CONSORTIUM AGREEMENT

This CONSORTIUM AGREEMENT is based upon

- Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, hereinafter referred to in this document as the Financial Regulation and as the Rules of Application of the Financial Regulation
- Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC, hereinafter referred to in this document as Regulation No. 282/2014
- Commission Implementing Decision of 28.1.2020 concerning the 2020 work programme in the framework of the third programme of Union action in the field of health (2014-2020) and the EU's financial contribution to the WHO Framework Convention on Tobacco Control, serving as a financing decision, hereinafter referred to as 2020 annual work programme
- Grant Agreement No. **951938,** as concluded between the European Commission, represented by Directorate-General for Communications Networks, Content and Technology, Data, Administration and Finance (DG CONNECT) and the *Parties*, referred to in this document as X-eHealth Grant Agreement, Grant Agreement or GA, which terms are fully applicable to and in case of doubt or contradiction take precedence over the present Consortium Agreement.

BETWEEN

(1) SPMS - SERVIÇOS PARTILHADOS DO MINISTÉRIO DA SAÚDE, E.P.E. (SPMS), established in Avenida da República No. 61, 1050-189 Lisboa, Portugal, public law enterprise 509540716

Hereinafter referred to as the *Coordinator*

AND

(2) BUNDESMINISTERIUM FÜR SOZIALES, GESUNDHEIT, PFLEGE UND KONSUMENTENSCHUTZ (ATNA), established in Austria
(3) GESUNDHEIT OSTERREICH GMBH (GÖG), established in Austria
(4) SERVICE PUBLIC FEDERAL SANTE PUBLIQUE, SECURITE DE LA CHAINE ALIMENTAIRE ET ENVIRONNEMENT, (FPS Health Be), established in Belgium
(5) INTEGRATING THE HEALTHCARE ENTERPRISE-EUROPE AISBL (IHE-EUR), established in Belgium

(6) HL7 INTERNATIONAL FONDATION (HL7 Europe), established in Belgium
(7) STICHTING KONINKLIJK NEDERLANDS NORMALISATIE INSTITUUT (NEN), established in Netherlands
(8) HRVATSKI ZAVOD ZA ZDRAVSTVENO OSIGURANJE (HZZO), established in Croatia
(9) UNIVERSITY OF CYPRUS (UCY), established in Cyprus
(10) MINISTERSTVO ZDRAVOTNICTVI CESKE REPUBLIKY (MZCR), established in Czechia
(11) VYSOCINA KRAJ (Kraj Vysočina), established in Czechia
(12) SOTSIAALMINISTEERIUM (MSAE), established in Estonia
(13) AGENCE DU NUMÉRIQUE EN SANTÉ (ANS), established in France
(14) MINISTERE DES AFFAIRES SOCIALES ET DE LA SANTE (MoH-FR), established in France
(15) BUNDESINSTITUT FUR ARZNEIMITTEL UND MEDIZINPRODUKTE (BfArM), established in Germany
(16) GEMATIK GmbH (GEMATIK), established in Germany
(17) TMF - TECHNOLOGIE UND METHODENPLATTFORM FUR DIE VERNETZTE MEDIZINISCHE FORSCHUNG EV (TMF), established in Germany
(18) MINISTRY OF HEALTH (MoHGR), established in Greece
(19) ORSZAGOS KORHAZI FOIGAZGATOSAG (OKFŐ), established in Hungary
(20) SEMMELWEIS EGYETEM (SE), established in Hungary
(21) DEPARTMENT OF HEALTH (DoH), established in Ireland
(22) AGENZIA PER L'ITALIA DIGITALE (AGID), established in Italy
(23) AZIENDA REGIONALE PER L'INNOVAZIONEE GLI ACQUISTI S.P.A. (ARIA), established in Italy
(24) MINISTERO DELLA SALUTE. (MIN SAL), established in Italy
(25) REGIONE LOMBARDIA. (REGLOMB), established in Italy
(26) NACIONALAIS VESELIBAS DIENESTS (NVD), established in Latvia
(27) LIETUVOS RESPUBLIKOS SVEIKATOS APSAUGOS MINISTERIJA (SAM), established in Lithuania
(28) STICHTING NATIONAAL ICT INSTITUUT IN DE ZORG (NICTIZ), established in Netherlands
(29) NARODNE CENTRUM ZDRAVOTNICKYCH INFORMACII (NCZI), established in Slovakia
(30) NACIONALNI INSTITUT ZA JAVNO ZDRAVJE (NIJZ), established in Slovenia
(31) FUNDACIO TICSALUT (TICSALUT), established in Spain
(32) EQUALIS AB (Equalis AB), established in Sweden
(33) E-HALSOMYNDIGHETEN (SEHA), established in Sweden
(34) INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM), established in France
(35) MINISTERIO DE SANIDAD (MoH-ES), established in Spain

hereinafter, jointly or individually referred to as "*Parties*" or "*Party*"

related to the Project entitled

eXchanging electronic Health Records in a common framework

in short

X-eHealth

hereinafter referred to as "*Project*" or *"action"*

WHEREAS:

