

This rate may be increased to between 4% and 20% in the event of the repeated breach in five years following the first. The beneficiary concerned shall be notified in writing of any decision made by EAHC to apply such financial penalties.

4.4 Involvement of third parties

A Party that enters into a subcontract or otherwise involves third parties in the Action remains solely responsible for carrying out its relevant part of the Action and for such third party's compliance with the provisions of this Consortium Agreement and of the Grant Agreement. It has to ensure that the involvement of third parties does not affect the rights and obligations of other Parties under this Consortium Agreement and the Grant Agreement.

Section 5: Liability towards each other

5.1 No warranties

In respect of any information or materials (including foreground and background) supplied by one Party to another under the Action, no warranty or representation of any kind is made, given or implied as to the sufficiency or fitness for purpose, nor as to the absence of any infringement of any IPRs of third parties.

Therefore, the recipient Party shall in all cases be entirely and solely liable for the use to which it puts such information and materials, and no Party granting access rights shall be liable in case of infringement of IPRs of a third party resulting from any other Party (or its Affiliates) exercising its access rights.

5.2 Limitations of contractual liability

No Party shall be responsible to any other Party for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue or loss of contracts, provided such damage was not caused by a wilful act or by a breach of confidentiality.

5.3 Damage caused to third parties

Each Party shall be solely liable for any loss, damage or injury to third parties resulting from the performance of the said Party's obligations by it or on its behalf under this Consortium Agreement or from its use of foreground or background.

5.4 Force majeure

No Party shall be considered to be in breach of this Consortium Agreement, if such breach is caused by force majeure. Each Party shall notify the Coordinator of any force majeure as soon as possible. If the consequences of force majeure for the Action are not overcome

within 6 weeks after such notification, the transfer of tasks and financial resources - if any - shall be decided by the Coordinator.

Section 6: Joint Action Governance Structure

Work Package 1 (WP 1) concerns the overall management and coordination of the action to be led by the Coordinator.

6.1 General structure

The Joint Action Governance Structure was created with a clear division of responsibilities and tasks, consisting of two levels of action as depicted in Figure 1:

- a) Joint Action Plenary Assembly (PA)
- b) Joint Action Executive Committee (ExCo)

The ExCo is further supported by the Joint Action Secretariat (hereinafter the Secretariat) established by the Coordinator.

