# **OriON**

# Joint Action on Contribution to the Cancer Inequalities Registry to Monitor National Cancer Control Policies

# **Consortium Agreement**

631-40/2023-2 (271)

Version 1 – October 2023

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# **Change Records**

Version	Date	Changes
Version 0	September 2023	First version of the Consortium Agreement
Version 1	October 2023	Second draft of the Consortium Agreement

## Remarks

This Consortium Agreement is created for OriON and will be a complement to the Grant Agreement of the Action entitled Joint Action on Contribution to the Cancer Inequalities Registry to Monitor National Cancer Control Policies.

The Parties are aware that this Consortium Agreement is based upon the DESCA model Consortium Agreement, which was modified to reflect the provisions set out in the Grant Agreement.

# **Consortium Agreement**

This Consortium Agreement is based upon Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014, and on the European Commission's General Model Grant Agreement and its Annexes, and is made on 01-01-2024, hereinafter referred to as the Effective Date.

## **BETWEEN**

1. NACIONALNI INSTITUT ZA JAVNO ZDRAVJE (NIJZ), the Coordinator

Trubarjeva cesta 2
1000 Ljubljana, Slovenia
PIC 948891346

represented for the purposes of signing the Agreement by General Director Branko Gabrovec

SCIENSANO (Sciensano)
 Juliette Wytsmanstraat 14
 Elsene 1050, Belgium
 PIC 90616080

3. HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO (CIPH)

Rockefellerova 7 Zagreb 10000, Croatia PIC 998128255

4. MINISTRY OF HEALTH OF THE REPUBLIC OF CYPRUS (MoH CY)

1 Prodromou Street & 17 Chilonos Street Nicosia 1448, Cyprus PIC 994267946

5. MINISTRY OF HEALTH OF THE REPUBLIC OF GREECE (MoH GR)

Aristotelous Street 17 Athina 10187, Greece PIC 950261665

6. ORSZAGOS ONKOLOGIAI INTEZET (OOI)

Rath Gyorgy Utca 7-9 Budapest 1122, Hungary PIC 991549909

7. NATIONAL CANCER REGISTRY BOARD (NCRI)

Kinsale Road, Building 6800, Cork Airport Business Park T12CDF7 Cork, Ireland PIC 998392095

8. ISTITUTO SUPERIORE DI SANITÀ (ISS)

Viale Regina Elena 299

Roma 00161, Italy PIC 999978821

# 9. NACIONALINIS VEZIO INSTITUTAS - NATIONAL CANCER INSTITUTE (NCI)

Santariskiu Str. 1 Vilnius 08660, Lithuania PIC 912763114

## 10. MINISTRY FOR HEALTH - GOVERNMENT OF MALTA (MFH)

Palazzo Castellania, Merchants Street 15 Valletta VLT 200, Malta PIC 974144423

## 11. STICHTING INTEGRAAL KANKERCENTRUM NEDERLAND (IKNL)

Godebaldkwartier 419 3511 DT Utrecht, Netherland PIC 937584444

## 12. OSLO UNIVERSITETSSYKEHUS HF (OUS)

Kirkeveien 166 Tårnbygget Oslo 0450, Norway PIC 991104000

## 13. THE MINISTRY OF HEALTH OF THE REPUBLIC OF POLAND (MZ)

Miodowa 15 00-952 Warsaw, Poland PIC 973658453

## 14. INSTITUTUL NATIONAL DE SANATATE PUBLICA (INSP)

Str. Dr Leonte 1-3 Sector 5 050463, București, Romania PIC 985926237

# 15. NÁRODNE CENTRUM ZDRAVOTNICKYCH INFORMACII (NCZI)

Lazaretska 26 811 09 Bratislava, Slovakia PIC 998884370

# 16. FUNDACIÓN PARA EL FOMENTO DE LA INVESTIGACIÓN SANITARIA Y BIOMÉDICA DE LA COMUNITAT VALENCIANA (FISABIO)

Calle Micer Masco 31 46010 Valencia, Spain PIC 951714046

## 17. SOCIALSTYRELSEN (NBHW)

Ralambsvagen 3 Stockholm 106 30, Sweden PIC 998248147 hereinafter, jointly or individually, referred to as "Party" or "Parties"

relating to the Action entitled

Joint Action on Contribution to the Cancer Inequalities Registry to Monitor National Cancer Control Policies

in short

## OriON

Hereinafter referred to as "Project" or "Joint Action" or "JA"

#### WHEREAS:

The Parties, having considerable experience in the field concerned, have submitted a proposal for the Project to the Granting Authority as part of the EU4Health programme 2021-2027.

