CONSORTIUM AGREEMENT

This AGREEMENT is made on '01.12.2019

BETWEEN

- (1) empirica Gesellschaft für Kommunikations- und Technologieforschung (EMP, Coordinator)
- (2) SPMS Serviços Partilhados do Ministério da Saúde, E.P.E. (SPMS)
- (3) AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS (AEMPS)
- (4) Agencija za lijekove i medicinske proizvode (HALMED)
- (5) College ter Beoordeling van Geneesmiddelen (CBG)
- (6) Azienda Ospedaliera Universitaria Federico II (FOUND)
- (7) Beth Israel Deaconess Medical Center, Inc (BIDMC)
- (8) Bundesinstitut für Arzneimittel und Medizinprodukte (BFARM)
- (9) COMITE EUROPEEN DE COORDINATION DES INDUSTRIES RADIOLOGIQUES ELECTROMEDICALES ET D INFORMATIQUE DE SANTE AISBL (COCIR)
- (10) DATAWIZARD SRL (DWIZ)
- (11) Department of Health (IEDOH)
- (12) ELGA GmbH (ELGA)
- (13) European Health Telematics Association (EHTEL)
- (14) Agence fédérale des médicmanets et des produits de santé (AFMPS)
- (15) Gnomon Informatics SA (GNOMON)
- (16) Health Products Regulatory Authority (HPRA)
- (17) HL7 Fondation (HL7)
- (18) Hrvatski zavod za zdravstveno osiguranje (HZZO)
- (19) IDMP1 GmbH (IDMP1)
- (20) E Government Center for Social Security Services S.A. (IDIKA)
- (21) INDRA SOLUCIONES TECNOLOGÍAS DE LA INFORMACIÓN SL (INDRA)
- (22) INFARMED National Authority of Medicines and Health Products, I.P. (INFARMED)
- (23) Integrating The Healthcare Enterprise-Europe (IHE)
- (24) IHTSDO trading as SNOMED International (SNOMED)
- (25) Kansaneläkelaitos (KELA)
- (26) Lääkealan turvallisuus- ja kehittämiskeskus Fimea (FIMEA)
- (27) AZIENDA REGIONALE PER L'INNOVAZIONEE GLI ACQUISTI S.P.A. (ARIA)

- (28) Medical Products Agency (SEMPA)
- (29) Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH (AGES)
- (30) Regione Lombardia (REGLOMB)
- (31) Servicio Andaluz de Salud (SAS)
- (32) State Agency of Medicines (EESAM)
- (33) Sieć Badawcza Łukasiewicz Instytut Logistyki i Magazynowania (ILIM)
- (34) Stichting Nationaal ICT Instituut in de Zorg (NICTIZ)
- (35) The European Institute for Innovation through Health Data (IHD)
- (36) Norwegian Medicines Agency (NOMA)
- (37) VIDALFrance (VIDAL)
- (38) Z-Index B.V. (ZINDEX)
- (39) Medicines and Healthcare products Regulatory Agency (MHRA)

relating to the *Project* "Scaling up the univocal identification of Medicinal products" (Unicom).

WHEREAS:

- (A) The *Parties*, having considerable experience in the field concerned, have submitted or intend to submit a *Proposal* for the *Project* to the Horizon 2020 Programme
- (B) The Parties intend to enter into the Contract
- (C) The Parties wish to specify or supplement, between themselves, the provisions of the *Contract*

NOW THEREFORE IT IS HEREBY AGREED AS FOLLOWS:

Section 1 Definitions

1.1 *Contract* Definitions

Words appearing in italics have the meaning defined in this Section 1 or in the *Contract*. Definitions in this Section shall have precedence.

1.2 List of definitions

"Accession Applicant" means a legal entity which is not a Party that has made a proposal to a Party for joining the Project and acceding to the Contract.

"Access Rights" means licenses and user rights to Foreground or Background.

"*Affiliate*" of a *Party* means any linked third party specified in the *Contract* and any organisation listed in the agreed Schedules to this *Consortium Agreement* as *Affiliate* of the *Party*.

"Affiliated Third Party" means a party associated in the Grant Agreement to any of the Parties

"*Background*" means information which is held by *Parties* prior to their accession to this *Consortium Agreement* as well as copyrights or other intellectual property rights pertaining to such information and which is needed for carrying out the *Project* or for using *Foreground*.

"Commission" means the European Union, the European Commission or other body awarding the Contract.

"Contract" means (i) after its signature by all Parties, the Grant Agreement including the Terms and Conditions for the undertaking by the Parties of the Project; (ii) before such signature, the model Grant Agreement proposed by the Commission at the date of this Consortium Agreement for projects in the Horizon 2020 Programme for which the Proposal has been or is to be submitted. "Contract" shall, as applicable, also mean any amendment to the Grant Agreement or the Terms and Conditions.

"Coordinator" is the Party so designated above.

"Defaulting Party" means a Party breaching its obligations under the Contract or this Consortium Agreement.

"Financial Coordinator" is the Coordinator or the Party so designated above.

"*Foreground*" means the results, including information, generated in the course of the Project, whether or not they can be protected, including any associated rights not limited to intellectual property rights.

"Party" or "Parties" means a party or the parties to this Consortium Agreement.

"*Party Activity Budget*" means the amount so designated in Schedule 6 allocated to the Party concerned or as set pursuant to Section 6.12.

"*Party Activity EC Funding*" means the amount so designated in Schedule 6 allocated to the Party concerned or as set pursuant to Section 6.12.

"*Party Activity Cofunding Contribution*" means the amount so designated in Schedule 6 allocated to the Party concerned.

"*PCC*" means the Project Coordination Committee established in accordance with Section 4, reference to which may use a different term in the *Contract* Annex I

"*PCC email address*" means the address to which *PCC Meeting* agenda and minutes are sent as defined in Section 4.

"*PCC Meeting*" means a meeting of the Project Coordination Committee as defined in Section 4.

"Project" means the Action defined in the Contract.

"Project Share" means for each Party, the sum of Party Activity Budget allocated to that Party.

"*Proposal*" means the proposal for the *Project* submitted or intended to be submitted (as the case may be) by the *Parties* to the *Commission*. "*Proposal*" shall, as applicable, also mean any amendment to a *Proposal* which is so submitted or intended to be submitted.

"Third Party" means any other party than the Parties or Linked Third Parties.