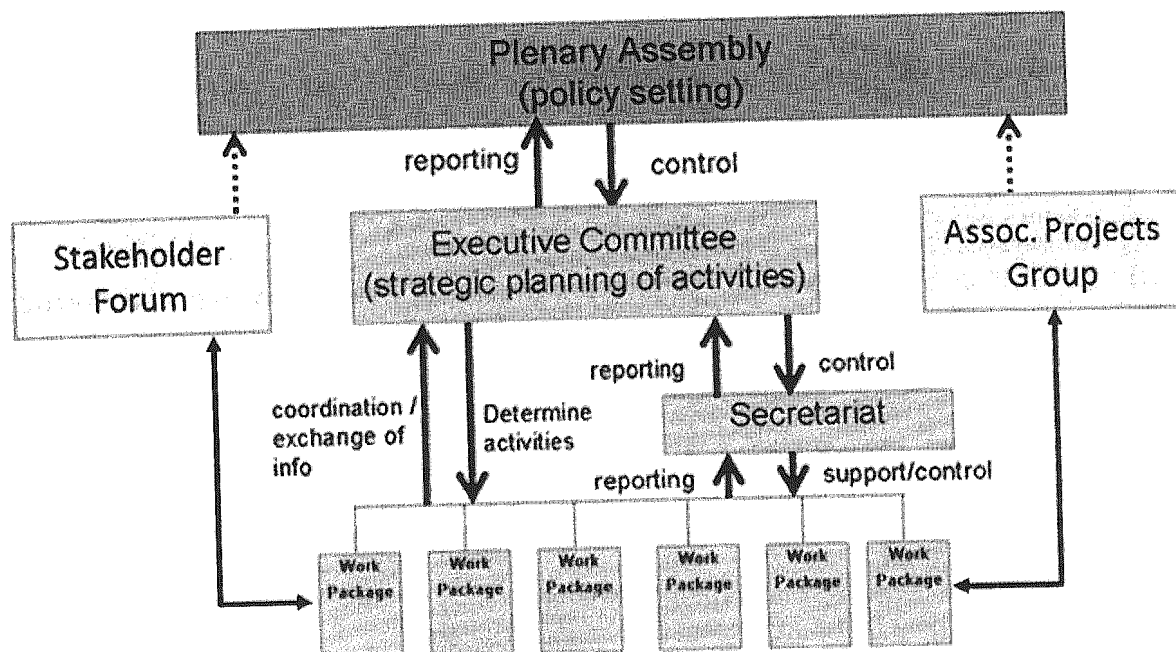


Figure 1: PARENT Governance Structure

6.2 Specific operational procedures for the Joint Action Governance Structure

The Coordinator (National Institute of Public Health of the Republic of Slovenia - NIPH)

The Coordinator shall be the intermediary between the Parties and EAHC and shall perform all tasks assigned to it as described in the Grant Agreement and in this Consortium Agreement.

In particular, the Coordinator shall be responsible for:

- (a) monitoring compliance by Parties with their obligations,
- (b) keeping the address list of Parties and other contact persons updated and available,

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- (c) collecting and submitting reports and other deliverables (including financial statements and related certifications) to EAHC,
- (d) transmitting documents and information connected with the Action to and between Parties, as appropriate, and any other Parties concerned,
- (e) administering the EU financial contribution.

The Coordinator shall not be entitled to act or to make legally binding declarations on behalf of any other Party.

The Coordinator shall not enlarge its role beyond the tasks specified in this Consortium Agreement and in the Grant Agreement.

Joint Action Secretariat (the Secretariat)

The Secretariat, established by the Coordinator shall have overall responsibility for administratively managing the execution of the Action. It shall thus be the official liaison for EC and EAHC as regards reporting requirements, budgetary management and timely delivery of the Action's deliverables.

The following proposals are to be prepared by the Secretariat under the direction and for use of the ExCo and PA:

- (a) proposal for changes (when the Coordinator requests an amendment) to the Annex I and Annex II to the Grant Agreement to be agreed by the EC,
- (b) entry of a new Party to the Consortium,
- (c) withdrawal of a Party from the Consortium,
- (d) declaration of a Party to be a defaulting Party,
- (e) remedies to be performed by a defaulting Party,
- (f) termination of a defaulting Party's participation in the Consortium and measures relating thereto.

The Secretariat is also responsible for overall:

- (a) financial and budgetary management,
- (b) support of the EAHC and EC related administrative processes,
- (c) assuring that project agreements are in line with the Consortium Agreement and the Grant Agreement,
- (d) monitoring of resource distribution and usage,
- (e) facilitating timely and transparent flow of information.

The Secretariat shall ensure timely and accurate financial and technical reports in liaison with Parties and Work Package Leaders (WPLs).

Information on progress with regard to timeframes shall be provided by WPLs using collaborative project management tools (e.g. telephone, e-mail, fax, ProjectPlace).

The Secretariat shall also liaise with all Parties regularly for provision of deliverables as instructed by ExCo and/or PA.

The Secretariat shall meet with Parties at PA and with WPLs at ExCo meetings. In lieu of face-to-face meetings, the Secretariat shall hold audio conferences when required and shall regularly liaise by phone and e-mail.

Plenary Assembly (the PA)

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The PA shall consist of associated partners (voting right), collaborating partners, EAHC, EC, APG and stakeholder representatives (no voting right). PA shall meet once a year in person and accordingly to a yearly plan via teleconference. It shall review ExCo decisions, provide ExCo with strategic guidance and ensure that the Action's objectives are met.

The PA meetings shall be co-chaired by a representative of the Coordinator and a representative of the EC.

The main task of the PA is to review and comment decisions made by the ExCo. The PA shall therefore serve as an oversight committee with regard to the Action's main objectives and anticipated goals. It shall also review the results of all the Work Packages and make additional suggestions as to the course of the action to be taken in the future.

Joint Action Executive Committee (the ExCo)

The ExCo was established to manage the execution of the Action, as well as to oversee the engagement of Associated Partners, the Associated Project Group (APG) and Stakeholders. It shall provide strategic guidance and support to the PA.

