DigiONE I3 Consortium Agreement

THIS CONSORTIUM AGREEMENT is based upon Regulation (EU) No 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation (2021-2027), laying down its rules for participation and dissemination (hereinafter referred to as "Horizon Europe Regulation") and on the regulations of the Interregional Innovation Investments Instrument ("I3"), and on the European Commission's General Model Grant Agreement and its Annexes, and is made on **March 25 2024**, (hereinafter referred to as the "Effective Date") BETWEEN:

1. **DIGITAL INSTITUTE FOR CANCER OUTCOMES RESEARCH (DGCR)**, PIC 890481923, established in RUE D'EGMONT 11, BRUSSELS 1000, Belgium,
2. **GRAND HOPITAL DE CHARLEROI (GHdC)**, PIC 959948473, established in RUE MARGUERITE DEPASSE 6, CHARLEROI 6060, Belgium,
3. **MASARYKUV ONKOLOGICKY USTAV (MMCI),** PIC 986107627, established in ZLUTY KOPEC 7, BRNO 656 53, Czechia,
4. **SIHTASUTUS TARTU ULIKOOLI KLIINIKUM (TUH)**, PIC 999518556, established in PUUSEPA 1A, TARTU 50406, Estonia,
5. **CHARITE - UNIVERSITAETSMEDIZIN BERLIN (Charite)**, PIC 999992692, established in Chariteplatz 1, BERLIN 10117, Germany,
6. **UNIVERSITATSMEDIZIN GREIFSWALD KORPERSCHAFT DES OFFENTLICHEN RECHTS (UMG)**, PIC 947193555, established in FLEISCHMANNSTRASSE 8, GREIFSWALD 17475, Germany,
7. **TECHNISCHE UNIVERSITAET DRESDEN (TUD)**, PIC 999897729, established in HELMHOLTZSTRASSE 10, DRESDEN 01069, Germany,
8. **THE PROVOST, FELLOWS, FOUNDATION SCHOLARS & THE OTHER MEMBERS OF BOARD, OF THE COLLEGE OF THE HOLY & UNDIVIDED TRINITY OF QUEEN ELIZABETH NEAR DUBLIN (TCD)**, PIC 999845446, established in COLLEGE GREENTRINITY COLLEGE, DUBLIN 2 D02 CX56, Ireland,
9. **ISTITUTI FISIOTERAPICI OSPITALIERI (IFO)**, PIC 985625925, established in VIA CHIANESI 53, ROMA 00144, Italy,
10. **OSPEDALE SAN RAFFAELE SRL (OSR)**, PIC 953176030, established in VIA OLGETTINA 60, MILANO 20132, Italy,
11. **VIESOJI ISTAIGA VILNIAUS UNIVERSITETO LIGONINE SANTAROS KLINIKOS (VULSK)**, PIC 991636530, established in SANTARISKIU G 2, VILNIUS LT-08661, Lithuania,
12. **UNIVERSITEIT MAASTRICHT (MUMC)**, PIC 999975911, established in MINDERBROEDERSBERG 4, 6, 6211 LK | PO Box 616, 6200 MD, MAASTRICHT , Netherlands,
13. **STICHTING MAASTRICHT RADIATION ONCOLOGY MAASTRO CLINIC (MC)**, PIC 98618784, established in Dr. Tanslaan 12, MAASTRICHT 6229 ET, Netherlands,

14. **ACADEMISCH ZIEKENHUIS GRONINGEN (UMCG)**, PIC 999914801, established in HANZEPLEIN 1, GRONINGEN 9713 GZ, Netherlands,
15. **NARODOWY INSTYTUT ONKOLOGII IM. MARII SKLODOWSKIEJ-CURIE - PANSTWOWY INSTYTUT BADAWCZY (MSCI)**, PIC 999533203, established in UL. W K ROENTGENA 5, WARSZAWA 02-781, Poland,
16. **EUROSCAN INTERNATIONAL NETWORK EV (ESIN)**, PIC 906262271, established in SCHAEVENSTR 1 RHEINISCHE FACHHOCHSCHULE KOLN GGMBH, KOLN 50676, Germany,
17. **EDENCEHEALTH (EH)**, PIC 895597994, established in VELDKANT 33A, KONTICH 2550, Belgium,
18. **IQVIA CANCER RESEARCH (IQCR)**, PIC 881920218, established in DA VINCILAAN 7, ZAVENTEM 1930, Belgium,
19. **ONCODNA (ODNA)**, PIC 881844170, established in RUE LOUIS BREGUET 1, CHARLEROI 041, Belgium,
20. **KAIROS GMBH (KRS)**, PIC 952699469, established in GESUNDHEITSCAMPUS SUD 17, BOCHUM 44801, Germany,
21. **IQVIA SOLUTIONS B.V. (IQS)**, PIC 893425970, established in HERIKERBERGWEG 314, AMSTERDAM 1101CT, Netherlands,
22. **MAASTRO INNOVATIONS BV (MI)**, PIC 986092301, established in DR TANSLAAN 12, MAASTRICHT 6229 ET, Netherlands,
23. **MEDICAL DATA WORKS BV (MDW)**, PIC 904574762, established in DR TANSLAAN 12, MAASTRICHT 6229 ET, Netherlands,
24. **CLININOTE SPOLKA Z OGRANICZONAODPOWIEDZIALNOSCIA (CN)**, PIC 89911272, established in UL. MELGIEWSKA NR 7-9 LOK. 122, LUBLIN 20-952, Poland,
25. **COMPUGROUP MEDICAL POLSKA SPOLKA OGRANICZONA ODPOWIEDZIALNOSCIA (CGM)**, PIC 881841551, established in UL. DO DYSA 9, LUBLIN 20-149, Poland,

(hereinafter, jointly or individually, referred to as ”Parties” or ”Party”)

relating to the Action entitled **DIGItal Infrastructure for ONcology in Europe**

in short **DigiONE I3**

(hereinafter referred to as “Project”)

WHEREAS:

The Parties, having considerable experience in the field concerned, have been awarded with funds for a proposal for the Project to the Granting Authority as part of Interregional Innovation Investments Instrument (I3).

The Parties wish to specify and supplement binding commitments among themselves in addition to the provisions of the specific Grant Agreement signed by the Coordinator and the Granting Authority, and the relevant Accession forms for beneficiaries (hereinafter “Grant Agreement”).

The Parties are aware that this Consortium Agreement is based upon the DESCA model consortium agreement found at https://www.desca-agreement.eu/

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

1 Definitions

Words beginning with a capital letter shall have the meaning defined either herein or in the Grant Agreement including its Annexes.

“Access Rights” means rights to use Results or Background under terms and conditions laid down in accordance with the Horizon Europe Regulation.

"Accession document” means the document enabling the Party to join this Consortium Agreement alongside existing Partners. Such accession shall have effect from the date identified in the Accession document. A template is enclosed as Annex 3.

“Background” means any data, know how or information whatever its form or nature, tangible or intangible, including any rights such as intellectual property rights, that is: (i) held by beneficiaries prior to their accession to a given action; and (ii) identified by the beneficiaries in this agreement in Annex 1.

“Consortium Agreement” means this agreement, including its Annexes.

“Consortium Body” means any management body described in Section 6 (Governance structure) of this Consortium Agreement

“Consortium Plan” means the description of the Action and the related agreed budget as first defined in the Grant Agreement, and which may be updated by the Partner Assembly.

“Defaulting Party” means a Party which the Partner Assembly has declared to be in breach of this Consortium Agreement and/or the Grant Agreement as specified in Section 4.2 of this Consortium Agreement.

“Dissemination” means the public disclosure of the Results by appropriate means, other than resulting from protecting or exploiting the Results, including by scientific publications in any medium.

“Exploitation” means the use of Results in further R&I activities other than those covered by the action concerned, including among other things, commercial exploitation such as developing, creating, manufacturing and marketing a product or process, creating and providing a service, or in standardisation activities.

"Fair and Reasonable Conditions" means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the Results or Background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged;

"Granting Authority" means the body awarding the grant for the Project.

"Intellectual Property Rights" or "IP Rights" means patents, utility rights, inventions, trademarks, service marks, trade and service names, registrable business names, topography rights, designs, design rights, unregistered design rights, industrial designs, database rights and copyright, including copyright in computer programs (in each case whether or not the same are registered or capable of registration and whether vested, contingent future or otherwise and including all applications and rights to apply for registration of any of them and including all supplementary protection certificates), trade secrets, know-how, moral rights to the extent permitted by law, all accrued rights of action and all other intellectual property rights and rights of a similar character or having similar or equivalent effect to any of them which may subsist in any part of the world.

"Needed" means:

For the implementation of the Project:

Access Rights are Needed if, without the grant of such Access Rights, carrying out the tasks assigned to the recipient Party would be technically or legally impossible, significantly delayed, or require significant additional financial or human resources.

For Exploitation of own Results:

Access Rights are Needed if, without the grant of such Access Rights, the Exploitation of own Results would be technically or legally impossible.

"Results" means any tangible or intangible effect of a given action, such as data, knowhow or information, whatever its form or nature and whether or not it can be protected, as well as any rights attached to it, including intellectual property rights.

"Software" means sequences of instructions to carry out a process in, or convertible into, a form executable by a computer and fixed in any tangible medium of expression.

2 Purpose

The purpose of this Consortium Agreement is to specify with respect to the Project the relationship among the Parties concerning the organization of the work between the Parties, the management of the Project, and the rights and obligations of the Parties inter alia to liability, Access Rights, and dispute resolution.