(A) The *Parties*, having considerable experience in the field concerned, have submitted a proposal for the project to the Directorate-General for Communications Networks, Content and Technology, Data, Administration and Finance (DG CONNECT), under the power delegated by the European Commission, as part of the third Programme for the Union's action in the field of health (2014-2020);
(B) The *Parties* intend to enter into the contract;
(C) The *Parties* wish to specify or supplement binding commitments among themselves in addition to the provisions of the Grant Agreement,

NOW, THEREFORE IT IS HEREBY AGREED AS FOLLOWS:

Section 1: DEFINITIONS

1.1 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.

1.2 Additional Definitions

For the purposes of this agreement, the terms hereinafter shall mean:

"***Consortium Partner***" means a beneficiary in the X-eHealth Grant Agreement that is entitled to directly receive EC funding.

"Linked Third Party" (TP) means an entity with an administrative and/or financial legal link with a *Party.* TPs are entitled to directly receive EC funding.

"***Background***" means an information and knowledge held by *Parties* prior to the accession to the GA, including any intellectual property rights needed for carrying out the *Project* or for using *Foreground.*

"***Collaborative partner***" (CP) means an entity that is not a formal *Party* to the *Project* but that contributes to it, namely by participation to meetings (by invitation). *Collaborative partners* are not entitled to receive EC funding under the *Project* neither entitled to be reimbursed of travel expenses for participation in project activities.

"***Project Coordinator***" (PC) means the *Coordinator* of the *Project* as referred to in the GA.

"***Deliverable***" means a product or service which specifies functions and characteristics of the *Project* that must be produced at a given moment during the action by the *Parties*. A *Deliverable* has a due date and is tangible, measurable and specific and satisfies a milestone that is produced in the *Work Plan*.

"***Defaulting Party***" means a *Party* which the *Steering Board* has identified to be in breach of this Consortium Agreement and/or the GA as specified in Section 4.2 of this Agreement.

"***Eligible Costs***" means expenses of *Parties* and Third Parties incurred for the purposes of the *Project*, covered by the budget (cf. Sect. 7) and accepted by the Steering Board.

"***External Expert***" means a natural person with appropriate knowledge in specific field(s) that undertakes one or various tasks and supports the *Parties* in the preparation of *Deliverables* and who is external to the *Project*.

"***Foreground***" means the results, including *namely, but not exclusively, all documents, recommendations, guidelines,* information, materials and knowledge, generated within the Project *or as a result of it*. It includes *all* intellectual property rights (*such as, but not limited to, the* rights resulting from copyright protection, related rights, design rights, patent rights) and knowhow.

"***Executive Board***" (EB) means the body responsible for aligning and coordinating the ongoing work across all WPs through a continuous assessment of inputs and emerging results. It is composed of all WP leaders, co-leaders and task leaders and is chaired by the *Coordinator*. EB is also responsible for preparing proposals for *SB* as well as carrying out executive decisions, i.e. actions that do not require SB approval.

"***Party***" means a *Consortium Partner* in this Consortium Agreement. *Subcontractors*, *external experts* and *collaborative stakeholders* are not *Parties* for the purpose of this Agreement.

"***Steering Board***" (SB) means the body in charge of the strategic implementation of the X-eHealth. The SB is chaired by the *Coordinator* and is composed of all *Consortium Partners* and *Third Parties*. Nominated entities which are not *Consortium Partners* may participate in the SB without voting rights.

"***Advisory Group***" (AG) means the external body with counselling functions instituted to assist the EB with technical-scientific expertise.

"***Subcontractor***" means a natural or legal person that acts as a service provider to carry out specific tasks of the work of the action.

"***Third Party***" means any legal entity not being a *Party* to this Agreement or associated to the implementation of the action.

"***Work Package***" (WP) means a thematic structure of the project carrying out specific work as described in the *Work Plan*.

"***Work Package Leader/Co-Leader/Task Leaders***" means Consortium Partners co-responsible for leading the work of a given *Work Package* and the respective tasks.

"Work Plan" means the structure, agreed by the project, to conduct the work and to organize the production of its *deliverables*.