The ExCo shall be chaired by the Coordinator and consist of the WPLs, non voting representatives of EAHC and DG SANCO.

The ExCo shall:

- (a) supervise the progress of the Action,
- (b) review the project outcomes and identify the strong/weak points with respect to the objectives of their execution,
- (c) identify issues that bear an impact on deliverables and milestones of the Action,
- (d) undertake necessary and appropriate actions (modification of plan, issuing a warning to a partner, further measures) to achieve goals,
- (e) promote the exposure of the Action and link it to other similar EU and international efforts,
- (f) consider other potential applicants that may join the Action,
- (g) deliberate and decide on the method and terms by which potential partners can join the Action (as Collaborating Partners), approval of the settlement on the conditions of the accession of a new Party, and the approval of the settlement on the conditions of the withdrawal of a Party,
- (h) deliberate and decide on the method and terms by which representatives of projects related to the Action can join the Action (as members of Associated Projects Group) – as outlined in the Associated Projects Group Rules of Procedure,
- (i) deliberate and decide on the method and terms by which potential external stakeholders can join the Action (as members of Stakeholder Forum) – as outlined in Stakeholder Involvement Policy,
- (j) supervise technical and financial modifications of the Action.

The ExCo shall meet every 3 months in person during the course of the Action and shall be convened together with the PA.

At every ExCo meeting, the WPLs shall present progress report on their activities, milestones and deliverables vis-à-vis the work package plan.

Members of the ExCo shall communicate regularly using collaborative project management tools, such as ProjectPlace, and communicate regularly via e-mail, telephone/teleconferences and online.

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Work Package Leaders (WPLs)

Work Package Leaders are identified in Annex 1a of the Grant Agreement.

They shall manage the activities of the Work Package they are responsible for

- (a) the timely delivery of deliverables,
- (b) the timely execution of milestones,
- (c) reviewing the quality of deliverables and determining if deliverables are in line with the described objectives and description of deliverables as outlined in Annex 1 of the Grant Agreement,
- (d) alerting the ExCo and the Coordinator in case of delay in the performance (goals, deliverables etc.) of the Work Package or in case of breach of responsibilities of any Party involved in the Work Package, and preparing an action plan to improve the performance, which shall be approved by the ExCo,
- (e) analysing and documenting, at the request of the ExCo, a presumed breach of responsibilities of a Party involved in the Work Package and proposing measures to the ExCo,
- (f) submitting technical reports to the Secretariat every 3 months (using predefined templates).

Associated Projects Group

Please refer to *APG Rules of Procedure*.

Stakeholders

Please refer to *Stakeholder Involvement Policy*.

Section 7: Financial provisions

7.1 General Principles

7.1.1 Distribution of Financial Contribution

The Union financial contribution to the Action shall be distributed by the Coordinator according to the budget as included in Annex II of the Grant Agreement, the approval of reports by EAHC, and payment arrangements in Article I.5 of the Grant Agreement.

A Party shall be funded only for its tasks carried out in accordance with the budget.

7.1.2 Justifying Costs

In accordance with its own usual accounting and management principles and practices, each Party shall be solely responsible for justifying its costs with respect to the Action towards EAHC. The Coordinator shall not be in any way liable or responsible for such justification of costs towards EAHC.

Each Party's internal accounting and auditing procedures shall permit direct reconciliation of the costs and revenue declared in respect of the Action with the corresponding accounting statements and supporting documents.

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The Coordinator is an intermediary between Parties and the EAHC. The Coordinator is responsible for passing on to Parties any claims the EAHC might have in respect of the Grant Agreement, and supplying all the required documents and information to the EAHC.

Parties themselves shall certify that the information provided in their financial reports to the EAHC (via the Coordinator) is full, reliable and true. They shall also certify that the costs incurred can be considered eligible in accordance with the Grant Agreement (II General Conditions – Part B – Financial Provisions).