Section 2 Purpose and Duration

- 2.1 The purpose of this *Consortium Agreement* is to specify the organisation of the work between the *Parties*, supplement the provisions of the *Contract* concerning *Access Rights* and to set out rights and obligations of the *Parties* supplementing but not conflicting with those of the *Contract*. In case of conflict the provisions of the *Contract* shall have precedence over this *Consortium Agreement*.
- 2.2 This *Consortium Agreement* shall come into force on the 1st December 2019 and shall continue in full force and effect until terminated in accordance with Section 15 or complete discharge of all obligations for the carrying out of the *Project* undertaken by the *Parties* under the *Contract* and under this *Consortium Agreement*, whichever is the earlier.

Section 3 Coordinator and Accession to the Contract

- 3.1 In addition to the *Coordinator*'s functions pursuant to the *Contract*, the *Coordinator* shall have the following functions only: administration, preparation of minutes and provision of the chairman of the *PCC*, and follow-up of its decisions.
- 3.2 The *Coordinator* shall not be entitled to act or to make legally binding declarations on behalf of any other *Party* other than those which follow from the *Contract* and this *Consortium Agreement*.
- 3.3 If one or more of the *Parties* is late in submission of financial reports or management reports pursuant to the *Contract* Article 20 or deliverables, the *Coordinator* may submit the other *Parties'* reports and deliverables to the *Commission*.
- 3.4 With reference to the *Contract* Article 56.2 the *Coordinator* shall obtain the approval of the *PCC* and the signed acceptance by any *Accession Applicant* of this Consortium Agreement before submitting a proposal to the *Commission* that an *Accession Applicant* should accede to the *Contract*.
- 3.5 The *Coordinator* shall not allow any entity which is not *Party* to this *Consortium Agreement* to accede to the *Contract*
- 3.6 The *Financial Coordinator* shall support the *Coordinator* in the function of administrative and financial management. Without prejudice to the *Contract*, the distribution of tasks between *Coordinator* and *Financial Coordinator* shall be as specified in the Schedule, providing always that this distribution may be amended by mutual agreement between *Coordinator* and *Financial Coordinator* notified to all *Parties*.

Section 4 Project Coordination Committee

4.1 The *Parties* shall establish, within thirty days after the date of this *Consortium Agreement*, the *PCC* composed of one duly authorised representative of each of them ("*PCC representative*"). Each *PCC Representative* shall have a deputy. A *Party* can at all times change its *PCC Representative* or deputy. Appointment of *PCC Representative* and deputy and the email address to which written communication is to be sent ("*PCC email address*") shall be valid when such has been notified to the *Coordinator* in writing and signed by an authorised signatory of the *Party* concerned. In making such notification, *Parties* are to conform to reasonable procedural requirements set by the *Coordinator* or the *Financial Coordinator*.

The PCC Representative or deputy is entitled to attend *PCC Meetings* or to participate by proxy. The proxy must present a power of attorney document from the *Party* concerned in a form and substance reasonably acceptable to the Chairman. All proxies must by their terms be freely revocable by the *Party* and are deemed revoked if the PCC Representative or deputy is present at a *PCC Meeting*. A *Party* shall use all reasonable endeavours to maintain the continuity of its representation.

4.2 *PCC Meetings* shall be chaired by the *Coordinator's* authorised representative.

The Chairman shall convene PCC Meetings

- a) at a frequency decided by the *PCC* or at the request of any *Party* who has provided the Chairman with a draft agenda stating reasonable cause and
- b) with at least fifteen (15) calendar days prior notice to all *Parties* with an agenda (hereinafter "original agenda").

The Chairman may invite other persons to attend a *PCC Meeting* provided details of the invitation are contained in the original agenda and no *Party* objects within 7 calendar days.

Minutes of a *PCC Meeting* shall be transmitted to the other *Parties* without delay. The minutes shall be considered as accepted by the other *Parties* if, within fifteen (15) calendar days from receipt, no *Party* has objected in a traceable form to the *Coordinator*. Decisions of the *PCC* recorded in accepted minutes shall constitute written agreement of all *Parties* for the purposes of this *Consortium Agreement* and the *Contract* except where signature by the authorised signatory is required in or through this *Consortium Agreement*.

- 4.3 Without prejudice to the *Contract*, the *PCC* shall be in charge of overall direction of the *Project*. To that end, the *PCC* shall be responsible for:
 - (a) agreeing tasks and responsibilities of the *Parties* and the distribution of budget and funding among the *Parties* in the *Contract* and in Schedule 6;
 - (b) proposing amendments to the *Contract* and authorising the *Coordinator* to apply to the *Commission* for such amendment;
 - (c) with reference to Section 12 approving applications from *Parties* to make individual documents publicly available and giving other permissions conforming to agreed publication policy;
 - (d) assisting the *Coordinator* in preparing reports on the whole *Project;*

- (e) with reference to Section 12 agreeing a publication policy specifying procedures for press releases and making documents publicly available;
- (f) authorising the *Coordinator* to serve notices on a *Defaulting Party* in accordance with Section 8.6 and to assign the *Defaulting Party*'s tasks to specific entity(ies) (preferably chosen from the remaining *Parties*);
- (g) carrying out calls for proposals for third parties to participate in the Project and accepting *Accession Applicants;*
- (h) agreeing to extend *Access Rights* to a third party;
- (i) approving withdrawal of a *Party* pursuant to Section 15.2.
- (j) with reference to Section 10.1 agreeing modifications to the Schedule of *Background* needed for the *Project* and/or for use of *Foreground*
- (k) modifying any provision of the *Contract* where this is possible without amendment
- (1) agreeing changes to the schedule of rules in Schedule 5 allowing the *Coordinator* to withhold or reduce payments to any or all *Parties*
- 4.4 At *PCC Meetings*, each *Party* shall have one vote. A quorum shall be a minimum of 2/3 of the *Parties*. Where decisions are to be taken unanimously, all *Parties* must be represented at the meeting.

In the case of Section 4.3 (a) to (d), (i), (k) and in other cases not referred to below, decisions shall be taken by the majority of the votes of the *Parties* present or represented by proxy at a quorate meeting, provided always that any *Party* whose scope of work, time for performance, costs, budget, funding, payments under this Agreement, liabilities or intellectual property rights are to be changed or whose legitimate interests are otherwise affected may veto such decisions. Any veto is to be raised in timely fashion and at the latest by way of objection to the minutes within the time limit specified above.

In the case of Section 4.3 (e), (g), (h), (j) and (l) and in any case where the *Contract* requires written agreement of all *Parties* decisions shall be taken unanimously by all of the *Parties*. In the case of Section 4.3(f), the decision shall be taken unanimously by all of the non-*Defaulting Parties*.

Any decision requiring a vote at a *PCC Meeting* must be identified as such in the original agenda unless all *Parties* are present or represented and there is unanimous agreement to vote.