Section 2: PURPOSE/SCOPE

2.1- Purpose of this Agreement

This Agreement specifies the relationship among the *Parties*, namely concerning the organisation, management and competences of the *Project's* bodies, the voting procedures and the rights and obligations of the *Parties* concerning, inter alia, liability and dispute resolution.

2.2- Scope of the Project

The major objective of the *Project* is to develop the foundations for the future adoption of a European health governance framework that allows secure access to patient health information between member states and other EU countries. As so, X-eHealth intends to contribute to the Digital Single Market Strategy of the European Commission. The underlying idea of realising a connected Digital Single Market in Europe is based on three pillars:

1. Pillar 1: Citizens' secure access to their health data, also across borders;
2. Pillar 2: Personalised medicine through shared European data infrastructure;
3. Pillar 3: Citizen empowerment with digital tools for user feedback and person-centred care.

On this basis and building upon the already in place Patient Summary, X-eHealth purpose is to develop the foundations for a common framework for medical imaging, discharge letters, laboratory results and rare diseases to flow both alongside citizens care pathway and across health entities between EU Member States and Neighbour Countries.

Section 3: ENTRY INTO FORCE, DURATION, TERMINATION AND AMENDMENTS

3.1- Entry into force

A *Consortium Partner* entity becomes a *Party* to this Consortium Agreement upon signature of this Agreement by a duly authorised representative.

This Consortium Agreement shall have effect for the *Parties* from the starting date of the action as specified in the Grant Agreement.

A new *Party* enters the Consortium after a positive evaluation of the request for amendment submitted by the *Coordinator* in accordance with Article 55 of the Grant Agreement. Such Accession is effective from the date specified in the Accession Form.

3.2- Duration and termination

The duration of this Consortium Agreement is from the starting date of the action until the end of the action as foreseen in the GA, without prejudice to the complete fulfilment of obligations undertaken by the Parties under the Grant Agreement and this Agreement.

However, this Agreement or the participation of one or more *Parties* to it may be terminated in accordance with the terms of this Agreement

3.3- Amendments to this Agreement

Any amendment to this Agreement voted by the *Steering Board* shall be concluded in writing. To meet this requirement, it shall be deemed sufficient to enter the amendments in the minutes of the respective meeting of the *Steering Board*. A consolidated version with the newly

introduced changes shall be circulated by the *Coordinator* within one month after the meeting in which the amendments are concluded.

Section 4: RESPONSIBILITIES OF PARTIES

4.1- General principles

a) Each *Party* undertakes to use all reasonable endeavours to:

aa) take part in the efficient implementation of the *Project*, and to cooperate, perform and fulfil, promptly and on time, all its obligations under the Grant Agreement and this Agreement as may be reasonably required from it and in good faith.

ab) notify promptly the *Coordinator* of any significant matter, fact, problem or delay likely to affect the *Project*.

ac) inform the *Coordinator* and the other *Parties* of relevant communications it receives from *third parties* in relation to the *Project*.

ad) inform the *Coordinator* without delay if there are any issues that change or are likely to change the terms of the *Party*'s participation in the Project.

b) Each *Party* shall promptly provide all information reasonably required by the *Coordinator* or a body of the consortium, necessary for the carrying out of its/their tasks.

c) Each *Party* shall take reasonable measures to ensure the accuracy of any information or materials it supplies hereunder or under the Grant Agreement, and shall promptly correct any error therein of which it becomes aware. The receiving *Party(ies)* shall undertake efforts to ensure using appropriate information and materials.

d) In addition to the obligations specified in the Grant Agreement, each *Party* agrees not to use knowingly, as a part of a *Deliverable* or in the design and preparation of such *Deliverable* or in any information supplied hereunder or under the Grant Agreement, any proprietary rights of *Third Parties* for which such *Party* has not acquired the right to grant licenses and user rights to the other *Parties* in accordance with the Grant Agreement.

4.2- Breach

In the event of a reasonable suspicion that a *Party* breached its obligations under this Agreement or the Grant Agreement, a body of the consortium shall notify the *Coordinator* who, in turn, will give written notice to such *Party* to remedy that situation or to present its defence within 30 calendar days, before the *Steering Board* decides that the breach occurred.

If such breach is not remediated within the 30 days period or the *Party* is not capable of adequate remedy, the *Steering Board* will appreciate the conflict and might declare the *Party* as *Defaulting Party*, deciding on the consequences thereof, which may include termination of its participation.

4.3- Involvement of third parties

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

Section 5: SETTLEMENT OF DISPUTES

5.1- General

In the case of disputes or differences arising relating to this Agreement, the *Parties* shall first try to solve such disputes amicably or following the conflict resolution process (described in section 6.1 and in figure 2). In case it is not possible to reach a solution, the differences or disputes shall either be set by mediation or arbitration, as explained below.