The Parties hereby agree that, to have a better financial overview of the Action, actual expenditure by the Partner and by the Work Package, with supporting documents, shall be submitted to the Coordinator after the following reporting periods:

- (a) RP1 (M1-6): 02.05.2012 - 01.11.2012
- (b) RP2 (M7-M15): 02.11.2012 - 01.08.2013
- (c) RP3 (M16-M22): 02.08.2013 - 01.03.2014
- (d) RP4 (M23-M30): 02.03.2014 - 01.11.2014
- (e) RP5 (M31-M36): 02.11.2014 - 01.5.2015

The interim technical and financial implementation report(s) with all supporting documents for the EAHC shall be submitted to the Coordinator according to the dispositions of the Grant Agreement.

7.1.3 Funding Principles for the pre-financing payments

Payments

Payments to Parties are the exclusive tasks of the Coordinator.

In particular, the Coordinator shall:

- (a) notify the Party concerned promptly of the date and composition of the amount transferred to its bank account, giving the relevant references,
- (b) perform diligently its tasks in the proper administration of any funds and in maintaining financial accounts.

Within 45 days from the day on which the bank account of the Coordinator has been credited, the Coordinator shall – under the precondition of provided financial identification from Parties – transfer to each Party the amounts corresponding to their participation in the Action in accordance with their pro rata share of the estimated costs and defined in the breakdown in Annex II when pre-financing payments are made, and their share of validated costs actually incurred when other payments are made (Grant Agreement Article I.7.3).

The payment schedule, which contains the transfer of pre-financing payments from the Coordinator to Parties, shall be handled according to the following (Grant Agreement Article I.5.2):

- (a) pre-financing payment equivalent to 40% of the EAHC contribution,
- (b) first further pre-financing payment equivalent to 30% of the EAHC contribution,
- (c) second further pre-financing payment equivalent to 30% of the EAHC contribution,
- (d) payment of the balance

Pre-financing from EAHC to the Coordinator may be paid in several instalments (Grant Agreement Article I.5.2). In that case, payment of each further instalment to the Coordinator

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may not be made until at least 30% of the previous pre-financing payment has been used up. Where the consumption of the previous pre-financing is less than 70%, the amount of the new pre-financing payment shall be reduced by the unused amounts of the previous pre-financing.¹ The Coordinator shall transfer payments to Parties in accordance with these terms of consumption.

All Parties shall provide the Coordinator with all the necessary supporting scanned documents. The Coordinator shall transfer the instalment once the Party submits all of the supporting documentation for the previous financial reporting period. If all of the supporting documents are not received by the agreed deadline, the Coordinator shall not be able to transfer the instalment to the Party in question; the Party in question shall receive their instalment at the next instalment period.

The Coordinator is entitled to withhold any payments due to a Party identified by the Advisory Committee to be in breach of its obligations under this Consortium Agreement or the Grant Agreement. The Coordinator is entitled to recover any payments already paid to a defaulting Party.

7.2 Submission of reports and other documents

The technical implementation reports, financial statements and other documents referred to in Article I.5 of the Grant Agreement shall be submitted to the Coordinator. The Coordinator shall pass on these documents to EAHC.

The Coordinator shall submit to EAHC interim reports and other documents related to a request for a first further pre-financing (as specified in Article I.5.2.) within 2 months following a period of 15 months after the starting date of the Action.

All Parties shall submit the technical implementation reports, financial statements and other documents to the Coordinator no later than 1 month following the reporting period.

The Coordinator shall submit to EAHC final reports and other documents related to a request for payment of the balance within 2 months following the closing date of the Action specified in Article I.2.2. of the Grant Agreement, covering the whole project duration.

All Parties shall submit the technical implementation reports, financial statements and other documents to the Coordinator no later than 1 month following the reporting period.

Section 8: Foreground

8.1 Ownership

Unless stipulated otherwise in the Grant Agreement, ownership of the results of the Action, including industrial and intellectual property rights, and of the reports and other documents relating to it shall be vested in the Parties (see Grant Agreement Article II.3.1 and paragraphs 4 and 5 of this article).

Without prejudice to paragraph 1, the Parties grant EAHC the right to make free use of the results of the Action as it deems fit, provided it does not thereby breach its confidentiality

¹ The new pre-financing instalment shall be reduced by the amount corresponding to the difference between the 70% threshold and the amount that was actually consumed (Example: previous pre-financing 300 of which 100 (<70%) was consumed; calculation: 210 (70% threshold of 300) – 100 consumed = deduction of 110 from following pre-financing instalment).