4.5 A *Party* is deemed present at a *PCC Meeting* if

- a) the *PCC* Representative or deputy of the *Party* is connected via conference telephone or similar medium of adequate audio quality to the other *Parties* also present at the meeting and full details allowing all *Parties* to connect to the *PCC Meeting* via such medium are contained in the original agenda, or
- b) the original agenda consists only of requests that *Parties* vote in writing on specified decisions and the *Party* sends to the Chairman by email or otherwise in

writing within a time limit set in the original agenda either a vote on a specified decision or clear acceptance of that Party being counted towards the quorum of those present.

Section 5 Responsibilities of each *Party*

5.1 General Responsibilities

Each *Party* undertakes to each other *Party* to use reasonable endeavours to perform and fulfil, promptly, actively and on time, all of its obligations under the *Contract* and this *Consortium Agreement*.

5.2 Towards the *Coordinator* and the *PCC*

Each *Party* hereby undertakes to use reasonable endeavours to supply promptly to the *Coordinator* all such information or documents as the *Coordinator* and the *PCC* need to fulfil obligations pursuant to this *Consortium Agreement* and the *Contract*.

5.3 Towards each other

- 5.3.1 (a) Each *Party* undertakes to use reasonable endeavours:
 - (i) to notify each of the other *Parties* promptly of any significant delay or expected delay in performance or other deviation from the *Project*;
 - (ii) to inform other *Parties* of relevant communications it receives from third parties in relation to the *Project*.
 - (b) Each *Party* shall use reasonable endeavours to ensure the accuracy of any information or materials it supplies hereunder or under the *Contract* and promptly to correct any error therein of which it becomes aware. The recipient *Party* shall be entirely responsible for the use to which it puts such information and materials.
 - (c) In addition to the obligations specified in the *Contract*, each *Party* agrees not to use knowingly, as part of a deliverable or in the design of such deliverable or in any information supplied hereunder or under the *Contract*, any proprietary rights of a third party for which such *Party* has not acquired the right to grant licences and user rights to the other *Parties* in accordance with the *Contract*.
 - (d) Acting in good faith, when a *Party* believes that for carrying out the *Project* or its use of *Foreground* from the *Project*
 - (i) it might require Access Rights to another Party's Background or
 - (ii) another Party might need Access Rights to that Party's Background,

it will promptly notify such other *Party* of the *Background* required, and in particular, where possible it shall do so before submission of the *Proposal* to the *Commission* or entering into the *Contract*. Failure to so notify another *Party* shall not be a breach of this *Consortium Agreement* unless such failure is due to an action in bad faith.

- (e) When a *Party* is unable to grant *Access Rights* which it reasonably believes that another *Party* will require, it will promptly notify such other *Party* and in particular where possible shall do so before submission of the *Proposal* to the *Commission* or entering into the *Contract*.
- 5.3.2 If this *Agreement* conflicts with the *Contract* Annex I, unless the *Parties* agree otherwise, they shall cooperate in requesting the *Commission* to change the *Contract* Annex I to accord with this *Agreement*.
- 5.3.3 All documents required under the *Contract* and this *Consortium Agreement* shall be delivered in the format prescribed by the *Commission* and where not so prescribed in the most appropriate of the permitted formats listed in the Schedule to this *Consortium Agreement*. The *Parties* may unanimously agree to extend or modify the permitted formats. Documents made available for electronic access by a recipient shall be deemed received only when the recipient has been properly notified of the availability of that document.
- 5.3.4 Nothing in this Consortium 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.

Section 6 Costs – Payment

6.1 Each *Party* shall bear its own costs in connection with the making of the *Proposal*, the negotiation of the *Contract* and the carrying out of the *Project*.

The costs and budget of an *Affiliated Third Party* are treated as if they were the costs and budget of the respective *Party*.

- 6.2 With reference to the *Contract* Article 21 and without prejudice to the provisions of Sections 6.1, 6.4, 6.5 and 6.6 each *Party* shall be entitled to receive for each activity for which it has been allocated a *Party Activity Budget*
 - (a) the proportion of the *Party Activity EC Funding* given by dividing the activity costs to date by the *Party Activity Budget*,

(activity costs to date) x (Party Activity EC Funding) / (Party Activity Budget),

where the said activity costs to date are to be the eligible costs of the *Party* necessary for the activity, formally declared by the *Party* to the *Coordinator*, approved by the *Commission*, not exceeding the respective *Party Activity Budget* and for which the *Coordinator or the Financial Coordinator* has received the respective Community financial contribution, and

(b) the proportion of the sum available for pre-financing given by dividing the *Party Activity EC Funding* by the sum *Party Activity EC Funding* over all *Parties*

(sum available for pre-financing) x (*Party Activity EC Funding*) / (sum of all *Party Activity EC Funding*),

the said sum available for pre-financing is to be that part of pre-financing received by the *Coordinator* following the *Contract* Article 21.2 which is not required to make payments due under (a) above and which has not been limited in Schedule 5,

(c) together not exceeding the ceiling provided for in the *Contract* Article 21.3, providing always that the *Coordinator* may under exceptional financial circumstances within the *Project* declare a reduction in the ceiling applicable to all activities of all *Parties*.

The sums a *Party* is entitled to receive are reduced by any sum due under Section 6.9 and, proportionate to *Project Share*, by any repayment outstanding under Section 6.8 and without prejudice to Section 6.9 by any amount withheld by the *Commission* pursuant to the *Contract* Chapter 6.

- 6.3 All payments under this *Consortium Agreement* shall be made less bank charges to the bank account notified in due time to the *Financial Coordinator* by each *Party* in a document bearing the signature of the authorised signatory of the *Party* following procedures reasonably required by the *Financial Coordinator*. The *Financial Coordinator* shall take any reasonable effort to minimise bank charges, in particular, by ensuring that handling of payments takes place in the Euro currency and the most advantageous transfer process is selected.
- 6.4 No payment shall be made to any *Party* until that *Party* has acceded to the *Contract* in accordance with the provisions of the *Contract* and has signed this *Consortium Agreement*.
- 6.5 The *Coordinator* shall not transfer any sum due under the *Contract* and this *Consortium Agreement* to a *Party* on whom written notice requiring that a serious breach be remedied has been served under the provisions of Section 8.6.
- 6.6 The *Coordinator and the Financial Coordinator* shall apply the rules for withholding funding specified in Schedule 5 provided always that the *Parties* may by unanimous agreement modify Schedule 5.
- 6.7 The *Coordinator* shall take reasonable measures to ensure that any balance accrued from payments by the *Commission* to the *Parties* in respect of the *Project* is adequately secured against liabilities incurred by the *Coordinator*.
- 6.8 In the event of an overpayment being made to any *Party* that *Party* shall return the amount within thirty (30) calendar days of receiving a formal written request for repayment from the *Coordinator or the Financial Coordinator*. Damages for late repayment shall be set at an annual rate of interest 6 percentage points above the standard inter-bank rate set by the European Central Bank, such damages to be refunded by the *Coordinator or the Financial Coordinator* to each *Party* (excluding the *Party* who is liable for the late payment) in proportion to *Project Share* or according to any rule agreed by all *Parties*. Any sum due for repayment are until received by the Coordinator deemed to be reductions in the sums paid by the *Commission* to the project share.
- 6.9 Any sum withheld by the *Commission* for a deliverable which is not accepted pursuant to the *Contract*, Chapter 6, shall be duly deducted from the amount the *Parties* responsible for the deliverable are entitled to receive under this *Consortium Agreement*. The sum to be deducted in respect of each *Party* shall be determined by taking into account any recommendations of the *Commission* as well as each *Party*'s proportion of