The purpose of the Project is to create a federated, privacy appropriate, high quality, digital research network that links routine clinical data with routine molecular data information from 14 large cancer centres in 9 countries, with 10 private partners in 18 S3 regions. The underlying digital infrastructure provides a minimal description of every patient's cancer diagnosis, biomarkers, treatment and outcomes in near real time and internationally standardised. It is built on open standards and through open innovation with multiple private sector vendors. Precision oncology researchers worldwide (academic and commercial) access federated, privacy-managed fee-for-service, reliable protocolised insights with which to study modern cancer treatments and diagnostics in real world data, or for health systems analysis to improve cancer care. The economic model will reflect differences in ability to pay and IP requirements: at-cost, open-source access for academics with peer-reviewed non-commercial funding, and fair-market-value pricing for larger companies developing patented commercial products.

For avoidance of doubt in case of differences in text or interpretation, the Project Grant Agreement signed by EISMEA with the Coordinator (and endorsed by the Parties via the Accession forms for beneficiaries) takes priority over this Consortium Agreement.

3 Entry into force, duration, and termination

3.1 Entry into force

An entity becomes a Party to this Consortium Agreement upon signature of this Consortium Agreement by a duly authorized representative.

This Consortium Agreement shall have effect from the Effective Date identified at the beginning of this Consortium Agreement.

3.2 Duration and termination

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

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

If the Grant Agreement is terminated, or a Party's participation in the Grant Agreement is terminated, this Consortium Agreement shall automatically terminate in respect of the affected Party/ies, subject to the provisions surviving the expiration or termination under Section 3.3 of this Consortium Agreement. Further termination details are described in the Grant Agreement (see Article 32).

3.3 Survival of rights and obligations

The provisions relating to Access Rights, Dissemination, and confidentiality, for the time period mentioned therein, as well as for liability, applicable law and settlement of disputes shall survive the expiration or termination of this Consortium Agreement.

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

4 Responsibilities of Parties

4.1 General principles

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

Each Party undertakes to notify promptly the Coordinator and the other Parties, in accordance with the governance structure of the Project (Section 6), of any significant information, fact, problem or delay likely to affect the Project and, if the situation requires (e.g., there is an issue with the Coordinator), directly notify the Granting Authority. Each Party shall promptly provide all information reasonably required by a Consortium Body or by the Coordinator to carry out its tasks and shall responsibly manage the access of its employees to the EU Funding & Tenders Portal.

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

In specific, each Party must undertake necessary actions towards efficient implementation of the Project according to detailed role described in the Project proposal, as follows:

a) Coordinator – ensuring efficient Project management, financial planning, forecasting and financial reporting, and appropriate monitoring & reporting of Project execution, providing proper communication towards Consortium and Grant Authority providing necessary resources and process in the Grant Agreement implementation, and ensure the project is delivered in alignment with DIGICORE's foundational statutes and protections towards hospitals and Grant Authority objectives to create two new European value chains in

    i. lower cost, better private sector solutions for hospital interoperability and
    ii. European precision oncology digital research services

b) Private sector technology vendors – work together in Work Packages 2, 3 and 4 to improve existing interoperability solutions and then work with participating hospitals and/or research organizations to

i. deploy the necessary technologies to create European precision oncology digital research service, and
ii. establish a value chain in hospital digital interoperability within the OMOP common data model.

Vendors must work with the Coordinator to appropriately document their activities within the project, actively manage delivery risks at their hospitals and support EISMEA reporting requirements

c) Hospitals and/or research organizations are essential counterparties in all IT technology deployments with the private sector vendors. They will work with their preferred or assigned technology vendors to

i. develop, cost, and contract a local technology deployment plan
ii. drive timely delivery of that plan to assemble local research data in Cancer OMOP for future academic and/or commercial research services
iii. support research contracting to allow timely delivery of agreed future research services.

Hospitals and/or research organizations must work with the Coordinator to appropriately document their activities within the project, actively manage delivery risks, and support EISMEA reporting requirements.

d) Research services development group [EuroScan, Medical Data Works (MDW) and IQVIA Cancer Research BV] – will work within Work Package 5 to develop commercial digital research offerings, with IQVIA engaging large pharma globally, MDW engaging European biotechs and EuroScan European Payers. These offerings need to be agreed with the participating hospitals and must be developed in accordance with DIGICORE's foundational statutes and protections for hospitals. IQVIA Cancer Research BV will also supply training and research contracting support to the hospitals to prepare them for the delivery of these commercial research services. Members of the research services development group must work with the Coordinator to appropriately document their activities within the project, actively manage delivery risks, and support EISMEA reporting requirements.

4.2 Breach

In the event that the Partner Assembly identifies a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement (e.g. improper implementation of the Project), the Coordinator or, if the Coordinator is in breach of its obligations, the Party appointed by the Partner Assembly, will give formal notice to such Party requiring that such breach will be remedied within 30 calendar days from the date of receipt of the written notice by the Party.

If such breach is not remedied within that period or is not capable of remedy, the Partner Assembly may decide to declare the Party to be a Defaulting Party and to decide 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 (including but not limited to other participants) in the Project remains responsible for carrying out its relevant part of the Project and for such third party's compliance with the provisions of this Consortium Agreement and of the Grant Agreement. Such Party has to ensure that the involvement of third parties does not affect the rights and obligations of the other Parties under this Consortium Agreement and the Grant Agreement.

4.4 Specific responsibilities regarding data protection

Where necessary, the Parties shall cooperate in order to enable one another to fulfil legal obligations arising under applicable data protection laws (the *Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data* and relevant national data protection law applicable to said Party) within the scope of the performance and administration of the Project and of this Consortium Agreement.

In particular, the Parties shall, where necessary, conclude a separate data processing, data sharing and/or joint controller agreement before any data processing or data sharing takes place.

5 Liability towards each other

5.1 No warranties

In respect of any information or materials (incl. Results and Background) supplied by one Party to another under the Project, no warranty or representation of any kind is made, given or implied as to the sufficiency or fitness for purpose nor as to the absence of any infringement of any proprietary rights of third parties.

Therefore,

a) the recipient Party shall in all cases be entirely and solely liable for the use to which it puts such information and materials, and
b) no Party granting Access Rights shall be liable in case of infringement of proprietary rights of a third party resulting from any other Party (or its entities under the same control) exercising its Access Rights.

5.2 Limitations of contractual liability

No Party shall be responsible to any other Party for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue or loss of contracts.

A Party's aggregate liability towards the other Parties collectively shall be limited to the Party's share of the total costs of the Project as identified in Annex 2 of the Grant Agreement.

A Party's liability shall not be limited to the extent such damage was caused by a wilful or gross negligence or to act to the extent that such limitation is not permitted by law.

5.3 Damage caused to third parties

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

5.4 Force Majeure

No Party shall be in breach of this Consortium Agreement if it is prevented from fulfilling its obligations under the Consortium Agreement by Force Majeure.

Each Party will notify the Partner Assembly of any Force Majeure without undue delay. If the consequences of Force Majeure for the Project are not overcome within 6 weeks after such notice, the transfer of tasks - if any - shall be decided by the Partner Assembly.

5.5 Export control

No Party shall be considered to be in breach of this Consortium Agreement if it is prevented from fulfilling its obligations under the Consortium Agreement due to a restriction resulting from import or export laws and regulations and/or any delay of the granting or extension of the import or export license or any other governmental authorization, provided that the Party has used its reasonable efforts to fulfil its tasks and to apply for any necessary license or authorization properly and in time.

Each Party will notify the Partner Assembly of any such restriction without undue delay. If the consequences of such restriction for the Project are not overcome within 6 weeks after such notice, the transfer of tasks - if any - shall be decided by the Partner Assembly.

6 Governance structure

6.1 General structure

The organizational structure of the consortium shall comprise the following Consortium Bodies:

a. The **Partner Assembly** (named the “Steering Committee” in the Consortium Plan) as the ultimate decision-making body of the Consortium.
b. The **Program Management Office** (named the “Management Team” in the Consortium Plan) as the supervisory body for the execution of the Project, which shall report to and be accountable to the Partner Assembly.
c. The **Coordinator** as the legal entity acting as the intermediary between the Parties and the Granting Authority. The Coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in the Grant Agreement and this Consortium Agreement.
d. The **Work Package Management Groups** as operational body under Coordinator and Program Management Office. Work Package Management Groups shall perform the tasks assigned as described in the Grant Agreement and this Consortium Agreement in direct relation of deliverables and outputs linked Work Packages.

6.2 General operational procedures for all Consortium Bodies

6.2.1 Representation in meetings

Any Party which is appointed to take part in a Consortium Body shall designate one representative (hereinafter referred to as "Member").

Any Member:

- should be present or represented at any meeting;
- may appoint a substitute or a proxy to attend and vote at any meeting;

and shall participate in a cooperative manner in the meetings.

6.2.2 Preparation and organization of meetings

6.2.2.1 Convening meetings:

The chairperson of a Consortium Body shall convene meetings of that Consortium Body.

	Ordinary meeting	Extraordinary meeting
Partner Assembly	At least once a year	At any time upon request of the Program Management Office or 1/3 of the Members of the Partner Assembly
Program Management Office	At least twice per quarter	At any time upon request of any Member of the Program Management Office

6.2.2.2 Notice of a meeting

The chairperson of a Consortium Body shall give written notice of a meeting to each Member of that Consortium Body as soon as possible and no later than the minimum number of days preceding the meeting as indicated below.

	Ordinary meeting	Extraordinary meeting
Partner Assembly	45 calendar days	15 calendar days
Program Management Office	7 calendar days	3 calendar days

6.2.2.3 Sending the agenda

The chairperson of a Consortium Body shall prepare and send each Member of that Consortium Body an agenda no later than the minimum number of days preceding the meeting as indicated below.