5.2- Mediation

Mediation is defined as an attempt to reach a peaceful settlement between disputing Parties though the friendly intervention of a neutral power. In the event mediation efforts fail the dispute shall finally be settled by arbitration.

The parties agree to discuss and consider referring the dispute to the ICC Mediation Rules. Besides, the parties agree that the costs of the mediator/mediation process shall be shared equally among the participating parties of the mediation and that any additional costs like lawyer fees or similar expenditures shall be borne by each Party itself.

5.3- Arbitration

Disputes which could not be settled according to the preceding paragraphs shall be settled under the *ICC Rules of Arbitration of the International Chamber of Commerce, according to its latest amendment,* by one or more arbitrators to be appointed under the terms of those rules. In any arbitration in which there are more than two arbitrators, the chairman shall be of juridical education. The award of the arbitration will be final and binding upon the *Parties*.

Section 6: GOVERNING BODIES AND COMPETENCES

6.1- General Structure

The Project internal governance structure was created with a clear division of roles and responsibilities as depicted in figure 1 and explained in detail below:

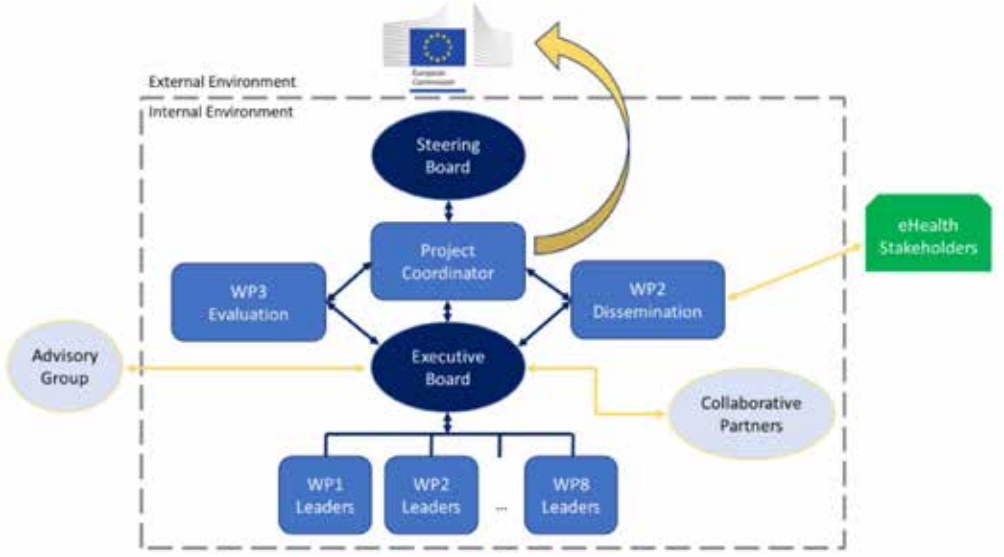

Figure 1 – X-eHealth's governance structure

Steering Board

The *Steering Board* (SB) is the highest decision-making body in the project, assembling all X-eHealth consortium partners to jointly leading the project on the strategic level. Its responsibilities range from decision-making to monitoring as all issues with possible significant effects on the project have to be decided within this body. These include financial/administrative decisions such as amendments to the Grant Agreement, project procedural rules, resources reallocation and deliberating recommendations.

The SB shall assemble at least once every three months to present the progress of the project to its associates and to disseminate outcomes. In-person meeting shall occur twice a year. Extraordinary meetings are to be arranged if circumstances demand so. Herein, voting rights are exclusively held by consortium partners (one per partner). The PC shall chair these body meetings.

Concerning decision-making procedures, a consensus is the preferred practice, however, the Steering Board decides by a two-thirds majority when the quorum is reached (half of the partners with voting rights are present).

Project *Coordinator*

The PC takes on the responsibility of organizing, controlling and coordinating the entire project. The project *Coordinator* shall guarantee by appropriate management tools that the project develops smoothly and effective communication is ensured between bodies, partners and associates.

To optimize its coordination responsibilities, the PC role (feature by WP1) shall be aligned with the WPs for dissemination and evaluation, WP2 and WP3 respectively. The PC chairs and shall act as a link between the Steering and the Executive Boards assemblies. PC team shall carry out all the project administrative issues, from legal to financial and from technical to organizational.

WP1 is responsible for monitoring project activities (including risk and quality management) while maintaining an up-to-date view of progress, serving at the same time as the official interface between the consortium and the EC.