budget associated with the relevant work package. The latter is calculated on the basis of the number of person months as set out in Annex 1 of the *Contract* allocated to the relevant work package. The *Parties* shall assume responsibility for any subcontracted work, accordingly, any funding for such sub-contracted work may also be deducted from sums payable to the responsible *Parties*.

- 6.10 Without prejudice to 6.12 below the distribution of funding and budget shall be as indicated in Schedule 6 provided always that the Schedule may be amended by the *PCC*. Each Party shall account separately and provide separate statements of costs for each activity defined in the Schedule. For all activities of a Party taken together, Party Activity EC Funding may not exceed Party Activity Total Costs and the Party Activity Total Costs, if greater than Party Activity Budget, may not be greater than 105% of the full cost of the Action for that Party. Where that Party has a duty under the Contract for a periodic audit certificate on eligible costs, this certificate shall also certify full costs for the PCC. For the avoidance of doubt, only Parties whose Party Activity Total Costs.
- 6.11 Each Party is deemed to have received under the terms of the *Contract* a Community financial contribution equal to both all the sums transferred under 6.2 above and the Party Activity Cofunding Contribution withheld in the calculation of the sums transferred. A *Party* remains responsible to the *Commission* for this total sum deemed received, in particular in the event of financial audit.
- 6.12 Each *Party* shall ensure that it receives timely approval by the *Commission* of *eligible costs* incurred for the *Project* such that the flow of funding to all *Parties* is not impaired. Each *Party* shall maintain an up to date, detailed plan of expenditure for the *Project* throughout. A *Party* reasonably expecting to be unable to submit eligible costs amounting to a *Party Activity Budget* allocated to that *Party* shall, without delay after the shortfall is identified, notify the *Coordinator* of the expected total amount of eligible costs which can be submitted. The Coordinator shall apply this sum as *Party Activity Budget* and reduce the *Party Activity* EU Funding by the calculated reduction in Grant from the Commission, whether or not the overall Grant to the *Project* has been or will be reduced.

Section 7 Confidentiality

- 7.1 All information of whatever nature or form as is disclosed to a *Party* in connection with the *Project* or the writing and submission of the *Proposal* shall be treated as confidential if marked or otherwise identified in writing by a *Party* (the owner) as proprietary or confidential or that, under the circumstances surrounding the disclosure, ought in good faith to be treated as proprietary or confidential and its disclosure may be prejudicial to the owner of the information, or if disclosed orally, is at the time of disclosure indicated to be "confidential" and within thirty (30) calendar days reduced to physical form and marked "confidential" by the owner, and each *Party* undertakes that:
 - (A) it will not during a period of five (5) years from the date of disclosure to the *Party* use any such information for any purpose other than in accordance with the terms of the *Contract* and of this *Consortium Agreement*; and

(B) it will during the period of five (5) years treat the same as (and use reasonable endeavours to procure that the same be kept) confidential and not disclose the same to any other third party without the prior written consent of such owner in each case;

provided always that:

- (i) such agreement and undertaking shall not extend to any information which the receiving *Party* can show:
 - (A) was at the time of disclosure to the *Party* published or otherwise generally available to the public, or
 - (B) has after disclosure to the *Party* been published or become generally available to the public otherwise than through any act or omission on the part of the receiving *Party*, or
 - (C) was already in the possession of the receiving *Party*, without any restrictions on disclosure, at the time of disclosure to the *Party*, or
 - (D) was rightfully acquired from others without any undertaking of confidentiality, or
 - (E) was developed independently of the work under the *Contract* by the receiving *Party*;
 - (F) is deemed not longer to be confidential because of subsequent information of the Recipient by the disclosing Party.
- (ii) nothing in this Section 7.1 shall prevent the communication of information
 - (A) as is needed to be communicated to comply with applicable laws or regulations or with a court of administrative order provided that insofar as reasonably possible the complying *Party* shall have informed the owner of the information of such need and shall have complied with such owner's reasonable instructions designed to protect the confidentiality of such information;
 - (B) subject to Section 7.2, to any third party insofar as needed for the proper carrying out of the *Contract* and/or this *Consortium Agreement*;
- 7.2 As respects any permitted communication of any of the information referred to in Section 7.1 by the recipient *Party* to a third party such *Party* will use reasonable endeavours to procure due observance and performance by such third party of the undertakings referred to in Section 7.1, (A) and (B) and all relevant undertakings in the *Contract*.

Section 8 Liabilities

8.1 No warranties

In respect of information or materials supplied by one *Party* to another hereunder or under the *Contract*, the supplier *Party* shall be under no obligation or liability other than as stated in Section 5.3.1(b) and no warranty condition or representation of any

kind is made, given or to be implied as to the sufficiency, accuracy or fitness for purpose of such information or materials, or, subject to Section 5.3.1(c), the absence of any infringement of any proprietary rights of third parties by the use of such information and materials and the recipient *Party* shall in any case be entirely responsible for the use to which it puts such information and materials.

8.2 Liability towards each other

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.

For any remaining contractual liability, a Party's aggregate liability towards the other Parties collectively shall be limited to the Party's project share provided such damage was not caused by a wilful act or gross negligence.

The terms of this Consortium Agreement shall not be construed to amend or limit any Party's statutory liability.

8.3 Claims of the Commission

If the *Commission*, in accordance with the provisions of the *Contract*, reduces the EU Funding, claims any reimbursement, liability or payment of damages from one or more *Parties* or from the *Consortium* then:

- (a) Parties whose default has caused or contributed to the claim being made shall be liable to the other Parties for such claim provided always that the total limit of liability of that Party to all of the other Parties collectively in respect of any and all such claims shall not exceed that Party's Project Share - any excess shall be apportioned between all the Parties pro rata to their Project Shares; and
- (b) in the event that it is not possible to attribute default to any *Party* before the amount claimed by the *Commission* is due, the amount claimed shall be apportioned between all the *Parties* pro rata to their *Project Shares* if it is subsequently possible to assign the damage to one Party, the latter must subsequently reimburse the other Parties for these costs incurred;;
- (c) Public Bodies recognised as such in the *Contract* shall only assume their own debts.