Partner Assembly	21 calendar days, 10 calendar days for an extraordinary meeting
Program Management Office	5 calendar days

6.2.2.4 Adding agenda items:

Any agenda item requiring a decision by the Members of a Consortium Body must be identified as such on the agenda.

Any Member of a Consortium Body may add an item to the original agenda by written notice to all of the other Members of that Consortium Body up to the minimum number of days preceding the meeting as indicated below.

Partner Assembly	14 calendar days, 7 calendar days for an extraordinary meeting
Program Management Office	1 calendar days

6.2.2.5

During a meeting the Members of a Consortium Body present or represented can unanimously agree to add a new item to the original agenda.

6.2.2.6

Meetings of each Consortium Body may also be held by tele- or videoconference, or other telecommunication means.

6.2.2.7

Decisions will only be binding once the relevant part of the minutes has been accepted according to Section 6.2.5.2.

6.2.2.8

Decisions without a meeting

Any decision may also be taken without a meeting if

a) the Coordinator circulates to all Members of the Partner Assembly a suggested decision with a deadline for responses of at least 15 calendar days after receipt by a Party and

b) the decision is agreed by 51 % of all Parties.

The Coordinator shall inform all the Parties of the outcome of the vote.

A veto according to Section 6.2.4 may be submitted up to 15 calendar days after receipt of this information.

The decision will be binding after the Coordinator sends a notification to all Members. The Coordinator will keep records of the votes and make them available to the Parties on request.

6.2.3 Voting rules and quorum

6.2.3.1

Each Consortium Body shall not deliberate and decide validly in meetings unless two-thirds (2/3) of its Members are present or represented (quorum).

If the quorum is not reached, the chairperson of the Consortium Body shall convene another ordinary meeting within 15 calendar days. If in this meeting the quorum is not reached once more, the chairperson shall convene an extraordinary meeting which shall be entitled to decide even if less than the quorum of Members is present or represented.

6.2.3.2

Each Member of a Consortium Body present or represented in the meeting shall have one vote.

6.2.3.3

A Party which the Partner Assembly has declared according to Section 4.2 to be a Defaulting Party may not vote.

6.2.3.4

Decisions shall be taken by a majority of the votes cast.

6.2.4 Veto rights

6.2.4.1

A Party which can show that its own work, time for performance, costs, liabilities, intellectual property rights or other legitimate interests would be severely affected by a decision of a Consortium Body may exercise a veto with respect to the corresponding decision or relevant part of the decision.

6.2.4.2

A Party may veto such decision during the meeting or within 15 calendar days after receipt of the draft minutes of the meeting.

A Party that is not appointed to participate to a particular Consortium Body may veto a decision within the same number of calendar days after receipt of the draft minutes of the meeting.

6.2.4.3

When a decision has been taken without a meeting a Party may veto such decision within 15 calendar days after receipt of written notice by the chairperson of the outcome of the vote.

6.2.4.4

In case of exercise of veto, the Members of the related Consortium Body shall make every effort to resolve the matter which occasioned the veto to the general satisfaction of all the Parties.

6.2.4.5

A Party may neither veto decisions relating to its identification to be in breach of its obligations nor to its identification as a Defaulting Party. The Defaulting Party may not veto decisions relating to its participation and termination in the consortium or the consequences of them.

6.2.4.6

A Party requesting to leave the consortium may not veto decisions relating thereto.

6.2.5 Minutes of meetings

6.2.5.1

The chairperson of a Consortium Body shall produce minutes of each meeting which shall be the formal record of all decisions taken. He/she shall send the draft minutes to all Members within 10 calendar days of the meeting.

6.2.5.2

The minutes shall be considered as accepted if, within 15 calendar days from receipt, no Member has sent an objection by written notice to the chairperson with respect to the accuracy of the draft of the minutes by written notice.

6.2.5.3

The chairperson shall send the accepted minutes to all the Parties and to the Coordinator, who shall retain copies of them.

6.3 Specific operational procedures for the Consortium Bodies

6.3.1 Partner Assembly

In addition to the rules described in Section 6.2, the following rules apply:

6.3.1.1 Members

1. The Partner Assembly shall consist of one representative of each Party (hereinafter Partner Assembly Member).

2. Each Partner Assembly Member shall be deemed to be duly authorized to deliberate, negotiate and decide on all matters listed in Section 6.3.1.2 of this Consortium Agreement.

3. The Coordinator shall chair all meetings of the Partner Assembly, unless decided otherwise in a meeting of the Partner Assembly.

4. The Parties agree to abide by all decisions of the Partner Assembly. This does not prevent the Parties from exercising their veto rights, according to Section 6.2.4.1 and 6.2.4.2, or from submitting a dispute to resolution in accordance with the provisions of Settlement of disputes in Section 11.8.

6.3.1.2 Decisions

The Partner Assembly shall be free to act on its own initiative to formulate proposals and take decisions in accordance with the procedures set out herein.

In addition, all proposals made by the Project Management Office shall also be considered and decided upon by the Partner Assembly.

The following decisions shall be taken by the Partner Assembly:

Content, finances, and intellectual property rights:

- Proposals for changes to Annexes 1 and 2 of the Grant Agreement to be agreed by the Granting Authority
- Changes to the Consortium Plan
- Modifications or withdrawal of Background in Annex 1 (Background Included)
- Modifications of Annex 2 (Milestone and payment triggers)

Evolution of the consortium

- Entry of a new Party to the Project and approval of the settlement on the conditions of the accession of such a new Party
- Withdrawal of a Party from the Project and the approval of the settlement on the conditions of the withdrawal
- Proposal to the Granting Authority for a change of the Coordinator
- Proposal to the Granting Authority for suspension of all or part of the Project
- Proposal to the Granting Authority for termination of the Project and the Consortium Agreement
- Breach, defaulting party status and litigation
- Identification of a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement
- Declaration of a Party to be a Defaulting Party
- Remedies to be performed by a Defaulting Party
- Termination of a Defaulting Party's participation in the consortium and measures relating thereto
- Steps to be taken for litigation purposes and the coverage of litigation costs in case of joint claims of the parties of the consortium against a Party (Section 7.1.4)

Appointments

On the basis of the Grant Agreement, the appointment, if necessary, of:

- Program Management Office Members
- Constituting external committee and advisory boards with coordination with the Coordinator

6.3.2 Program Management Office

In addition to the rules in Section 6.2, the following rules shall apply:

6.3.2.1 Members

The Program Management Office shall consist of the Coordinator and the representatives of the Parties appointed to it by the Partner Assembly as leaders of Work Packages.

The Coordinator shall chair all meetings of the Program Management Office, unless decided otherwise by a majority of two-thirds.

6.3.2.2 Minutes of meetings

Minutes of Program Management Office meetings, once accepted, shall be sent by the Coordinator to the Partner Assembly Members for information.

6.3.2.3 Tasks

1. The Program Management Office shall prepare the meetings, propose decisions and prepare the agenda of the Partner Assembly according to Section 6.3.1.2.

2. The Program Management Office shall seek a consensus among the Parties.

3. The Program Management Office shall be responsible for the proper execution and implementation of the decisions of the Partner Assembly.

4. The Program Management Office shall monitor the effective and efficient implementation of the Project.

5. In addition, the Program Management Office shall collect information at least every 6 months on the progress of the Project, examine that information to assess the compliance of the Project with the Consortium Plan and, if necessary, propose modifications of the Consortium Plan to the Partner Assembly.

6. The Program Management Office shall:

    a. support the Coordinator in preparing meetings with the Granting Authority and in preparing related data and deliverables,

b. prepare the content and timing of press releases and joint publications by the consortium or proposed by the Granting Authority in respect of the procedures of the Grant Agreement Article 17 and Grant Agreement Annex 5 Section "Communication, Dissemination, Open Science and Visibility" and of Section 8 of this Consortium Agreement.

7. In the case of abolished tasks as a result of a decision of the Partner Assembly, the Program Management Office shall advise the Partner Assembly on ways to rearrange tasks and budgets of the Parties concerned. Such rearrangement shall take into consideration any prior legitimate commitments which cannot be cancelled.

6.4 Coordinator

6.4.1

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

6.4.2

In particular, the Coordinator shall be responsible for:

- monitoring compliance by the Parties with their obligations under this Consortium Agreement and the Grant Agreement
- keeping the address list of Members and other contact persons updated and available
- collecting, reviewing to verify consistency and submitting reports, other deliverables (including financial statements and related certifications) and specific requested documents to the Granting Authority
- transmitting documents and information connected with the Project to any other Parties concerned
- administering the financial contribution of the Granting Authority and fulfilling the financial tasks described in Section 7.2
- providing, upon request, the Parties with official copies or originals of documents that are in the sole possession of the Coordinator when such copies or originals are necessary for the Parties to present claims.

If one or more of the Parties is late in submission of any Project deliverable, the Coordinator may nevertheless submit the other 'Parties' Project deliverables and all other documents required by the Grant Agreement to the Granting Authority in time.

6.4.3

If the Coordinator fails in its coordination tasks, the Partner Assembly may propose to the Granting Authority to change the Coordinator.

6.4.4

The Coordinator shall not be entitled to act or to make legally binding declarations on behalf of any other Party or of the consortium, unless explicitly stated otherwise in the Grant Agreement or this Consortium Agreement.

6.4.5

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

6.5 Work Packages Management Groups

6.5.1 Members

As The Program Management Office consist of the Coordinator and leaders of Work Packages, these leaders shall coordinate and execute the Consortium Plan in relevant Work Packages.

The Work Packages Management Groups, apart from leaders appointed by Partner Assembly, shall consists of Parties' representatives to serve most efficient execution of Consortium Plan by each Work Package.