Executive Board

The Executive Board is responsible for aligning, coordinating and monitoring the course of the project across all WPs. These liabilities shall factor to address the PC with recommendations for its overall coordination and are to be reported to the SB semi-annually.

Although the SB stands as the highest decision-making in X-eHealth, it is the EB's competence to undertake executive decision that does not require the SC approval. Executive decisions that go beyond its competence shall be prepared by this body and proposed as recommendations for deliberation in the SB.

The EB is chaired by the PC and comprises the representatives of each WP: Leaders, Co-Leaders and Task Leaders (the risk and quality managers are herein represented by WP1 Leaders). The EB shall assemble via monthly telephone conferences and might have face to face meetings each half a year.

The EB decides by a simple majority, still, a consensus is the preferred practice. Each WP and Task Leader holds one vote only, despite of leading more than one WP or Task within the project.

The quorum is reached if half of the partners with voting rights are present.

Advisory Group

Designed as an external body with counselling functions, the Advisory Group for digital health innovation and practice was instituted to assist the EB with the technical-scientific expertise in the following domains: interoperability assets, use cases, and future pilots.

Jointly composed of senior experts and representatives of international organizations, this body gathers a set of high-level strategic advisors eager in the abovementioned domains with a special focus on the EEHRxF component. Their role in X-eHealth is to contribute with high-quality advice to the project strategic direction, to provide operational guidance and to assess programme effectiveness when the group needs.

The AB shall meet twice a year by using remote communication means. The AG does not have voting rights neither budget allocation. However, travel costs to attend X-eHealth conferences may be provided by the project funds.

Collaborative Partners

CPs bring together a set of international organizations with the interest and expertise to be a significant asset for X-eHealth areas of focus.

Established as an external resource aimed at supporting the project development, engaged collaborative partners are free to integrate the WPs of their area of interest. Still, the EB shall encourage CPs involvement to match the project needs.

CPs shall be part of EB meetings whenever X-eHealth consortium considers their expertise needed and appropriated. CPs do not hold voting rights neither budget allocation. Still, travel costs to attend X-eHealth face-to-face meetings may be granted if consortium partners deem it appropriate.

Quality Management

Since knowledge generated by the project arises from the elaboration of deliverables, X-eHealth could not but have a fraction focuses exclusively on the Quality Assurance of Deliverables.

The Quality Manager (QM) is liable to ensure that the process of deliverables production follows a structural approach, to meet the required standards in order to be considered final and therefore, delivered thoroughly to the European Commission.

The Quality Manager shall be nominated by the PC. The QM stands as an integral part of WP1.

Risk Management

Risk Management (RM) is accountable for the process of Risk Assessment and the management of all the risks which are to arise throughout the project lifetime. Divided into three stages, the RM shall systematically: (1) identify and assess potential risks, while in parallel, (2) plan and perform mitigation measures and (3) control outcomes and track the project's response and progress.

To perform these tasks, a risk manager shall be nominated by the PC and is an integral part of WP1.

Work Package Leaders (WPL)

By acknowledging the operational challenge of X-eHealth purposes, this consortium agreed that the number of managerial agents should be enlarged in order to ensure better coordination and engagement. This way, each WP is jointly represented by a designated Leader, Co-Leader and Task Leaders.

These Leaders shall be co-responsible for leading their designated WP and its respective Tasks, according to the objectives put forward in that same WP description of work. They shall coordinate, monitor and assess the progress of work package activities in close cooperation, supporting each other, making decisions and being able to substitute each other, if needed, in meetings and communication events.

Innovation Management

With the view of setting up X-eHealth in pursuit of Digital Health Innovation Practices, this consortium recognised the need to establish an IM fraction.

Aimed at capitalizing the innovative potential that are to arise from the multiple tasks, this fraction brings together the collaborative partners and the working group Leaders for innovative ways for EEHRxF exploitation (WP8). These responsibilities shall be herein aligned to enhance the deployment of EEHRxF.

To perform this task, the IM is responsible for nominating a spokesperson who shall factor as a direct link to effective communication between IM insights and the overall governance of X-eHealth.

The operationalization of this responsibility should be done through teleconferences on a regular basis. IM ideas shall be presented in the form of recommendations to the PC and the EB.

The IM is overseen and shall report to the SB.

Conflict Resolution

In order to strengthen X-eHealth's internal management, a conflict resolution process has been established and is to be followed whenever consensus cannot be reached over on the conduct and purpose of the project activities.