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obligations or existing industrial and intellectual property rights (see Grant Agreement Article II.3.2).

In case of pre-existing intellectual property rights the Parties need to establish their list and disclose it to EAHC prior to the commencement of implementation. The Parties shall ensure to have all rights to use any pre-existing intellectual property rights in implementation of the Grant Agreement (see Grant Agreement Article II.3.3).

Foreground resulting from the project shall be owned by the Party generating it. When foreground is generated jointly (i.e. where the separate parts of some result cannot be attributed to different Parties), it shall be jointly owned, unless the Parties concerned agree on a different solution.

The method of defining joint ownerships shall be based on their contributing efforts towards particular results of the Action in shares proportionate to the scope of work / budget for that particular result. In particular cases ownership may be dealt with in separate joint ownership agreements developed as needed for each joint ownership situation, and which may include also matters pertaining to transfer, protection, use and dissemination of foreground.

Ownership of background is not affected by participation in the Action.

8.2 Dissemination

8.2.1 Publication

8.2.1.1 Dissemination activities including but not restricted to publications shall be subject to the following provisions.

A regularly updated yearly dissemination plan shall be created. Any objection to the planned publication shall be made in writing to the Work Package 2 Leader and to any Party concerned as soon as possible and no later than 20 days before the planned submission of the publication. If no objection is made within the time limit stated above, the publication shall be permitted.

The Parties shall inform the Work Package 2 Leader of any publication, dissemination of results or promotion/exposure of the Action in order to ensure a timely publication of the press clippings on the website www.patientregistries.eu and to keep history of all dissemination activities.

8.2.1.2 An objection is justified if

- (a) the objecting Party's legitimate interests are compromised by the publication, or
- (b) the protection of the objecting Party's foreground or background is adversely affected.

The objection has to include a precise request for necessary modifications.

8.2.1.3 If an objection has been raised, the involved Parties shall discuss how to overcome the justified grounds for the objection. If an agreement cannot be reached, ExCo is to be informed of the objection and ExCo shall resolve the issue in 30 days.

8.2.2 Use of names, logos or trademarks

Nothing in this Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Parties or any of their logos or trademarks without their prior written approval.

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8.3 Access rights

8.3.1 In addition to the obligations pursuant to the EC contractual rules, each Party shall take appropriate measures to ensure that it can grant access rights to existing background and fulfil the obligations under the Grant Agreement and this Consortium Agreement notwithstanding any rights of its employees, or any person it assigns or engages to perform its own Work Package for the Action.

Any Party shall notify the others of any limitation on access rights promptly and in writing before accession to this Consortium Agreement.

The Parties agree that access rights are granted on a non-exclusive basis. The Parties also agree that, if not otherwise provided in this Consortium Agreement or granted by the owner, the access rights shall not include the right to grant sub-licenses.

Any grant of access rights not covered by this section shall be at the absolute discretion of the owning Party and subject to such terms and conditions as may be agreed between the owning and receiving Party.

8.3.2 Access rights needed for carrying out the requesting Party's own work under the Action shall be granted to a Party on a royalty-free basis.

Access rights shall be granted by the holder of the rights upon request and in writing. The requesting Party shall identify the extent of the access rights needed and provide reasonable evidence on its needs.

8.3.3 Any and all access rights granted to the defaulting Party by the other Parties under this Consortium Agreement as well as under the Grant Agreement shall cease immediately. Any and all access rights granted by the defaulting Party to the other Parties under this Consortium Agreement as well as under the Grant Agreement shall remain in full force and effect.

Section 9: Non-disclosure of information

9.1 All information in whatever form or mode of transmission, which is disclosed by a Party (the "Disclosing Party") to any other Party (the "Recipient") in connection with the Action during its implementation and which has been explicitly marked as "confidential", or when disclosed orally, has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within 15 days from oral disclosure at the latest as confidential information by the Disclosing Party, shall be considered as confidential information.