8.4 Liability towards Third Parties

Subject always to such other undertakings and warranties as are provided for in this *Consortium Agreement* and the *Contract*, each *Party* shall be solely liable for any loss, damage or injury to third parties resulting from its carrying out its parts of the *Project* and from its use of *Foreground*.

8.5 Third Parties

- (a) Each *Party* shall be fully responsible for the performance of any part of its share of the *Project* in respect of which it enters into any contract with a third party or which it assigns to an *Affiliate* and shall ensure that the other *Parties' Access Rights* are the same as would have been the case had the contracting *Party* itself performed that part of the *Project*.
- (b) Each Party shall in writing inform the other Parties if it intends to enter into a contract referred to in Section 8.5(a) (giving the rationale therefore) if such is not already described in the Contract Annex I and the contract is other than for a minor part of its share of the Project. Such Party shall consider in good faith comments made in relation to such contract.
- (c) Each *Party* shall ensure that all its *Affiliates* fulfil the confidentiality and other obligations accepted by the *Parties* under the *Contract* and this *Consortium Agreement* as if such *Affiliates* were *Parties*.
- (d) In addition to the obligations pursuant to the *Contract*, each *Party* shall ensure that it can grant *Access Rights* and fulfil the obligations under the *Contract* notwithstanding any rights of its employees, or persons it engages to perform part of its share of the *Project*, in the *Foreground* they create.

8.6 Defaults and Remedies

In the event of (i) a substantial breach, but not in case of force majeure, by a *Party* of its obligations under this *Consortium Agreement* or the *Contract* which is irremediable or which is not remedied within one month of written notice from the other *Parties* requiring that it be remedied, or (ii) if Section 15.4 applies, or (iii) if the *Commission* terminates the *Contract* in respect of a *Party*, the other *Parties* may jointly terminate this *Consortium Agreement* with respect to the *Defaulting Party* concerned by not less than one month's prior written notice.

Such termination shall take place with respect to such *Defaulting Party* as of the date of such notice, subject to the provisions in (a) to (b) below.

Notice of such termination pursuant to (i) or (ii) above shall be given to the *Commission* and the *Commission* shall be requested to terminate the *Contract* with respect to the *Defaulting Party* or to state it does not object to the withdrawal from the *Project* of the *Defaulting Party*, provided always that:

- (a) the *Access Rights* granted to the *Defaulting Party* and its *Affiliates* pursuant to this *Consortium Agreement* shall cease immediately, unless the other Parties decide unanimously to grant access rights to *Affiliates*;
- (b) the *Access Rights* granted and the obligations to grant *Access Rights* pursuant to this *Consortium Agreement* or the *Contract* by the *Defaulting Party* shall remain in full force and effect;
- (c) the *Defaulting Party* shall

- (i) be responsible for and pay all reasonable direct cost increase (if any) resulting from the assignment referred to in Section 4.3 (f) in comparison with the costs of the tasks of the *Defaulting Party* as specified in the *Contract* Annex I at the date of termination of this *Consortium Agreement* with respect to the *Defaulting Party*; and
- (ii) be liable for any so resulting additional direct cost incurred by the other Parties, up to a total amount which taken together with any liability to the Commission under Section 8.2 shall not exceed the total maximum limit of liability specified in that Section in respect of the Defaulting Party
- (iii) however, according to Art. 13.2 of the Regulation (EC) 2321/2002 of the European Parliament and of the Council of 16 December 2002 a Public Body shall be solely responsible for its own debt and shall not bear the debt of any other Contractor.

The *Defaulting Party* shall be deemed to have agreed to the termination or its withdrawal from the *Project* as the case may be with the proviso that such deemed agreement shall be without prejudice to the rights of the *Defaulting Party* to appeal against such termination or withdrawal as the case may be.

Section 9 Force Majeure

A failure in the performance of this *Consortium Agreement* cannot be imputed or assumed to a *Party* to the extent it is due to "Force Majeure".

The expression "Force Majeure" shall mean any unforeseeable and insuperable event affecting the *Party* fulfilling its obligations hereunder.

Each *Party* will notify the other *Parties* in writing of any "Force Majeure" event as soon as possible. The *Parties* shall discuss in good faith the possibilities of a transfer of tasks affected by the event. Such discussions shall commence as soon as reasonably possible. If such "Force Majeure" event is not overcome within 6 weeks after such notification, the transfer of tasks shall be carried out.

Section 10 Access and Ownership

- 10.1 The *Parties* have identified and listed in the Schedule to this *Consortium Agreement* the *Background* needed for carrying out the *Project* or for use of *Foreground* and any conditions for the exercise of *Access Rights* in respect of such *Background*. The *Parties* agree that all other *Background* shall be considered as unnecessary for the implementation of the Project and/or excluded, provided always that the *Parties* may by unanimous agreement modify the Schedule.
- 10.2 With reference to the Contract Articles 25.4 and 31.4 Access Rights for using Foreground and Background are granted only to Affiliates. Such Access Rights to Affiliates shall be granted on Fair and Reasonable conditions and upon written bilateral agreement. Affiliates which obtain Access Rights in return grant Access Rights to all Parties and fulfil all confidentiality and other obligations accepted by the Parties under the Contract or this Consortium Agreement as if such Affiliates

were Parties. Access Rights may be refused to Affiliates if such granting is contrary to the legitimate interests of the Party which owns the Background or the Foreground. Access Rights granted to any Affiliate are subject to the continuation of the Access Rights of the Party to which it is affiliated, and shall automatically terminate upon termination of the Access Rights granted to such Party. Upon cessation of the status as an Affiliate, any Access Rights granted to such former Affiliate shall lapse.

10.3 In case of joint ownership of *Foreground* unless otherwise agreed by all joint owners and without prejudice to further permissions which may be granted in the publication policy in the Schedule, each joint owner shall be entitled to use the jointly owned *Foreground* for non-commercial research and teaching activities on a royalty-free basis and to otherwise exploit the jointly owned *Foreground* and to grant nonexclusive licenses without any right to sub-license to third parties, if the other joint owners are given:

(a) at least 45 calendar days advance notice; and

(b) fair and reasonable compensation in accordance with applicable law

The joint owners shall agree on all protection measures and the division of related cost in advance.