In accordance with figure 2, the process of conflict resolution shall first be addressed, informally, by the WP Leaders at issue. If the issue persists, the EB shall be formally informed to settle the conflict. Within this phase, the Advisory Group and the Collaborative Partners shall be approached to express their view on the issue. At the last resort, the SB shall assemble to take the final decision.

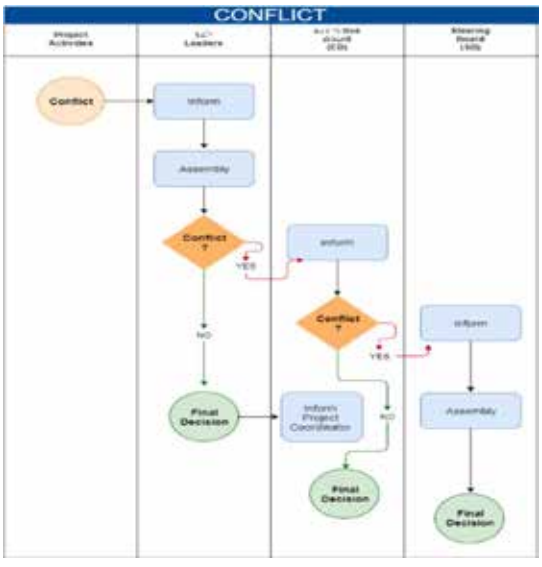

Figure 2 – Conflict resolution process

6.2- General provisions for Boards functioning

Representatives (natural persons representing Consortium Partners) shall be duly authorised to deliberate, negotiate and decide on all matters.

The *Coordinator* shall chair all meetings.

The Parties agree to abide by the decisions of the Boards, without prejudice to the possibility to submit a dispute for resolution in accordance with Sect. 5.

6.3- Operational procedures for the Boards

6.3.1 – Convening meetings

The *Coordinator* shall convene ordinary meetings of the SB and of the EB. Extraordinary meetings may be called at any time by the *Coordinator* if deemed necessary. The *Coordinator* shall convene an extraordinary meeting when requested by a minimum of 5 Consortium Partners.

6.3.2- Participation and representation at meetings

6.3.2.1 – Steering Board

All *Parties*:

a) Shall participate or be represented, by prior communication to the coordinator for that purpose and indicating to whom assigns the representation, at meetings
b) May, exceptionally and only for the purpose of the meeting concerned, appoint another Consortium Partner as substitute to attend and vote on its behalf. The Coordinator shall be previously informed about the substitution of the partner and the definition of vote agreed between the two partners.
   No Consortium Partner shall be given the right of representation or vote of more than one Consortium Partner.
c) Shall participate in a collaborative and constructive manner in meetings.

All *Linked Third Parties* and *Collaborative partners* may participate at meetings.

6.3.2.2 – Executive Board

Work Packages Leaders, Co-Leaders and Task Leaders:

a) Shall participate at meetings
b) Shall participate in a collaborative and constructive manner in meetings.

6.3.3- Requirements for binding decisions

6.3.3.1- General provisions__

The SB aims at adopting decisions by consensus. If no consensus can be reached, a vote shall be taken. Only Parties hold voting rights. Linked Third Parties shall align their voting intention with its respective Party.
Adoption shall be reached by simple majority of Parties with voting rights present or represented at the meeting, except for issues of accession of new *Parties* or termination of the participation of a *Party*, where adoption shall be reached by a majority of two-thirds (2/3). In both cases voting can occur when there is quorum at the meeting. Quorum is reached where half (1/2) of the *Parties* with voting rights are present or represented at the meeting. Representatives from the European Commission may participate in SB meetings as observers, but don't have voting rights.

Decisions of the EB are adopted by simple majority of votes provided quorum is reached. Quorum is reached where half (1/2) of the WP leaders and co-Leaders are present.

6.3.3.2 – Alternative forms of decision-making

In case of meetings of the Boards held via teleconference or other means of telecommunication, decisions taken in these meetings will be considered binding when the quorum of Parties needed is verified and the relevant points of the minutes have not been objected by meeting participants (or represented) within 5 working days after circulation via email.

In cases where quorum has not been reached during the meeting, the meeting minutes to be circulated will include the voting points and the number of votes needed to reach the majority. In such case, *Parties* not present or represented may express their approval or rejection in writing within a deadline. The deadline is agreed upon in the meeting, it shall be at least 5 working days. If the number of *Parties* not present or represented at the meeting that expressly approve the voting points reaches the needed majority, the point is considered approved.

Section 7: FINANCIAL PROVISIONS

7.1- Maximum amount of EU contribution and disbursement by the *Coordinator*

The EU financial contribution to this *Project* is 100% of the eligible costs.