Their Project proposal was selected for funding and the Parties entered into the Grant Agreement preparation phase with the Granting Authority.

At the end of the Grant Agreement preparation phase, the Coordinator was requested to sign the ensuing Grant Agreement on behalf of the other Parties, which afterwards acceded to this Grant Agreement by signing an accession form.

Therefore, for the proper implementation of the Project, the Parties wish to specify or supplement binding commitments among themselves in addition to the provisions of the Grant Agreement number 101127673, to be signed by the Parties and the Granting Authority (hereinafter "Grant Agreement" and "GA").

The Parties acknowledge that they are responsible for the compliance of their Affiliated Entities with the relevant EU provisions (Grant Agreement and its annexes) and this Consortium 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 Rules or in the Grant Agreement including its Annexes.

## 1.2 Additional Definitions

## "Access Rights"

Access rights means rights to use Results or Background under the terms and conditions laid down in accordance with this Consortium agreement.

#### "Data"

Data means any and all data which is part of a Party's Background included in the Joint Action or which is generated under the Joint Action as "results", including, as the case may be, personal data as defined and protected under the European or national applicable legislation(s).

#### "Data Protection Laws"

Data Protection Laws means all applicable legislation concerning the protection of personal data, including 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 repealing Directive 95/46/EC (hereinafter referred to as General Data Protection Regulation or "GDPR"), any other data protection legislation applicable to the Joint Action, as well as the binding orders of data protection authorities.

## "Defaulting Party"

Defaulting Party means a Party which the majority of the Steering Committee has identified to be in breach of this Consortium Agreement and/or the Grant Agreement as specified in Section 4.4 of this Consortium Agreement.

#### "Dissemination"

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

## "Exploitation"

Exploitation means the use of Results in further research activities other than those covered by the Joint Action concerned, including among other things, commercial exploitation such as developing, creating and marketing a product or process, or in creating and providing a service, or standardisation activities.

## "Fair and reasonable conditions"

Fair and reasonable conditions mean appropriate conditions, including possible financial terms or royalty-free conditions, considering 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.

## "Force Majeure"

Force Majeure means any situation or event that (a) prevents a Party from fulfilling its obligations under this Consortium Agreement, (b) was an unforeseeable, exceptional situation and beyond that Party's control, (c) was not due to error or negligence on the part of the Party (or on the part of Third Parties involved in the Action), and (d) proves to be inevitable in spite of exercising all due diligence. Notwithstanding the foregoing, Article 35 of the Grant Agreement and its annotations shall apply in any interpretation of whether specific circumstances shall constitute an event of Force Majeure. The following cannot be invoked as Force Majeure: (aa) any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of Force Majeure, (bb) labour disputes or strikes, or (cc) financial difficulties.

## "Granting Authority"

Granting Authority means the body awarding the grant for the Joint Action.

#### "Needed"

Means

For the implementation of the Joint Action:

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.

## "Project Plan"

Project 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 Steering Committee.

#### "Results"

Results means any tangible or intangible output of the Joint Action, such as data, knowledge or information, that is generated in the Joint Action, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights.

#### "Software"

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.

#### "Third Parties"

Third Parties can be defined as any entity/person who is not in an OriON Consortium Body i.e. that is not a Party, Affiliated Entity or Associated Partner, and is not bound by rules of confidentiality under OriON. These rules are e.g., stipulated in the Grant Agreement, Consortium Agreement, collaboration agreements and confidentiality agreements. Subcontractors are included in this definition.