10.4 Access Rights granted to a leaving Party

a) Defaulting Party

Access Rights granted to a Defaulting Party and such Party's right to request Access Rights shall cease immediately upon receipt by the Defaulting Party of the formal notice of the decision to terminate its participation in the Consortium.

b) Non-defaulting Party

A non-defaulting Party leaving voluntarily and with the other Parties' consent shall have Access Rights to the Foreground developed until the date of the termination of its participation.

It may request Access Rights within up to twelve months after the termination of its participation in the Project.

c) Access Rights to be granted by any leaving Party

Any Party leaving the Project shall continue to grant Access Rights pursuant to the Contract and this Consortium Agreement as if it had remained a Party for the whole duration of the Project.

Section 11 Standards

Deleted

Section 12 Dissemination

- 12.1 No *Party* may publish or otherwise disclose *Foreground* except in conformance with the *Contract* and with the publication policy as detailed in the Schedule, provided always that the *Parties* may by unanimous agreement modify the Schedule.
- 12.2 Any *Party* may replicate or publish information from a document whose publication has been agreed by the *Parties* or which is a deliverable listed as public in the *Contract*. Any such publication shall with appropriate prominence reference the document including title, all authors and full name of the project.

Section 13 No partnership or agency

Nothing in this *Consortium Agreement* shall create a partnership or agency or other legal body or identity between any of the *Parties* other than a Consortium for the sole purpose of fulfilling the *Contract*.

Section 14 Assignment

No *Party* shall, without the prior written consent of the other *Parties*, assign or otherwise transfer partially or totally any of its rights and obligations under this *Consortium Agreement*. Such consent shall not be unreasonably withheld when such assignment or transfer is in favour of an *Affiliate* of that *Party*

Section 15 Termination

- 15.1 Before signature of the Contract,
 - (i) any *Party* may withdraw from and terminate this *Consortium Agreement* in respect of itself by informing the other *Parties* in writing of such termination (which shall take effect as of the latest date of such notice) if at its sole option it decides it will not participate either in the submission of the *Proposal* or in the carrying out of the *Project*
 - (ii) the *Parties* may by agreement terminate this *Consortium Agreement* forthwith;
 - (iii) this Consortium Agreement shall terminate if and on the date that
 - (a) the Parties agree not submit a Proposal to the Commission or
 - (b) the Commission rejects the Proposal.
- 15.2 After signature of the *Contract*, no *Party* shall be entitled to withdraw from this *Consortium Agreement* and/or participation in the *Project* unless:
 - (a) that *Party* has obtained the prior consent of the *Parties* and of the *Commission*, to the withdrawal from, or termination of, the *Contract*; or
 - (b) that *Party*'s participation in the *Contract* is terminated by the *Commission* or
 - (c) the *Contract* is terminated by the *Commission* for any reason whatsoever,
 - (d) that *Party* terminates in conformance with the *Contract* Article 50.1

provided always that a *Party* shall not by withdrawal or termination be relieved from

- (i) its responsibilities under this *Consortium Agreement* or the *Contract* in respect of that part of that *Party's* work on the *Project* which has been carried out (or which should have been carried out) up to the date of withdrawal or termination; or
- (ii) any of its obligations or liabilities arising out of such withdrawal or termination.
- 15.3 If any Party's participation in the *Contract* is terminated by the *Commission* or a *Party* withdraws from the *Project*, then, without prejudice to any other rights of the other *Parties* the provisions of Sections 4.3(f) and 8.6(a) and (b) shall apply correspondingly.
- 15.4 If any *Party* enters into bankruptcy or liquidation or any other arrangement for the benefit of its creditors the other *Parties* shall, subject to approval by the *Commission*, be entitled to take over the fulfilment of such *Party's* obligations and to receive subsequent payments under the *Contract* in respect thereof.

In such event all rights and obligations under the *Contract* and this *Consortium Agreement* shall in good faith be redistributed among the remaining *Parties* and the affected *Party* on the basis of the work performed by the affected *Party* prior to the occurrence of the above circumstance.

- 15.5 The provisions of Sections 1, 7, 8, 10, 11, 15 and 16 shall survive the expiration or termination of this *Consortium Agreement* to the extent needed to enable the *Parties* to pursue the remedies and benefits provided for in those Sections.
- 15.6 For the avoidance of doubt, termination or withdrawal shall not affect any rights or obligations incurred prior to the date of the termination.

Section 16 Settlement of Disputes

Regarding all disputes or differences arising in connection with this Consortium Agreement which cannot be settled amicably the courts of Brussels shall have exclusive jurisdiction.

Section 17 Language

This *Consortium Agreement* is drawn up in English which language shall govern all documents, notices and meetings for its application and/or extension or in any other way relative thereto.

Section 18 Notices

- 18.1 Any notice to be given under this *Consortium Agreement* shall be in writing. For the avoidance of doubt, information contained in text in email and in similar electronic media is in writing.
- 18.2 Notices shall be deemed to have been served when personally delivered, delivered by registered mail or, if transmitted by telefax, email or other electronic means provided that receipt is confirmed by e-mail. The address and recipient for such delivery is to be notified to the *Coordinator* by each *Party* in a document bearing the signature by the

authorised signatory of the *Party* following procedures reasonably required by the *Coordinator*.

- 18.3 Notices shall also be deemed to have been served when personally delivered to a *PCC* representative or deputy, or if transmitted by email to the *PCC email address*, provided that receipt is confirmed by the *PCC* representative or deputy in an email, sent to or copied to the *Coordinator*, which includes a copy of the notice.
- 18.4 The *Coordinator* is to take reasonable steps to ensure the current addresses and recipients according to 18.2 above and the *PCC email address* of each *Party* are known to all *Parties*.
- 18.5 Each Party is to ensure that the *PCC email address* functions properly and that known faults are dealt with promptly and to respond immediately on receipt to requests by any *Party* for acknowledgement of delivery of a notice according to 18.3 above.

Section 19 Applicable Law

This *Consortium Agreement* shall be construed according to and governed by the laws of Belgium excluding its conflict of law provisions.

Nothing in this Consortium Agreement shall be deemed to require a Party to breach any mandatory statutory law under which the Party is operating.

Section 20 Entire Agreement, Amendments, Inconsistency

- 20.1 This *Consortium Agreement* and the *Contract* constitute the entire agreement between the *Parties* in respect of the *Project*, and supersede all previous negotiations, commitments and writings concerning the *Project* including any memorandum of understanding between the *Parties* (whether or not with others) which relate to the *Project* or its proposal to the *Commission*.
- 20.2 Amendments or changes to this *Consortium Agreement* shall be valid only if made in writing and signed by an authorised signatory of each of the *Parties*.
- 20.3 If any provision in this *Consortium Agreement* should be wholly or partly ineffective, the *Parties* undertake to replace the ineffective provision by an effective provision which comes as close as possible to the purpose of the ineffective provision. A loophole in the *Consortium Agreement* shall be regarded as an ineffective provision.