6.5.2 Tasks

The Work Package Management Groups are responsible for day-to-day delivery of Consortium Plan according to detailed scope of Work Packages.

The Work Package Management Groups report directly to Program Management Office.

7 Financial provisions

7.1 General Principles

7.1.1 Distribution of Financial Contribution

The financial contribution of the Granting Authority to the Project shall be distributed by the Coordinator according to:

- the Consortium Plan
- the approval of reports by the Granting Authority, and
- the provisions of payment in Section 7.2.

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

7.1.2 Justifying Costs

In accordance with its own usual accounting and management principles and practices, each Party shall be solely responsible for justifying its costs with respect to the Project towards the Granting Authority. Neither the Coordinator nor any of the other Parties shall be in any way liable or responsible for such justification of costs towards the Granting Authority.

7.1.3 Funding Principles

A Party that spends less than its allocated share of the budget as set out in the Consortium Plan or – in case of reimbursement via unit costs - implements less units than foreseen in the Consortium Plan will be funded in accordance with its units/actual duly justified eligible costs only.

A Party that spends more than its allocated share of the budget as set out in the Consortium Plan will be funded only in respect of duly justified eligible costs up to an amount not exceeding that share.

7.1.4 Excess payments

A Party has received excess payment

a) if the payment received from the Coordinator exceeds the amount declared or

b) if a Party has received payments but, within the last year of the Project, its real Project costs fall significantly behind the costs it would be entitled to according to the Consortium Plan.

In case a Party has received excess payment, the Party has to inform the Coordinator and return the relevant amount to the Coordinator without undue delay. In case no refund takes place within 30 days upon request for return of excess payment from the Coordinator, the Party is in substantial breach of the Consortium Agreement.

Amounts which are not refunded by a breaching Party, and which are not due to the Granting Authority, shall be apportioned by the Coordinator to the remaining Parties pro rata according to their share of total costs of the Project as identified in the Consortium Budget, until recovery from the breaching Party is possible. The Partner Assembly decides on any legal actions to be taken against the breaching Party according to Section 6.3.1.2.

7.1.5 Revenue

In case a Party earns any revenue that is deductible from the total funding as set out in the Consortium Plan, the deduction is only directed toward the Party earning such revenue. The other Parties' financial share of the budget shall not be affected by one Party's revenue. In case the relevant revenue is more than the allocated share of the Party as set out in the Consortium Plan, the Party shall reimburse the funding reduction suffered by other Parties.

7.1.6 Financial Consequences of the termination of the participation of a Party

A Party leaving the consortium shall refund to the Coordinator any payments it has received except the amount of contribution accepted by the Granting Authority or another contributor.

In addition, a Defaulting Party shall, within the limits specified in Section 5.2 of this Consortium Agreement, bear any reasonable and justifiable additional costs occurring to the other Parties in order to perform the leaving Party´s task and necessary additional efforts to fulfil them as a consequence of the Party leaving the consortium. The Partner Assembly should agree on a procedure based on consensus regarding additional costs which are not covered by the Defaulting Party.

7.2 Payments

7.2.1 Payments to Parties are the exclusive task of the Coordinator

In particular, the Coordinator shall:

- notify the Party concerned promptly of the date and composition of the amount transferred to its bank account, giving the relevant references

- perform diligently its tasks in the proper administration of any funds and in maintaining financial accounts

- undertake to keep the Granting Authority's financial contribution to the Project separated from its normal business accounts, its own assets and property, except if the Coordinator is a Public Body or is not entitled to do so due to statutory legislation.

With reference to Article 22 of the Grant Agreement, no Party shall before the end of the Project receive more than its allocated share of the maximum grant amount less the amounts retained by the Granting Authority for the final payment.

7.2.2

The transfer of the initial pre-financing and interim milestone-driven payments to Parties will be handled in accordance with Article 22.1. and Article 7 of the Grant Agreement following the milestone-based schedule outlined in Annex 2.

Payments will be made by the Coordinator to the Parties without undue delay and in conformity with the provisions of the Grant Agreement. Costs accepted by the Granting Authority will be paid to the Party concerned.

The Coordinator is entitled to withhold any payments due to a Party identified by the Partner Assembly to be in breach of its obligations under this Consortium Agreement or the Grant Agreement or to a party which has not yet signed this Consortium Agreement.

The Coordinator is entitled to recover any payments already paid to a Defaulting Party except the costs already claimed by the Defaulting Party and accepted by the Granting Authority. The Coordinator is equally entitled to withhold payments to a Party when this is suggested by or agreed with the Granting Authority.

8 Results

8.1 Ownership of Results

Results are owned by the Party that generates them. IP Rights and Access Rights relating to Results are subject to Article 16 and in Annex 5 of the Grant Agreement.

8.2 Joint ownership

Joint ownership is governed by Grant Agreement Article 16 and its Annex 5, Section Ownership of results, with the following additions:

Unless otherwise agreed:

- each of the joint owners shall be entitled to use their jointly owned Results for non-commercial research and teaching activities on a royalty-free basis, and without requiring the prior consent of the other joint owner(s).
- each of the joint owners shall be entitled to otherwise Exploit the jointly owned Results and to grant non-exclusive licenses to third parties (without any right to sub-license), if the other joint owners are given: (a) at least 45 calendar days advance notice; and (b) fair and reasonable compensation on fair and reasonable conditions.
- Joint improvements to open-source common data models (like OMOP) and open-source statistical code will remain in open source.

The joint owners shall agree on all protection measures and the division of related cost in advance. Such use may take place only after joint owners have consented to the exploitation of the Results and the proposed sharing of costs.

8.3 Transfer of Results

1. Each Party may transfer ownership of its own Results, including its share in jointly owned Results, following the procedures of the Grant Agreement Article 16.4 and its Annex 5, Section Transfer and licensing of results, sub-section “Transfer of ownership”.

2. Each Party may identify specific third parties it intends to transfer the ownership of its Results. The other Parties hereby waive their right to prior notice and their right to object to such a transfer

to listed third parties according to the Grant Agreement Article 16.4 and its Annex 5, Section Transfer of licensing of results, sub-section “Transfer of ownership”, 3rd paragraph.

3. The transferring Party shall, however, at the time of the transfer, inform the other Parties of such transfer and shall ensure that the rights of the other Parties will not be affected by such transfer. Any addition requires a decision of the Partner Assembly.

4. The Parties recognize that in the framework of a merger or an acquisition of an important part of its assets, it may be impossible under applicable EU and national laws on mergers and acquisitions for a Party to give at least 45 calendar days prior notice for the transfer as foreseen in the Grant Agreement.

5. The obligations above apply only for as long as other Parties still have - or still may request - Access Rights to the Results.

8.4 Dissemination

For the avoidance of doubt, the confidentiality obligations set out in Section 10 apply to all Dissemination activities described in this Section 8.4 as far as Confidential Information is involved.

8.4.1 Dissemination of own (including jointly owned) Results

8.4.1.1

During the Project and for a period of 1 year after the end of the Project, the Dissemination of own Results by one or several Parties including but not restricted to publications and presentations, shall be governed by the procedure of Article 17.4 of the Grant Agreement and its Annex 5, Section Dissemination, subject to the following provisions.

Prior notice of any planned publication shall be given to the other Parties at least 30 calendar days before the publication. Any objection to the planned publication shall be made in accordance with the Grant Agreement by written notice to the Coordinator and to the Party or Parties proposing the Dissemination within 15 calendar days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.

8.4.1.2

An objection is justified if

a) the protection of the objecting Party's Results or Background would be adversely affected, or

b) the objecting Party's legitimate interests in relation to its Results or Background would be significantly harmed, or

c) the proposed publication includes Confidential Information of the objecting Party.

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

8.4.1.3

If an objection has been raised the involved Parties shall discuss how to overcome the justified grounds for the objection on a timely basis (for example by amendment to the planned publication and/or by protecting information before publication) and the objecting Party shall not unreasonably continue the opposition if appropriate measures are taken following the discussion.

8.4.1.4

The objecting Party can request a publication delay of not more than 60 calendar days from the time it raises such an objection. After 60 calendar days the publication is permitted, provided that the objections of the objecting Party have been addressed.

8.4.2 Dissemination of another Party's unpublished Results or Background

A Party shall not include in any Dissemination activity another Party's Results or Background without obtaining the owning Party's prior written approval, unless they are already published.

8.4.3 Cooperation obligations

The Parties undertake to cooperate to allow the timely submission, examination, publication and defence of any dissertation or thesis for a degree that includes their Results or Background subject to the confidentiality and publication provisions agreed in this Consortium Agreement.

8.4.4 Use of names, logos, or trademarks

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.

9 Access Rights

9.1 Background included

9.1.1

In Annex 1 the Parties have identified and agreed on the Background for the Project and have also, where relevant, informed each other that Access to specific Background is subject to legal restrictions or limits.

Anything not identified in Annex 1 shall not be the object of Access Right obligations regarding Background.

9.1.2

Any Party may add additional Background to Annex 1 during the Project provided they give written notice to the other Parties. However, approval of the Partner Assembly is needed should a Party wish to modify or withdraw its Background in Annex 1.

For avoidance of doubt, under no circumstances should the withdrawal of any Background impair the implementation of the Project.

9.2 General Principles

1. Each Party shall implement its tasks in accordance with the Consortium Plan and shall bear sole responsibility for ensuring that its acts within the Project do not knowingly infringe third party property rights.

2. Any Access Rights granted exclude any rights to sublicense unless expressly stated otherwise.

3. Access Rights shall be free of any administrative transfer costs.

4. Access Rights are granted on a non-exclusive basis.

5. Results and Background shall be used only for the purposes for which Access Rights to it have been granted.

6. All requests for Access Rights shall be made in writing. The granting of Access Rights may be made conditional on the acceptance of specific conditions aimed at ensuring that these rights will be used only for the intended purpose and that appropriate confidentiality obligations are in place.