9.2 The Recipients hereby undertake in addition and without prejudice to any commitment of non-disclosure under the GA, for a period of 5 years after the end of the Action:

- (a) not to use confidential information otherwise than for the purpose for which it was disclosed,
- (b) not to disclose confidential information to any third party without the prior written consent by the Disclosing Party,
- (c) to ensure that internal distribution of confidential information by a Recipient shall take place on a strict need-to-know basis, and
- (d) to return to the Disclosing Party on demand all confidential information which has been supplied to or acquired by the Recipients, including all copies thereof, and to delete all information stored in a machine readable form. If needed for the recording of ongoing

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obligations, the Recipients may however request to keep a copy for archival purposes only.

9.3 The Recipients shall be responsible for the fulfilment of the above obligations on the part of their employees and shall ensure that their employees remain so obliged, as far as legally possible, during and after the end of the Action and/or after the termination of employment.

9.4 The above shall not apply for disclosure or use of confidential information, if and in so far as the Recipient can show that:

- (a) the confidential information becomes publicly available by means other than a breach of the Recipient's confidentiality obligations,
- (b) the Disclosing Party subsequently informs the Recipient that the confidential information is no longer confidential,
- (c) the confidential information is communicated to the Recipient without any obligation of confidence by a third party who is in lawful possession thereof and under no obligation of confidence to the Disclosing Party,
- (d) the disclosure or communication of the confidential information is foreseen by provisions of the Grant Agreement,
- (e) the confidential information, at any time, was developed by the Recipient completely independently of any such disclosure by the Disclosing Party, or
- (f) the confidential information was already known to the Recipient prior to the disclosure.

9.5 The Recipient shall apply the same degree of care with regard to the confidential information disclosed within the scope of the Action as with its own confidential and/or proprietary information, but in no case less than reasonable care.

9.6 Each Party shall promptly advise the other Party and the Coordinator in writing of any unauthorised disclosure, misappropriation or misuse of confidential information after it becomes aware of such unauthorised disclosure, misappropriation or misuse.

9.7 If any Party becomes aware that it will be required or is likely to be required to disclose confidential information in order to comply with applicable laws or regulations or with a court or administrative order, it shall to the extent the Party is lawfully able to do so and prior to any such disclosure:

- (a) notify the Disclosing Party, and
- (b) comply with the Disclosing Party's reasonable instructions to protect the confidentiality of the information.

9.8 The confidentiality obligations under this Consortium Agreement and the Grant Agreement shall not prevent the communication of confidential information to EAHC.

All documentation created for the purpose of the Action shall be considered internal if not specified otherwise.

9.9 Coordination of work, meetings, documents and any other information shall be carried out by using an online collaboration platform. Until further notice, ProjectPlace (PP) – available at www.projectplace.com – shall be used for this purpose. Rights and access to the online collaboration platform shall be set by ExCo and paid for centrally so that particular partners and experts have access to the online collaboration platform free of charge. All Parties agree that the information and use of documents shall be used only for the benefit of the Action within the rights granted.

Section 10: Miscellaneous

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10.1 Attachments, inconsistencies and severability

This Consortium Agreement consists of this core text and the Accession Document in Attachment 1.

In case the terms of this Consortium Agreement are in conflict with the terms of the Grant Agreement, the terms of the latter shall prevail. In case of conflicts between the attachments and the core text of this Consortium Agreement, the latter shall prevail.

If any provision of this Consortium Agreement becomes invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of this Consortium Agreement. In such a case, the Parties concerned shall be entitled to request that a valid and practicable provision be negotiated, which fulfils the purpose of the original provision.

10.2 No representation, partnership or agency

The Parties shall not be entitled to act or to make legally binding declarations on behalf of any other Party. Nothing in this Consortium Agreement shall be deemed to constitute a joint venture, agency, partnership, interest grouping or any other kind of formal business grouping or entity between the Parties.

10.3 Notices and other communication

Any notice to be given under this Consortium Agreement shall be in writing to the addresses and recipients as listed in the most current address list kept by the Coordinator.

10.3.1 Formal notices:

If it is required in this Consortium Agreement that a formal notice, consent or approval shall be given, such notice shall be signed by an authorised representative of a Party and shall either be served personally or sent by mail with recorded delivery or telefax with receipt acknowledgement.

10.3.2 Other communication:

Other communication between the Parties may also be effected by other means such as e-mail with acknowledgement of receipt, which fulfils the conditions of written form.