Section 21 Counterparts

This *Consortium Agreement* may be executed in any number of counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

This Consortium Agreement is concluded in 39 copies, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

AS WITNESS the *Parties* have caused this *Consortium Agreement* to be duly signed by the undersigned authorised representatives the day and year first above written.

Authorised to sign on behalf of

(1) empirica Gesellschaft für Kommunikations- und Technologieforschung

Signature

Dr. Velitchka Stroetmann and/or Dr. Rainer Thiel

Schedule 1 to the Consortium Agreement Unicom

List of Affiliates

Party	Affiliate

Schedule 2 to the Consortium Agreement Unicom

List of Background

HPRA Background

HPRA will provide access to the source code and documentation for the CESP system, as Background, and as required, only to participants in WP3.

Z-Index Background

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Z-Index BV owns all exclusive rights concerning the G- Standaard, the database that contains all the products in the Netherlands that are dispensed by or used in the pharmacy. These rights include rights based on database law, copyrights, trademarks, and trade secrets. Licenses are available from Z-Index BV. General license terms apply, <u>https://www.z-index.nl/general-license-terms</u>.

Schedule 3 to the Consortium Agreement Unicom

Permitted Formats

Format	Permitted usage			
Microsoft WORD 2007	Any			
Microsoft EXCEL 2007				
Open Document Format ODP, ODT, ODS				
*.JPEG, *.PNG				
*.mp4				
*.wav, *.mp3				
*.PDF				
ASCII / CSV				
*.eml				

Schedule 4 to the Consortium Agreement Unicom

Publication policy

- 1. Any Party wishing to publish Foreground can provide the PCC with a draft or outline. The PCC can
 - approve publication conforming to the outline
 - set specific requirements for content to be or not to be included
 - assign a Party to review draft and or final publication
 - specify issues and require the reviewing Party to report to or consult other parties on those issues
 - ask for resubmission of the outline with requirements for modification or clarification
 - reject publication based on the outline
- 2. No Foreground may be published unless PCC approval has been given or the publication conforms to an outline approved by the PCC under (1) above.
- 3. Any publication approved by the PCC is to be provided without delay to all Parties
- 4. Any public information can be republished, translated and/or with minor modifications.
- 5. Any Foreground may be communicated to any Affiliate without restriction.
- 6. Any information foreseen to be contained in a public deliverable may be published at any time under any recognised open source licence by a Party or Affiliate.

Schedule 5 to the Consortium Agreement Unicom

Rules for withholding funding

Pre-financing shall be paid only to Parties listed as Public Bodies in the Contract or who provide appropriate clear evidence of financial viability, specifically that the EC financial viability self-check-tool, applied to publicly available balance sheet data less than 18 months old, gives the result of "acceptable" or "good" in the concise analysis.

No payments will be made in respect of Affiliates until an agreement between the Beneficiary and the Affiliate has been approved by the Consortium, accepting joint and several liability with the Beneficiary for any amount owed to the Commission and/or the Consortium by the Beneficiary under the Grant Agreement up to the maximum EU contribution indicated, for the Affiliate, in the estimated budget. The Affiliate irrevocably and unconditionally agrees to pay amounts requested under this Affiliate Agreement to the Project Coordinator, immediately and at first demand.

Beneficiary	Activity Nr.	Activity Type / Status	Activity Description	Party Activity Budget	Party Activity EC Funding	Party Activity Total Costs	Party Activity Cofunding Contribution
EMP	R	in force	Coordinator contribution	1.480.000	2.012.800	2.012.800	
SPMS	R	in force	Partner contribution	598.375	396.080	598.375	22.782
AEMPS	R	in force	Partner contribution	893.800	845.185	893.800	48.615
HALMED	R	in force	Partner contribution	413.750	391.246	413.750	22.504
CBG	R	in force	Partner contribution	1.753.851	1.658.458	1.753.851	95.394
FOUND	R	in force	Partner contribution	310.000	293.139	310.000	16.861
BIDMC	R	in force	Partner contribution	99.375	93.970	99.375	5.405
BFARM	R	in force	Partner contribution	674.031	637.370	674.031	36.661
COCIR	R	in force	Partner contribution	40.000	37.824	40.000	2.176
DWIZ	R	in force	Partner contribution	865.625	572.980	865.625	32.957
IEDOH	R	in force	Partner contribution	291.375	275.527	291.375	15.848
ELGA	R	in force	Partner contribution	236.250	223.400	236.250	12.850
EHTEL	R	in force	Partner contribution	290.000	274.227	290.000	15.773
AFMPS	R	in force	Partner contribution	480.000	453.892	480.000	26.108
GNOMON	R	in force	Partner contribution	836.125	553.453	836.125	31.834
HPRA	R	in force	Partner contribution	1.460.653	1.381.207	1.460.653	79.446
HL7	R	in force	Partner contribution	322.500	304.959	322.500	17.541
HZZO	R	in force	Partner contribution	181.000	171.155	181.000	9.845
IDMP1	R	in force	Partner contribution	225.000	148.933	225.000	8.567
IDIKA	R	in force	Partner contribution	333.300	315.172	333.300	18.128
INDRA	R	in force	Partner contribution	313.815	207.722	313.815	11.948
INFARMED	R	in force	Partner contribution	512.500	339.237	512.500	19.513
IHE	R	in force	Partner contribution	543.750	514.175	543.750	29.575
SNOMED	R	in force	Partner contribution	256.250	242.312	256.250	13.938
KELA	R	in force	Partner contribution	351.219	332.116	351.219	19.103
FIMEA	R	in force	Partner contribution	473.750	447.982	473.750	25.768
ARIA	R	in force	Partner contribution	797.375	527.804	797.375	30.359
SEMPA	R	in force	Partner contribution	722.994	683.669	722.994	39.324
AGES	R	in force	Partner contribution	1.392.121	1.316.403	1.392.121	75.719
REGLOMB	R	in force	Partner contribution	112.500	106.381	112.500	6.119
SAS	R	in force	Partner contribution	249.375	235.811	249.375	13.564
EESAM	R	in force	Partner contribution	451.438	426.883	451.438	24.554
ILIM	R	in force	Partner contribution	43.125	40.779	43.125	2.346
NICTIZ	R	in force	Partner contribution	277.500	262.407	277.500	15.093
IHD	R	in force	Partner contribution	1.636.875	1.547.844	1.636.875	89.031
NOMA	R	in force	Partner contribution	621.994	588.163	621.994	33.831
VIDAL	R	in force	Partner contribution	74.375	49.231	74.375	2.832
ZINDEX	R	in force	Partner contribution	83.750	55.436	83.750	3.189
MHRA	R	in force	Partner contribution	31.250	29.550	31.250	1.700
Total				20.730.966	18.994.884	21.263.766	976.800

Schedule 6 to the Consortium Agreement Unicom

Schedule 7 to the Consortium Agreement Unicom

Responsibilities of Financial Coordination

The *Financial Coordinator* where not *Coordinator* shall be responsible for execution of all processes of financial cost submission, payment and budget adjustment.