# **Section 2: Purpose**

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

# Section 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 authorised representative.

This Consortium Agreement shall have effect from the Effective Date identified at the beginning of this Consortium Agreement. An entity becomes a new Party to the Consortium Agreement upon signature of the accession document (Attachment 2) by the new Party and the Coordinator. Such accession shall have effect from the date identified in the accession document.

## 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. This includes amendments regarding any no-cost extension of OriON approved by the Granting Authority as well.

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 not signed by the Granting Authority or a Party, or
- is terminated,
- or if 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.

## 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 Consortium incurred prior to the date of termination, unless otherwise agreed between the Steering Committee and the leaving Party. This includes the obligation to provide all input, deliverables and documents for the period of its participation.

# **Section 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 Granting Authority and the other Parties, in accordance with the governance structure of the Project, of any significant information, fact, problem or delay likely to affect the Project.

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.

## 4.2 Specific Responsibilities

In addition to the foregoing provisions set out in Article 4.1, the Parties shall:

- Keep information stored in the Participant Portal (in the electronic exchange system) up to date (see Article 19.2 of the Grant Agreement);
- Inform the Coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the Joint Action (see Article 19.3 of the Grant Agreement);
- Discuss any proposed activities which are not part of the Grant Agreement, i.e. need an amendment, first with the WP lead, who can propose the changes to the Coordinator.
- Submit to the Coordinator in good time:
  - o Individual financial statements for itself and its Affiliated entities (if applicable) and, if required, certificates on the financial statements (see Article 24 of the Grant Agreement);
  - The data needed to draw up all requested reports under Article 24 of the Grant Agreement;
  - If applicable, ethics committee opinions and notifications or authorisations for activities raising ethical issues;
  - o Financial progress reports to the Coordinator in accordance with Section 7;
  - Any other document(s) or information required by the Granting Authority or the Commission under the Grant Agreement, unless the Grant Agreement requires the Party to submit this information directly to the Granting Authority or the Commission.

In addition, work package (WP) leaders shall:

- Submit technical reports to the Coordinator in accordance with Section 7;
- Monitor the effective and efficient implementation of the WP;
- Discuss any proposed activities which are not part of the Grant Agreement, i.e. need an amendment, with the Coordinator.

# 4.2 Involvement of third parties

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

## 4.3 Breach

In the event that the Steering Committee identifies a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement (e.g. improper implementation of the Joint Action), the Coordinator or, if

the Coordinator is in breach of its obligations, the Party appointed by the Steering Committee, 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 substantial and is not remedied within that period or is not capable of remedy, the Steering Committee may decide to declare the Party to be Defaulting and to decide on the consequences thereof which may include termination of its participation.

In accordance with the Grant Agreement, breaches by Affiliated Entities will be dealt with in the same way as breaches by the Parties.

If a Party is Defaulting, the General Assembly will find suitable arrangements for the concerned Affiliated Entities.

## 4.4 Compliance

Each Party shall ensure that its work on the Joint Action complies fully with all applicable local, government and international laws, regulations and guidelines which are effective during the period of the Grant Agreement, including those governing health and safety and data protection.

## 4.5 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 ("GDPR")* 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.

The Parties' specific responsibilities regarding data protection include that:

- They shall comply with all requirements of applicable privacy legislation with regard to the processing of personal data in relation to this Consortium Agreement, including the obligation to carry out risk assessments and to enter into data processing agreements with its data processor and joint controller agreements with joint controllers. In the event of any conflict, related to data protection issues, between such data processing, data sharing and/or joint controller agreement and this Consortium Agreement, the agreement regulating data protection shall prevail.
- In accordance with Article 32 GDPR, they shall take satisfactory technical, physical, and organisational safeguards to protect personal data comprised by this Agreement from unauthorised use, or access, alteration, deletion, damage, loss or inaccessibility.
- If they discover errors or signs of errors in connection with the processing of personal data under this Consortium Agreement, the Party that discovers the error shall immediately inform the other Party, and take reasonable remedial action to remedy the error(s).
- They have a sufficient legal basis for its respective processing of personal data, in accordance with Articles 6 and 9 GDPR.
- They will comply with the principle of data minimisation and only process personal data when it is adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed.