The EU financial contribution will be distributed by the *Coordinator* to the *Parties* (and *Third Parties* if requested by the *Party*) according to the budget detailed in Annex 2 of the Grant Agreement, the approval of payments and reports by DG CONNECT and provisions of payment indicated in Article 21 of the Grant Agreement. A *Party* shall be funded only for its tasks carried out in accordance with the foreseen budget and activities.

7.2- Funding principles for payments

There will be one pre-financing payment by the European Commission at the beginning of the Project, followed by one interim payment after the end of the first reporting period. A balance payment will occur after the end of the Project following the second reporting period.

7.2.1 - BUDGET

The calculation of the overall budget and the distribution of funds (EC Co-funding and *Parties* in-kind contribution) is done as shown below:

Category	Value
Direct personnel costs	**1 628 368,51 €**
Direct costs of subcontracting	**362 520,61 €**
Other direct costs	**481 599,00 €**
Travel	*429 400,00 €*
Equipment	*- €*
Other goods and services	*52 199,00 €*
Indirects costs	**527 491,88 €**
Total costs	**2 999 980,00 €**
Reimbursement rate (%)	*100%*
Maximum EU contribution	**2 999 980,00 €**
Maximum grant amount	**2 999 980,00 €**

Any shifting of the budget between budget categories within a *Party* budget or between *Parties* has to be internally approved by the project Steering Board, unless "direct costs of subcontracting" not provided for in GA Annex 1, that will require an Amendment and its agreement by DG CONNECT, according to Article 4.2 of the Grant Agreement.

7.2.2- Reporting periods

The Project is divided into two reporting periods (cf. Article 20.2 of the Grant Agreement), as follows:

a) RP1: from September 2020 to August 2021 (month 1 to month 12)
b) RP2: from September 2021 to November 2022 (month 13 to month 27)

7.2.3- Pre-financing payment

As per Article 21.2 of the Grant Agreement, there will be one pre-financing of 2,399,984.00 € (equivalent to 80% of the EC funding). An amount of 149,999.00 € corresponding to 5% of the maximum grant amount, is retained by the European Commission from the pre-financing payment and transferred into the "Guarantee Fund". The rational for the distribution of the pre-financing per Partner and Third *Party* is to apply it proportionally to their budget.

7.2.4- Interim payment

The amount of the interim payment will depend on the actual costs incurred by the *Parties* and *Third Parties* for the implementation of the action during the first reporting period and should be reported at the end of that period. If these costs are accepted by the European Commission, an interim payment will be made.

Regular evaluation of effort reported will be done in order to prevent future need for refunding. If refunding is needed, concrete procedure will be agreed at EB level and endorsed by SB.

7.2.5- Balance payment

The *Parties* and *Third Parties* shall receive a balance of what remains open to be reimbursed by the European Commission funding according to the *Parties* and *Third Parties* co-funding rate.

7.2.6- Miscellaneous

a) Although the *Coordinator* will transfer the payments directly to the *Parties* and their *Third Parties*, the financial responsibility of possible undue payments for costs declared by the *Partner* and its *Third Parties* remains on the *Partner*, according to GA (Article 44.1).
b) The *Coordinator* is entitled to withhold any payments due to a *Party* declared as a *Defaulting Party*. The *Coordinator* is entitled to recover any payments already paid to the *Defaulting Party*. The recover procedure will be agreed by all *Parties.*
c) The *Coordinator* shall be entitled, according to the GA (Article 21.7, § 4), to withhold all or part of the pre-financing to the *Parties*.
d) For the purposes of smooth and efficient project implementation, the *Coordinator* shall be authorised to propose budget reallocations to the Steering Board. Such proposed reallocations shall be based on the expenditure rate as presented by the monthly reporting received from the *Parties*.
e) Continuous evaluation of effort reported will be done to prevent future need for refunding. If refunding is needed, concrete procedure will be agreed at EB level, endorsed by SB and registered in the meeting minutes.

7.3- Financial reporting

The *Parties* must submit financial reports to the *Coordinator* and take full liability for the data included therein, including the accuracy of reported facts. The *Parties* are therefore solely responsible for the accuracy of their cost calculation and eligibility of the actual reported costs. *Third Parties* must also submit financial reports to the *Coordinator* with their related *Parties* knowledge. Each *Party* shall indemnify, defend and hold harmless the other *Parties* as well as its employees, agents, officers, directors, affiliates and subsidiaries from and against any damage arising from breaches of obligations, especially of obligations under social security and/or tax law.

7.3.1- Reporting of human resources

The actual consumption of person-months must be reported on monthly basis and submitted every six months until the 21st day of the month following of the reporting period.