7. The requesting Party must show that the Access Rights are Needed.

8. Access Rights shall be recorded in separate agreements between the Parties, including software & services agreements (or similar) in relation to the provision of software and related services, and research services master collaboration agreements (or similar) in relation to the provision of study data and related services for performing studies.

9.3 Access Rights for implementation

Access Rights to Results and Background Needed for the performance of the own work of a Party under the Project shall be granted on a royalty-free basis, unless otherwise agreed for Background in Annex 1.

9.4 Access Rights for Exploitation

9.4.1 Access Rights to Results

Access Rights to Results if Needed for Exploitation of a Party's own Results shall be granted on Fair and Reasonable Conditions.

Access rights to Results for non-commercial research and for teaching activities shall be granted on a royalty-free basis.

9.4.2

Access Rights to Background if Needed for Exploitation of a Party's own Results, shall be granted on Fair and Reasonable Conditions.

9.4.3

A request for Access Rights may be made up to twelve months after the end of the Project or, in the case of Section 9.7.2.1.2, after the termination of the requesting Party's participation in the Project.

9.5 Intentionally Omitted

9.6 Additional Access Rights

The Parties agree to negotiate in good faith any additional Access Rights to Results as might be asked for by any Party, upon adequate financial conditions to be agreed.

9.7 Access Rights for Parties entering or leaving the consortium

9.7.1 New Parties entering the consortium

As regards Results developed before the accession of the new Party, the new Party will be granted Access Rights on the conditions applying for Access Rights to Background.

9.7.2 Parties leaving the consortium

9.7.2.1 Access Rights granted to a leaving Party

9.7.2.1.1 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 of the Partner Assembly to terminate its participation in the consortium. Additional conditions of leaving the consortium are described in Grant Agreement (see Section 32).

9.7.2.1.2 Non-defaulting Party

A non-defaulting Party leaving voluntarily and with the other Parties' consent shall have Access Rights to the Results developed until the date of the termination of its participation. Additional conditions of leaving the consortium are described in Grant Agreement (see Section 32). It may request Access Rights within the period of time specified in Section 9.4.3.

9.7.2.2 Access Rights to be granted by any leaving Party

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

9.8 Specific Provisions for Access Rights to Software

9.8.1 Definitions relating to Software

“Application Programming Interface” or “API” means the application programming interface materials and related documentation containing all data and information to allow skilled Software developers to create Software interfaces that interface or interact with other specified Software.

"Controlled License Terms" means terms in any license that require that the use, copying, modification and/or distribution of Software or another work (“Work”) and/or of any work that is a modified version of or is a derivative work of such Work (in each case, “Derivative Work”) be subject, in whole or in part, to one or more of the following:

a) (where the Work or Derivative Work is Software) that the Source Code or other formats preferred for modification be made available as of right to any third party on request, whether royalty-free or not;

b) that permission to create modified versions or derivative works of the Work or Derivative Work be granted to any third party;

c) that a royalty-free license relating to the Work or Derivative Work be granted to any third party.

For the avoidance of doubt, any Software license that merely permits (but does not require any of the things mentioned in (a) to (c) is not under Controlled License Terms.

“Object Code” means Software in machine-readable, compiled and/or executable form including, but not limited to, byte code form and in form of machine-readable libraries used for linking procedures and functions to other software.

“Software Documentation” means Software information, being technical information used, or useful in, or relating to the design, development, use or maintenance of any version of a Software program.

“Source Code” means Software in human readable form normally used to make modifications to it including, but not limited to, comments and procedural code such as job control language and scripts to control compilation and installation.

9.8.2 General principles

For the avoidance of doubt, the general provisions for Access Rights provided for in this Section 9 are applicable also to Software as far as not modified by this Section 9.8.

Parties' Access Rights to Software do not include any right to receive Source Code or Object Code ported to a certain hardware platform or any right to receive Source Code, Object Code or respective Software Documentation in any particular form or detail, but only as available from the Party granting the Access Rights.

The introduction of Software under Controlled License Terms in the Project requires the prior approval of the Partner Assembly to implement such introduction into the Consortium Plan. Such approval is deemed granted for Software and shall be introduced in the Consortium Plan.

In case of an approved introduction of Software under Controlled License Terms in the Project, the Controlled License Terms shall prevail over any conflicting provisions of this Consortium Agreement for affected original and derivative Background and Results.

9.8.3 Access to Software

Access Rights to Software that is Results shall comprise:

- Access Rights to the Object Code; and,
- where normal use of such an Object Code requires an API, Access Rights to the Object Code and such an API; and,
- if a Party can show that the execution of its tasks under the Project or the Exploitation of its own Results is technically or legally impossible without Access Rights to the Source Code, Access Rights to the Source Code to the extent necessary provided such grant does not adversely affect a legitimate interest of the granting Party. Access Rights to Source Code shall only be granted upon mutual agreement stipulating the terms and conditions between the Parties concerned.

Background shall only be provided in Object Code unless otherwise agreed between the Parties concerned.

9.8.4 Software license and sublicensing rights

9.8.4.1 Object Code

9.8.4.1.1 Results - Rights of a Party

Where a Party has Access Rights to Object Code and/or API that is Results for Exploitation, such Access shall, in addition to the Access for Exploitation foreseen in Section 9.4, as far as Needed for the Exploitation of the Party's own Results, comprise the right:

- to make an agreed number of copies of Object Code and API; and
- to distribute, make available, market, sell and offer for sale such Object Code and API as part of or in connection with products or services of the Party having the Access Rights,

provided however that any product, process or service has been developed by the Party having the Access Rights in accordance with its rights to exploit Object Code and API for its own Results.

If it is intended to use the services of a third party for the purposes of this Section 9.8.4.1.1, the Parties concerned shall agree on the terms thereof with due observance of the interests of the Party granting the Access Rights as set out in Section 9.2 of this Consortium Agreement.

9.8.4.1.2 Results - Rights to grant sublicenses to end-users

In addition, Access Rights to Object Code shall, as far as Needed for the Exploitation of the Party's own Results, comprise the right to grant in the normal course of the relevant trade to end-user customers buying/using the product/services, a sublicense to the extent as necessary for the normal use of the relevant product or service to use the Object Code as part of or in connection with or integrated into products and services of the Party having the Access Rights and, as far as technically essential:

- to maintain such product/service;
- to create for its own end-use interacting interoperable Software in accordance with the Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs.

9.8.4.1.3 Background

For the avoidance of doubt, where a Party has Access Rights to Object Code and/or API that is Background for Exploitation, Access Rights exclude the right to sublicense. Such sublicensing rights may, however, be negotiated between the Parties.

9.8.5 Specific formalities

Each sublicense granted according to the provisions of Section 9.8.4 shall be made by a traceable agreement specifying and protecting the proprietary rights of the Party or Parties concerned.

9.9 Specific Provisions for Access Rights to Patient Data

9.9.1 In line with DIGICORE's legal statutes, patient data held initially in electronic medical records system at hospitals and/or research organization is owned and controlled by the hospitals and/or research organizations. The converted data in OMOP standard is also controlled and owned by hospitals.

9.9.2 The primary purpose of standardized data is firstly for care quality improvement, and secondly (where appropriate approval is granted) for research.

Prior approval shall be sought for each specific purpose of patient data processing if this purpose is materially different from prior approved purposes. Materially different includes different patient cohorts, different data elements on the same cohort and different questions to those data elements.

9.9.3 No subject-level patient data shall be transferred, only anonymous aggregated/statistical data shall be transferred according to the principle of federated learning unless otherwise agreed beforehand.

9.9.4 Any Result from patient data shall be considered a joint Result with joint ownership and/or revenue sharing unless otherwise agreed beforehand.

10 Non-disclosure of information

10.1

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

10.2

The Recipient hereby undertakes in addition and without prejudice to any commitment on non-disclosure under the Grant Agreement, for the duration of the Project and a period of 5 years after the final payment of the Granting Authority:

- not to use Confidential Information otherwise than for the purpose for which it was disclosed;
- not to disclose Confidential Information without the prior written consent by the Disclosing Party;
- to ensure that internal distribution of Confidential Information by a Recipient shall take place on a strict need-to-know basis; and
- to return to the Disclosing Party, or destroy, on request all Confidential Information that has been disclosed to the Recipients including all copies thereof and to delete all information stored in a machine-readable form to the extent practically possible. The Recipient may keep a copy to the extent it is required to keep, archive or store such Confidential Information because of compliance with applicable laws and regulations or for the proof of on-going obligations or to keep copies of electronically exchanged Confidential Information made as a matter of routine information technology back-up provided the Recipient complies with the confidentiality obligations herein contained with respect to such copy.

10.3

The Recipient shall be responsible for the fulfilment of the above obligations on the part of its employees, or third parties involved in the Project and shall ensure that they remain so obliged, as far

as legally possible, during and after the end of the Project and/or after the termination of the contractual relationship with the employee or third party.

10.4

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

- the Confidential Information has become or becomes publicly available by means other than a breach of the Recipient's confidentiality obligations;
- the Disclosing Party subsequently informs the recipient that the Confidential Information is no longer confidential;
- the Confidential Information is communicated to the recipient and / or any of its affiliates in the same company group without any obligation of confidentiality by a third party who is to the best knowledge of the Recipient in lawful possession thereof and under no obligation of confidentiality to the Disclosing Party;
- the disclosure or communication of the Confidential Information is foreseen by provisions of the Grant Agreement;
- the Confidential Information, at any time, was developed by the Recipient and / or any of its affiliates in the same company group completely independently of any such disclosure by the Disclosing Party;
- the Confidential Information was already known to the Recipient and / or any of its affiliates in the same company group prior to disclosure, or
- the Recipient is required to disclose the Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, subject to the provision Section 10.7 hereunder. This obligation does not alter the status of the information as a Confidential Information, and it is still to be treated as confidential unless otherwise regulated under the respective applicable law.