(1) The *Financial Coordinator* shall set up and manage an account dedicated to financial transactions of the *Project* ("Central Project Fund"). The *Financial Coordinator* shall ensure that all disbursements made from the *Central Project Fund* are in accordance with the provisions of the *Contract* and Section 6. The *Financial Coordinator* shall ensure the accounts for the Central Project Fund are accessible to the *Coordinator* and all *Parties*.

(2) The *Coordinator* shall transfer in line the provisions of the *Contract* Article 21.7 without delay all *EU Funding* received in respect of any *Party*, *Parties* or otherwise for the *Project* into the *Central Project Fund*, less any sums due to the *Coordinator* or that the *Coordinator* may transfer directly to another *Party* provided in each case that the amount and the recipient has been previously agreed in writing with the *Financial Coordinator*.

(3) Under no circumstances shall the *Financial Coordinator* allow the Central Project Fund to run into deficit.

Authorised to sign on behalf of

(2) SPMS - Serviços Partilhados do Ministério da Saúde, E.P.E.

Signature

Henrique Manuel Gil Martins

Authorised to sign on behalf of

(3) AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

Signature

María Jesus Lamas Díaz and/or Pedro Pablo de la Barrera Chaparro

Authorised to sign on behalf of

(4) Agencija za lijekove i medicinske proizvode

Signature

Dragomir Budimir

Authorised to sign on behalf of

(5) College ter Beoordeling van Geneesmiddelen

Signature

Hugo Hurts and/or Max Polano

Authorised to sign on behalf of

(6) Azienda Ospedaliera Universitaria Federico II

Signature

Anna Iervolino, CEO

Authorised to sign on behalf of

(7) Beth Israel Deaconess Medical Center, Inc

Signature

Marlena Konieczynska and/or Beth Doiron

Authorised to sign on behalf of

(8) Bundesinstitut für Arzneimittel und Medizinprodukte

Signature

Prof. Dr. Karl Broich and/or Dr. Peter Bachmann

Authorised to sign on behalf of

(9) COMITE EUROPEEN DE COORDINATION DES INDUSTRIES RADIOLOGIQUES ELECTROMEDICALES ET D INFORMATIQUE DE SANTE AISBL

Signature

Authorised to sign on behalf of

(10) DATAWIZARD SRL

Signature

Francesco Marcellino

Authorised to sign on behalf of

(11) Department of Health

Signature

Sarah Murphy and/or Niall Sinnott

Authorised to sign on behalf of

(12) ELGA GmbH

Signature

Dr. Franz Leisch

Authorised to sign on behalf of

(13) European Health Telematics Association

Signature

Simona Abbro and/or Marc Lange

Authorised to sign on behalf of

(14) Agence fédérale des médicmanets et des produits de santé

Signature

Xavier De Cuyper and/or Pascal Giloteau

Authorised to sign on behalf of

(15) Gnomon Informatics SA

Signature

Konstantinos Kangelidis

Authorised to sign on behalf of

(16) Health Products Regulatory Authority

Signature

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Authorised to sign on behalf of

(17) HL7 Fondation

Signature

Catherine Chronaki and/or Charles Jaffe

Authorised to sign on behalf of

(18) Hrvatski zavod za zdravstveno osiguranje

Signature

Lucian Vukelić, MD, Specialist

Authorised to sign on behalf of

(19) IDMP1 GmbH

Signature

Ursula Tschorn

Authorised to sign on behalf of

(20) E Government Center for Social Security Services S.A.

Signature

Niki Tsouma

Authorised to sign on behalf of

(21) INDRA SOLUCIONES TECNOLOGÍAS DE LA INFORMACIÓN SL

Signature

JESUS ANGEL GARCÍA SÁNCHEZ

Authorised to sign on behalf of

(22) INFARMED - National Authority of Medicines and Health Products, I.P.

Signature

Rui Santos Ivo

Authorised to sign on behalf of

(23) Integrating The Healthcare Enterprise-Europe

Signature

Jurgen Brandstatter / Stephane Spahni

Authorised to sign on behalf of

(24) IHTSDO trading as SNOMED International

Signature

Don Sweete and/or Duncan McNeil

Authorised to sign on behalf of

(25) Kansaneläkelaitos

Signature

Konstantin Hyppönen and/or Harri Nurmi

Authorised to sign on behalf of

(26) Lääkealan turvallisuus- ja kehittämiskeskus Fimea

Signature

Eija Pelkonen and/or Tuula Sandholm

Authorised to sign on behalf of

(27) AZIENDA REGIONALE PER L'INNOVAZIONEE GLI ACQUISTI S.P.A.

Signature

Francesco FERRI

Authorised to sign on behalf of

(28) Medical Products Agency

Signature

Catarina Andersson Forsman and/or Anette Nilsson

Authorised to sign on behalf of

(29) Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH

Signature

GF Anton Reinl and Thomas Kickinger

Authorised to sign on behalf of

(30) Regione Lombardia

Signature

Luigi Cajazzo and/or Marco Salmoiraghi

Authorised to sign on behalf of

(31) Servicio Andaluz de Salud

Signature

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Authorised to sign on behalf of

(32) State Agency of Medicines

Signature

Kristin Raudsepp

Authorised to sign on behalf of

(33) Sieć Badawcza Łukasiewicz - Instytut Logistyki i Magazynowania

Signature

Arkadiusz Kawa

Authorised to sign on behalf of

(34) Stichting Nationaal ICT Instituut in de Zorg

Signature

Drs. L.M. Niessen

Authorised to sign on behalf of

(35) The European Institute for Innovation through Health Data

Signature

Geert Thienpont and/or Dipak Kalra

Authorised to sign on behalf of

(36) Norwegian Medicines Agency

Signature

Audun Hågå and/or Sønneve Ølnes

Authorised to sign on behalf of

(37) VIDALFrance

Signature

Vincent Bouvier and/or Suzanne Bento Pereira

Authorised to sign on behalf of

(38) Z-Index B.V.

Signature

Leonora Grandia

Authorised to sign on behalf of

(39) Medicines and Healthcare products Regulatory Agency

Signature

Sarah Branch