7.3.2- Reporting of financial resources

The actual consumption of other direct costs (travel expenses, equipment, other goods and services) and subcontracting costs must be reported on monthly basis and submitted every six months until the 21st day of the month following of the reporting period.

Section 8: LIABILITIES

Each *Party* shall be liable for any loss, damage or injury to third parties resulting from carrying out its part of the *Project*. No *Party* shall be liable for acts or omissions of other *Parties*.

Each *Party* shall be fully responsible for the performance of any part of its share of the *Project*, or other obligations, including any portion thereof in which it has entered into contract with a Sub Contractor and shall ensure such contracts enable fulfilment of the Grant Agreement.

No *Party* shall be in breach of this Agreement if such breach is caused by Force Majeure. The expression Force Majeure shall mean any unforeseeable and insuperable event affecting the *Party* fulfilling its obligations under the Agreement and the Grant Agreement. Each *Party* must notify the *Coordinator* of any Force Majeure as soon as possible. If the consequences of Force Majeure are not possible to overcome within a period of six (6) weeks after notification, the *Steering Board* will decide on the transfer of tasks and financial resources of the *Party* unable to contribute with its share of the Project.

Section 9: RESULTS AND ACCESS RIGHTS

9.1- Ownership of results

Unless stipulated otherwise in the Grant Agreement, ownership of the results of the *Project*, including both intellectual property rights and of the reports and other documents relating to it, shall be vested in the *Parties*.

Foreground resulting from the Project shall be owned by the *Party* generating it. When *Foreground* is generated jointly, it shall be jointly owned, unless the *Parties* in question agree on a different solution.

The method of defining joint ownership shall be based on their contributing efforts towards the result in shares proportionate to their scope of work/budget for that result. All the joint owners shall agree in all protection measures, the division of related costs and rights to use their jointly owned results and grant non-exclusive licences in advance.

9.2- Access Rights

9.2.1 – Access rights for implementation

In case of pre-existing intellectual property rights necessary for carrying out the Project, the *Parties* and *Third Parties* need to declare background and compile a list of it, specifying the owner and any person that have a right of use. The final agreed list of background is to be communicated to DG CONNECT prior to the commencement of an implementation which may be based on such background, as in article 24.1 of the GA.

Each *Party* shall take appropriate measures to ensure it can grant access rights to existing background needed for carrying out the Project and fulfil the obligations under this Agreement and the Grant Agreement. Access rights shall be granted on a royalty-free basis.

Access rights are granted on a non-exclusive basis. Access rights do not include the right to grant sub-licences, unless otherwise expressly provided in this Agreement or the Grant Agreement.

Each *Party* shall notify the other *Parties* of any other limitation on access rights in Annex I.

9.2.2- Access rights for use

After completion of the Project and termination or expiration of this Agreement, each *Party* shall have the non-exclusive, royalty-free right to use, modify, copy or make derivative works of *Foreground* for non-commercial research, internal use and eHealth service provision purposes only.

Each of the *Parties* owning such *Foreground* shall enter into a separate arrangement with interested parties concerning any right to use such *Foreground* for purposes other than the above-mentioned ones.

Access rights to Foreground shall be granted under favourable conditions, subject to the *Parties*' concerned negotiating in good faith a bilateral agreement.

Section 10: LANGUAGE

This agreement is drawn up in English.

English language shall govern all documents, notices, meetings and procedures for application of this Agreement, its extension or in any other way related thereto.

ACCESSION

of a *Party* to

Consortium Agreement

GA N. 951938 – eXchanging electronic Health Records in a common framework

NARODNE CENTRUM ZDRAVOTNICKYCH INFORMACII (NCZI)

Hereby

- Consents to become a *Party* to the Consortium Agreement identified above,
- Accepts all rights and obligations of a *Party*, and
- Confirms to have received a copy of the Consortium Agreement.

This Accession document is drawn up in two originals to be duly signed by the authorised representatives identified here below.

Name of legal entity: *Národne centrum zdravotníckych informácií*

Name of the legal representative: *Mgr. Peter Lukáč, PhD.*

Title of the legal representative: *Chairman of the Board and CEO*

Date and signature of the legal representative: [redacted]

Stamp of the organisation

Name of *Coordinator*: SPMS – Serviços Partilhados do Ministério da Saúde, E.P.E.

Name of the legal representative: Luís Goes Pinheiro

Title of the legal representative: Chairman of the Board of Directors

Date and signature of the legal representative: [redacted]

[redacted]

Stamp of the organisation

Luís Goes Pinheiro
Presidente do Conselho de Administração