10.5

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

10.6

Each Recipient shall promptly inform the relevant Disclosing Party by written notice of any unauthorized disclosure, misappropriation or misuse of Confidential Information after it becomes aware of such unauthorized disclosure, misappropriation or misuse.

10.7

If any Recipient becomes aware that it will be required, or is likely to be required, to disclose Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, it shall, to the extent it is lawfully able to do so, prior to any such disclosure

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

11 Miscellaneous

11.1 Annexes, inconsistencies, and severability

This Consortium Agreement consists of this core text and:

- Annex 1 (Background information/Intellectual Property included)
- Annex 2 (List of milestones and payment triggers by Work Packages and Parties)
- Annex 3 (Accession document)

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

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

11.2 No representation, partnership or agency

Except as otherwise provided in Section 6.4.4, no Party shall be entitled to act or to make legally binding declarations on behalf of any other Party or of the consortium. Nothing in this Consortium Agreement shall be deemed to constitute a joint venture, agency, partnership, interest grouping or any other kind of formal business grouping or entity between the Parties.

11.3 Formal and written notices

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

Any change of persons or contact details shall be immediately communicated to the Coordinator by written notice. The address list shall be accessible to all Parties.

Formal notices:

If it is required in this Consortium Agreement (Sections 4.2, 9.7.2.1.1, and 11.4) that a formal notice, consent or approval shall be given, such notice shall be signed by an authorized representative of a Party and shall either be served personally or sent by mail with recorded delivery with acknowledgement of receipt.

Written notice:

Where written notice is required by this Consortium Agreement, this is fulfilled also by other means of communication such as e-mail with acknowledgement of receipt.

11.4 Assignment and amendments

Except as set out in Section 8.3, no rights or obligations of the Parties arising from this Consortium Agreement may be assigned or transferred, in whole or in part, to any third party without the other Parties' prior formal approval.

Amendments and modifications to the text of this Consortium Agreement not explicitly listed in Section 6.3.1.2 require a separate written agreement to be signed between all Parties.

11.5 Mandatory national law

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

In case a Party is obliged under its national law to publish the text of this Consortium Agreement in an official register or official journal, the Party may be allowed to do so provided all personal data and Confidential Information is omitted.

11.6 Language

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

11.7 Applicable law

This Consortium Agreement shall be construed in accordance with and governed by the laws of Belgium excluding its conflict of law provisions.

11.8 Settlement of disputes

The Parties shall endeavour to settle their disputes amicably. All disputes arising out of or in connection with this Consortium Agreement, which cannot be solved amicably, shall be finally settled by the courts of Brussels.

Annex 1 – Background information included

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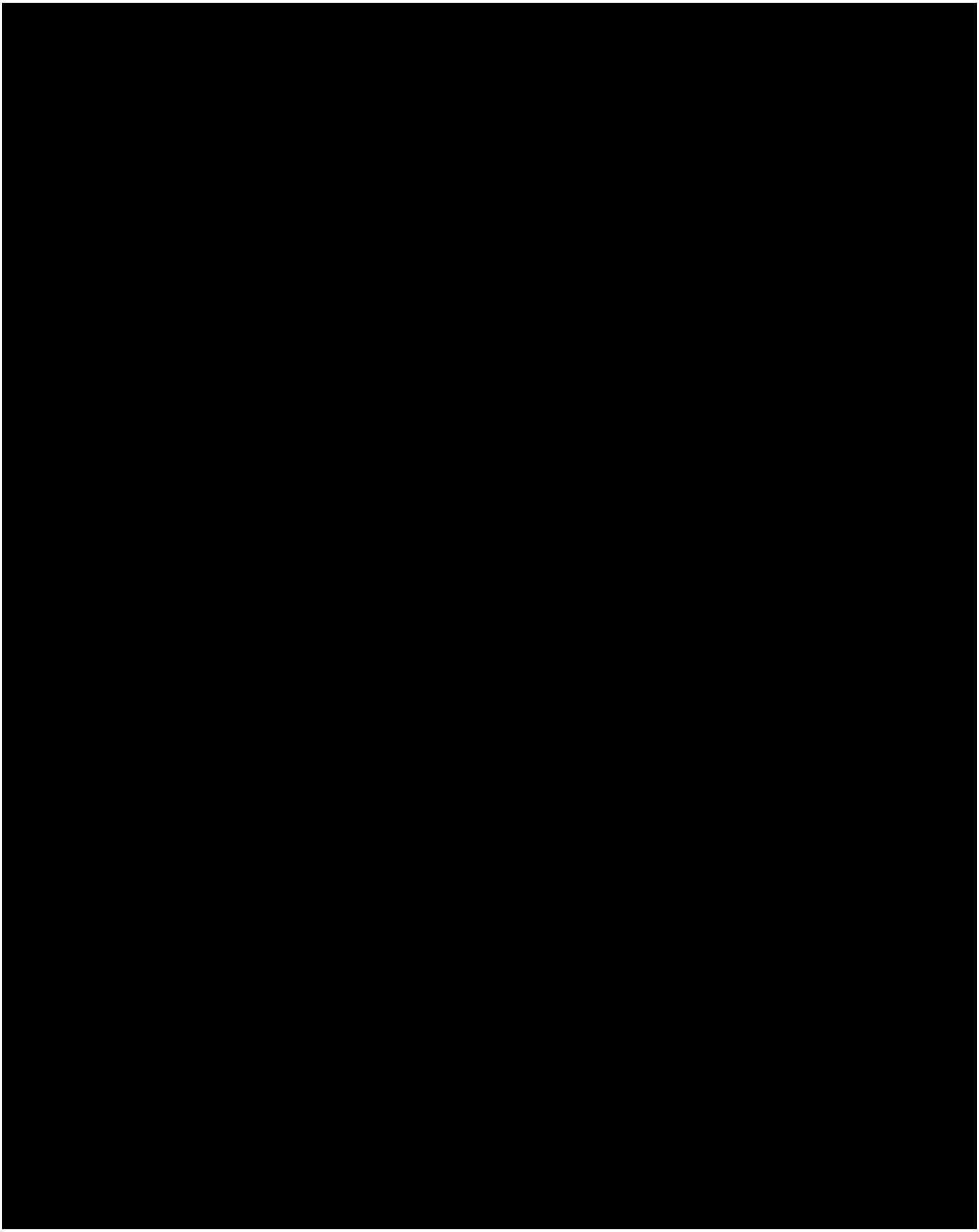
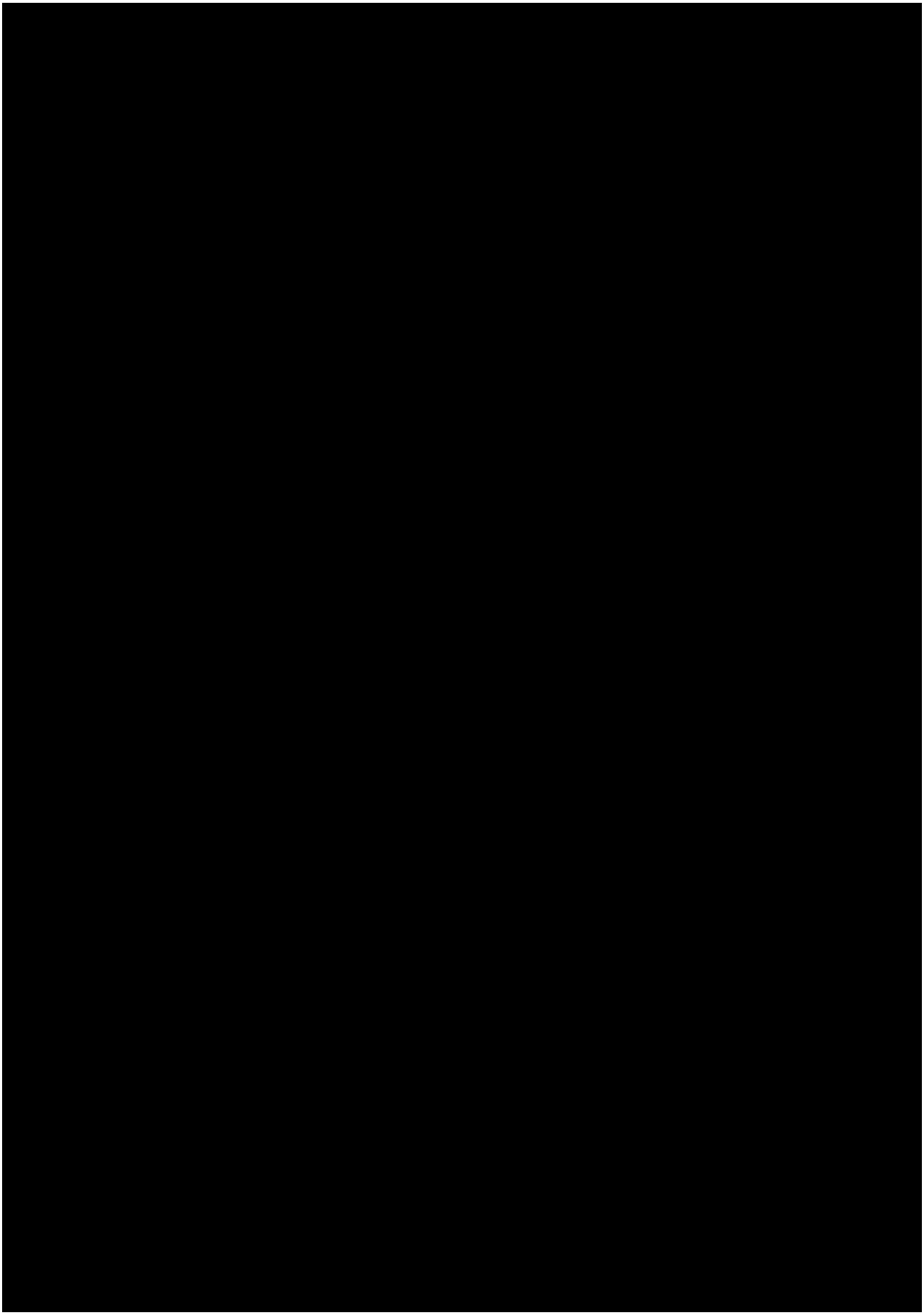
EDENCEHEALTH (EH), PIC 895597994