Any change of persons or contact details shall be notified immediately by the respective Party to the Coordinator. The address list shall be accessible to all concerned.

10.4 Assignment and amendments

No rights or obligations of the Parties arising from this Consortium Agreement may be assigned or transferred, in whole or in part, to any third party without the other Parties' prior formal approval.

10.5 Language

This Consortium Agreement is drawn up in English, which shall govern all documents, notices, meetings, arbitral proceedings and processes relative thereto.

10.6 Settlement of disputes

PARENT Consortium Agreement

Any disputes identified within or between Work Packages are to be submitted by the respective Work Package Leaders to ExCo within 10 days. ExCo solves the dispute using majority vote. In case a solution is not reached, ExCo shall submit the dispute to the PA that shall address it in 30 days by using majority vote.

10.6 Law applicable and competent court

This Consortium Agreement shall be construed in accordance with and governed by the laws provided in the Grant Agreement (Article 1.9).

PARENT Consortium Agreement

Section 11: Parties and authorised representatives for signature

The Parties have caused this Consortium Agreement to be duly signed by these authorised representatives.

- (1) **National Institute of Public Health of the Republic of Slovenia (NIPH)**
Marija Seljak
Acting Director
- (2) **Terveysten ja hyvinvoinnin laitos (THL) - National Institute of Health and Welfare**
Pekka Puska
Director General
- (3) **Národné centrum zdravotníckych informácií (NCZI) - National Health Information Center**
Luboš Černý
Director
- (4) **Ministeru Ghas-Sahha, L-Anzjani u Kura Fil-Komunita - Ministry of Health, the Elderly & Community Care (MHEC)**
Kenneth Grech
Permanent Secretary
- (5) **Gyógyszerészeti és Egészségügyi Minőség – és Szervezetfejlesztési Intézet (GYEMSZI) - National Institute for Quality- and Organizational Development in Healthcare and Medicines**
Krisztina Török
Director General
- (6) **Direcção geral de Saúde (DGS) – Directorate-General for Health**
Francisco George
Director General
- (7) **Ministero della Salute (MDS) - Ministry of Health**
Rossana Ugenti
Director General
- (8) **Centro Superior de Investigación en Salud Pública (CSISP)**
Andrés Moya
Director
- (9) **Hrvatski zavod za javno zdravstvo (HZJZ) - National Institute of Public Health**
Željko Baklaić
Director
- (10) **Ministrstvo za zdravje (MZ) – Ministry of Health**
Tomaž Gantar
Minister
- (11) **National and Kapodistrian University of Athens (NKUA)**
Thomas Sfikopoulos
Vice Rector

PARENT Consortium Agreement

Annex 1: Accession Document

Joining of a Party to

PARENT Consortium Agreement 631-056/12, hereinafter the Consortium Agreement

Národné centrum zdravotníckych informácií (NCZI) - National Health Information Center

hereby consents to become a Party to the Consortium Agreement identified above and accepts all the rights and obligations of a Party to the Consortium Agreement starting 2 May 2012.

National Institute of Public Health, Republic of Slovenia, Trubarjeva cesta 2, 1000 Ljubljana, hereby certifies the joining of the Národné centrum zdravotníckych informácií (NCZI) - National Health Information Center to the Consortium Agreement indicated above.

Národné centrum zdravotníckych informácií (NCZI) - National Health Information Center confirms to have received a copy of the Consortium Agreement printed on 17 September from National Institute of Public Health and accepts as 2 May 2012 in accordance with the provisions of the Consortium Agreement all rights and obligations of a Party of the Consortium Agreement.

This document has been printed in 3 originals to be duly signed by the undersigned authorised representatives. One original shall be kept by Národné centrum zdravotníckych informácií (NCZI) - National Health Information Center and two by National Institute of Public Health.

Národné centrum zdravotníckych informácií (NCZI) - National Health Information Center
Ľuboš Černý
Director

Signature and Stamp:

23.09.2012, BRATISLAVA
[Date and Place]

National Institute of Public Health, Republic of Slovenia
Marija Seljak
Acting Director

Signature and Stamp:

Ljubljana, 17 September 2012