IQVIA CANCER RESEARCH (IQCR), PIC 881920218

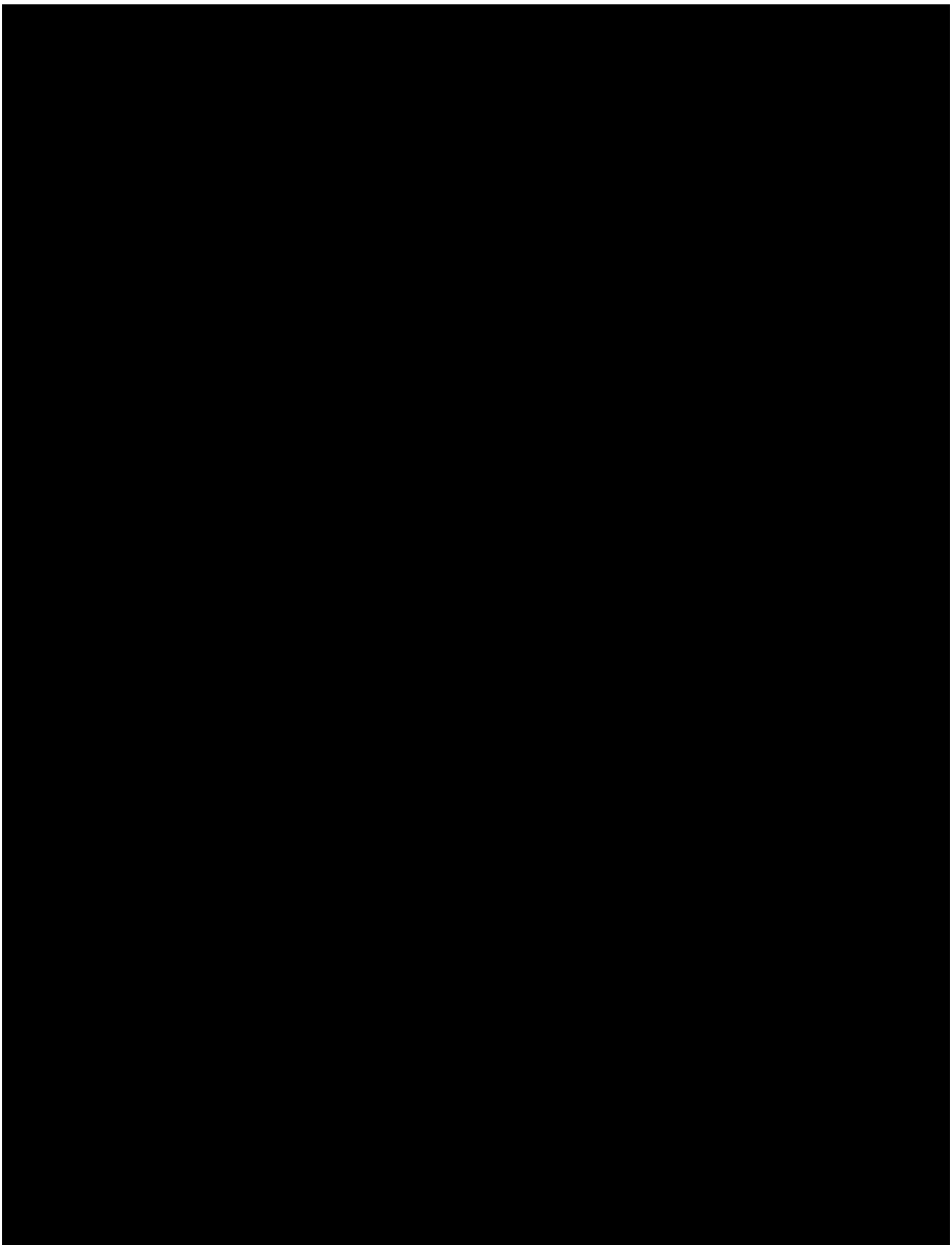
CLININOTE SPOLKA Z OGRANICZONAODPOWIEDZIALNOSCIA (CN), PIC 89911272

KAIROS GMBH (KRS), PIC 952699469 and **IQVIA SOLUTIONS B.V. (IQS)**, PIC 893425970

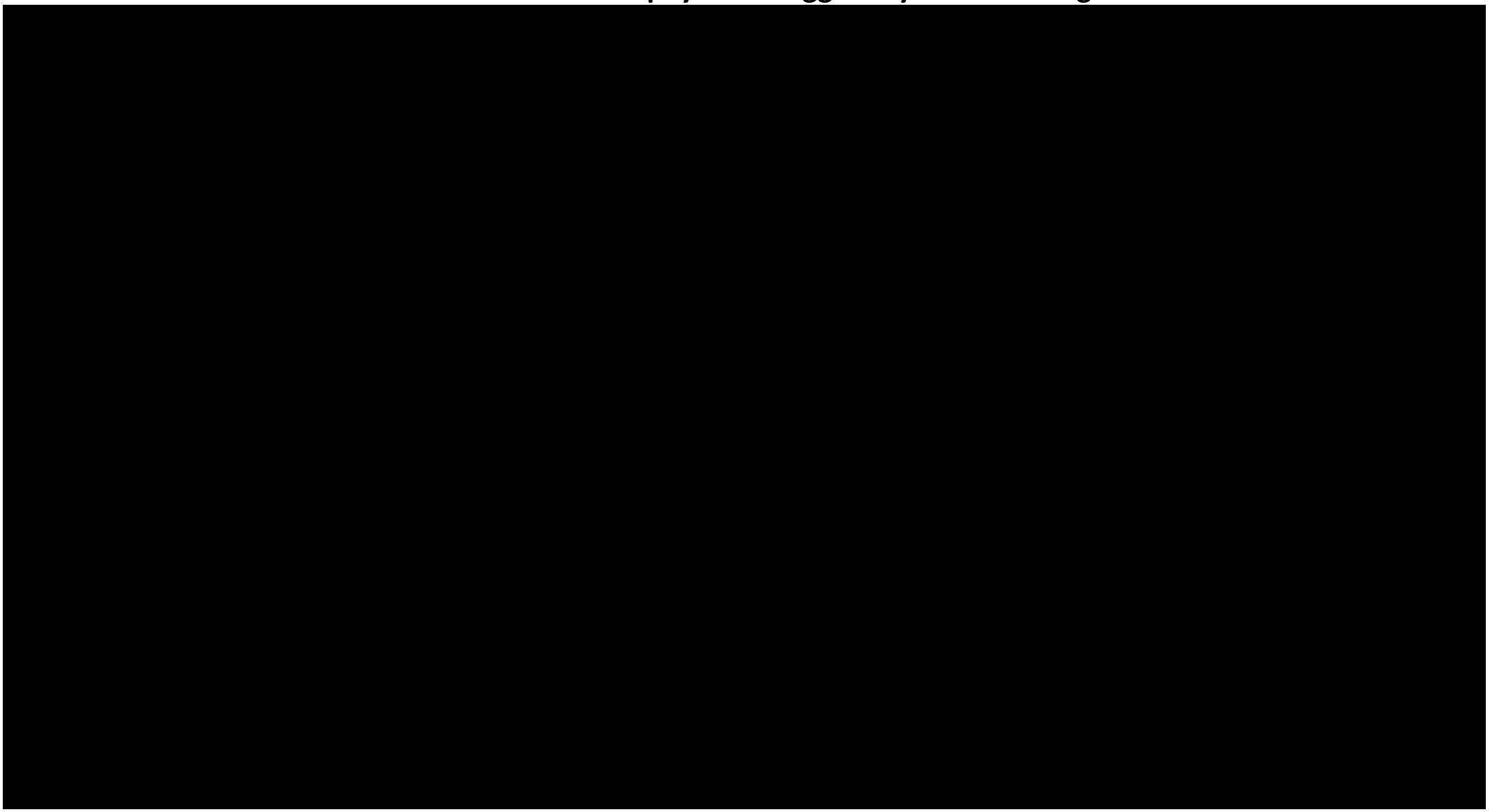




COMPUGROUP MEDICAL POLSKA SPOLKA OGRANICZONA ODPOWIEDZIALNOSCIA (CGM), PIC 881841551



Annex 2 – List of milestones and payment triggers by Work Packages and Parties



Annex 3: Accession document

ACCESSION **of a new Party to**
[Acronym of the Project] Consortium Agreement, version […, YYYY-MM-DD]
[OFFICIAL NAME OF THE NEW PARTY AS IDENTIFIED IN THE Grant Agreement]
hereby consents to become a Party to the Consortium Agreement identified above and accepts all the rights and obligations of a Party starting [date].
[OFFICIAL NAME OF THE COORDINATOR AS IDENTIFIED IN THE Grant Agreement]
hereby certifies that the consortium has accepted in the meeting held on [date] the accession of [the name of the new Party] to the consortium starting [date].
This Accession document has been done in 2 originals to be duly signed by the undersigned authorized representatives.

[Date and Place]
[INSERT NAME OF THE NEW PARTY]
Signature(s)
Name(s)
Title(s)

[Date and Place]
[INSERT NAME OF THE COORDINATOR]
Signature(s)
Name(s)
Title(s)

12 Beneficiary Signatures

AS WITNESS:

The Parties have caused this Consortium Agreement to be duly signed by the undersigned authorised representatives in separate signature pages the day and year first above written.

Beneficiary	Signature Page
DIGITAL INSTITUTE FOR CANCER OUTCOMES RESEARCH (DGCR)	54
GRAND HOPITAL DE CHARLEROI (GHdC)	55
MASARYKUV ONKOLOGICKY USTAV (MMCI)	56
SIHTASUTUS TARTU ULIKOOLI KLIINIKUM (TUH)	57
CHARITE - UNIVERSITAETSMEDIZIN BERLIN (Charite)	58
UNIVERSITATSMEDIZIN GREIFSWALD KORPERSCHAFT DES OFFENTLICHEN RECHTS (UMG)	59
TECHNISCHE UNIVERSITAET DRESDEN (TUD)	60
THE PROVOST, FELLOWS, FOUNDATION SCHOLARS & THE OTHER MEMBERS OF BOARD, OF THE COLLEGE OF THE HOLY & UNDIVIDED TRINITY OF QUEEN ELIZABETH NEAR DUBLIN (TCD)	61
ISTITUTI FISIOTERAPICI OSPITALIERI (IFO)	62
OSPEDALE SAN RAFFAELE SRL (OSR)	63
VIESOJI ISTAIGA VILNIAUS UNIVERSITETO LIGONINE SANTAROS KLINIKOS (VULSK)	64
UNIVERSITEIT MAASTRICHT (MUMC)	65
STICHTING MAASTRICHT RADIATION ONCOLOGY MAASTRO CLINIC (MC)	66
ACADEMISCH ZIEKENHUIS GRONINGEN (UMCG)	67
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DIGITAL INSTITUTE FOR CANCER OUTCOMES RESEARCH (DGCR), PIC 890481923, established in RUE D'EGMONT 11, BRUSSELS 1000, Belgium,

Signature:

Name: Giovanni Tonon

Title: President, Digicore

Date: 15. 4. 2024

GRAND HOPITAL DE CHARLEROI (GHdC), PIC 959948473, established in RUE MARGUERITE DEPASSE 6, CHARLEROI 6060, Belgium,

Signature:

Name: Gauthier Saelens

Title: Directeur Général

Date: 2. 4. 2024

MASARYKUV ONKOLOGICKY USTAV (MMCI), PIC 986107627, established in ZLUTY KOPEC 7, BRNO 656 53, Czechia,

Signature:

Name: prof. MUDr. Marek Svoboda, Ph.D.

Title: Director General

Date: 25. 4. 2024

SIHTASUTUS TARTU ULIKOOLI KLIINIKUM (TUH), PIC 999518556, established in PUUSEPA 1A, TARTU 50406, Estonia,

Signature:

Name: Joel Starkopf

Title: Member of Executive Board

Date: 27. 3. 2024

CHARITE - UNIVERSITAETSMEDIZIN BERLIN (Charite), PIC 999992692, established in Chariteplatz 1, BERLIN 10117, Germany,

Signature:

Name: XXXXXXX

Title: Faculty Bussiness Director

Date: 21. 4. 2024

UNIVERSITATSMEDIZIN GREIFSWALD KORPERSCHAFT DES OFFENTLICHEN RECHTS (UMG), PIC 947193555, established in FLEISCHMANNSTRASSE 8, GREIFSWALD 17475, Germany,

Signature:

Name: XXXXXXX

Title: Head of Administration of Third Party Funding Administration within Unit of Financing and controlling

Date: 25. 3. 2024

TECHNISCHE UNIVERSITAET DRESDEN (TUD), PIC 999897729, established in HELMHOLTZSTRASSE 10, DRESDEN 01069, Germany,

Signature:

Name: Jan Gerken

Title: Chancellor

Date: 8. 5. 2024

THE PROVOST, FELLOWS, FOUNDATION SCHOLARS & THE OTHER MEMBERS OF BOARD, OF THE COLLEGE OF THE HOLY & UNDIVIDED TRINITY OF QUEEN ELIZABETH NEAR DUBLIN (TCD), PIC 999845446, established in COLLEGE GREENTRINITY COLLEGE, DUBLIN 2 D02 CX56, Ireland,

Signature:

Name: XXXXXXX

Title: Vice-Provost/Chief Academic Officer and Deputy President

Date: 17.4.2024

ISTITUTI FISIOTERAPICI OSPITALIERI (IFO), PIC 985625925, established in VIA CHIANESI 53, ROMA 00144, Italy,

Signature:

Name: Dott.ssa Laura Figorilli

Title: Representante Legale

Date: 27. 3. 2024

OSPEDALE SAN RAFFAELE SRL (OSR), PIC 953176030, established in VIA OLGETTINA 60, MILANO 20132, Italy,

Signature:

Name: XXXXXXX

Title: Direttore Ricerca

Date: 28. 3. 2024

VIESOJI ISTAIGA VILNIAUS UNIVERSITETO LIGONINE SANTAROS KLINIKOS (VULSK), PIC 991636530, established in SANTARISKIU G 2, VILNIUS LT-08661, Lithuania,

Signature:

Name: Feliksas Jankevičus

Title: Director general

Date: 28. 3. 2024

UNIVERSITEIT MAASTRICHT (MUMC), PIC 999975911, established in MINDERBROEDERSBERG 4, 6, 6211 LK | PO Box 616, 6200 MD, MAASTRICHT , Netherlands,

Signature:

Name: XXXXXX

Title: Scientific Director GROW - Research Institute for Oncology and Reproduction

Date: 10. 4. 2024

STICHTING MAASTRICHT RADIATION ONCOLOGY MAASTRO CLINIC (MC), PIC 98618784, established in Dr. Tanslaan 12, MAASTRICHT 6229 ET, Netherlands,

Signature:

Name: Maria Jacobs

Title: CEO

Date: 27. 3. 2024

ACADEMISCH ZIEKENHUIS GRONINGEN (UMCG), PIC 999914801, established in HANZEPLEIN 1, GRONINGEN 9713 GZ, Netherlands,

Signature:

Name: Prof. Dr. W.J.Niessen

Title: Member Board of Directors

Date: 29. 3. 2024

NARODOWY INSTYTUT ONKOLOGII IM. MARII SKLODOWSKIEJ-CURIE - PANSTWOWY INSTYTUT BADAWCZY (MSCI), PIC 999533203, established in UL. W K ROENTGENA 5, WARSZAWA 02-781, Poland,

Signature:

Name: XXXXXXXXX

Title:

Date: 1. 7. 2024

EUROSCAN INTERNATIONAL NETWORK EV (ESIN), PIC 906262271, established in SCHAEVENSTR 1 RHEINISCHE FACHHOCHSCHULE KOLN GGMBH, KOLN 50676, Germany,

Signature:

Name: Hans-Peter Dauben

Title: Secretary General

Date: 28. 3. 2024

EDENCEHEALTH (EH), PIC 895597994, established in VELDKANT 33A, KONTICH 2550, Belgium,

Signature:

Name: Lars Halvorsen

Title: Managing Partner

Date: 26. 3. 2024

IQVIA CANCER RESEARCH (IQCR), PIC 881920218, established in DA VINCILAAN 7, ZAVENTEM 1930, Belgium,

Signature:

Name: José M. Fernandez

Title: Principal

Date: 2. 4. 2024

ONCODNA (ODNA), PIC 881844170, established in RUE LOUIS BREGUET 1, CHARLEROI 041, Belgium,

Signature:

Name: J-Detiffe

Title: CSIO

Date: 30. 4. 2024

KAIROS GMBH (KRS), PIC 952699469, established in GESUNDHEITSCAMPUS SUD 17, BOCHUM 44801, Germany,

Signature:

Name: Christian Stephan

Title: Managing Director

Date: 25. 4. 2024

IQVIA SOLUTIONS B.V. (IQS), PIC 893425970, established in HERIKERBERGWEG 314, AMSTERDAM 1101CT, Netherlands,

Signature:

Name: Martijn Nap

Title: General Manager

Date: 26. 3. 2024

MAASTRO INNOVATIONS BV (MI), PIC 986092301, established in DR TANSLAAN 12, MAASTRICHT 6229 ET, Netherlands,

Signature:

Name: Maria Jacobs

Title: CEO

Date: 27. 3. 2024

MEDICAL DATA WORKS BV (MDW), PIC 904574762, established in DR TANSLAAN 12, MAASTRICHT 6229 ET, Netherlands,

Signature:

Name: Johan van Soest

Title: CEO

Date: 27. 3. 2024

CLININOTE SPOLKA Z OGRANICZONAODPOWIEDZIALNOSCIA (CN), PIC 89911272, established in UL. MELGIEWSKA NR 7-9 LOK. 122, LUBLIN 20-952, Poland,

Signature:

Name: Rafal Szmuc

Title: COO

Date: 29. 3. 2024

COMPUGROUP MEDICAL POLSKA SPOLKA OGRANICZONA ODPOWIEDZIALNOSCIA (CGM), PIC 881841551, established in UL. DO DYSA 9, LUBLIN 20-149, Poland,

Signature:

Name: Waldemar Grudzien

Title:

Date: 17. 4. 2024