# **Section 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 Joint Action, no warranty or representation of any kind is made, given or implied as to the sufficiency or fitness for purpose nor as to the absence of any infringement of any proprietary rights of third parties.

#### Therefore,

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

For any remaining contractual liability, a Party's aggregate liability towards the other Parties collectively shall be limited to once the Party's share of the total costs of the Joint Action as identified in Annex 2 of the Grant Agreement provided such damage was not caused by a wilful act or gross negligence.

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

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

## 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 considered to be in breach of this Consortium Agreement if it is prevented from fulfilling its obligations under the Consortium Agreement by Force Majeure (as defined under 1.2 in this Consortium Agreement and in Article 35 of the Grant Agreement).

Each Party will notify the competent Consortium Bodies of any Force Majeure without undue delay. If the consequences of Force Majeure for the Joint Action are not overcome within 6 weeks after such notification, the transfer of tasks - if any - shall be decided by the Steering Committee.

#### 5.5 Conflict of interest

Each Party undertakes to timely and appropriately manage any identified conflict of interest with a view to mitigate, reduce or remove it. Management action might include: (i) disclosing actual or apparent conflicts of

interest, (ii) keeping the other Parties informed of any such management action, and (iii) on request of the Steering Committee hereunder, consult with such body on any reasonable concerns voiced by a Party.

## **Section 6: Governance structure**

#### 6.1 General structure

The organisational structure of the Consortium shall comprise the following Consortium Bodies:

The **General Assembly** is the decision-making body of the consortium. For the purpose of this project, **Joint Action meetings** act as General Assembly.

**Steering Committee (SC)** is the main oversight committee of the Joint Action and, if necessary, it is the overall decision-making body.

The **Coordinator** is 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.

In addition, the Consortium also comprises the following functions:

**Project Management Team (PMT)** as an internal working group of administrative, financial and scientific support within NIJZ.

**Work Package Leaders (WPL)** who will manage work packages by ensuring the performance and progress of the work package with regard to the overall work plan.

#### 6.2 Members

General Assembly (Joint Action (JA) meetings) consists of representatives of all Parties, Affiliated Entities and the Project Management Team (PMT) as well as representatives of the European Commission (hereinafter referred to as "Member" or "Members"). The meetings will be held to discuss progress on JA objectives with the entire OriON consortium.

**Steering Committee (SC)** is the main oversight committee of the Joint Action and consists of the WP Leaders, PMT, representatives of the European Commission and other invited experts, if necessary. And, if necessary, Steering Committee is the overall decision-making body.

Each Member shall be deemed to be duly authorised to deliberate, negotiate and decide on matters of this Consortium Agreement.

## 6.3 General operational procedures for all Consortium Bodies

## 6.3.1 Representation in meetings

Any Party which is a member of a Consortium Body (hereinafter referred to as "Member"):

- should be represented at any meeting of such Consortium Body;
- may appoint a substitute or a proxy to attend and vote at any meeting;
- and shall participate in a cooperative manner in the meetings.

## 6.3.2 Preparation and organisation of meetings

	Ordinary meeting
Project Management Team	Once a week
Troject Management Team	once a week
Work Package Leaders	Internal monthly meetings / meetings with PMT if necessary
Shaaring Committee	A
Steering Committee	At least four times during the course of the JA
General Assembly	Two JA meetings over the course of the JA

The Coordinator shall convene meetings of all Consortium Bodies.

Any decision may also be taken without a meeting if the Coordinator circulates to all Members of the Consortium Body a written document (e-mail) which is then agreed by all Members of the Consortium Body. Such a document shall include an appropriate deadline (minimum 7 calendar days) for responses. Non-response within the deadline and after sending a written reminder including a grace period (minimum 7 calendar days) shall be considered as agreement provided that the document has been sent to an address given to the Coordinator by each Member. The decisions will be binding after the Coordinator sends written notification of acceptance to all Members of the Consortium Body.

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

Decisions will only be binding once the relevant part of the Minutes has been accepted according to Section 6.3.4.

## 6.3.3 Voting rules and quorum

Consortium bodies shall aim to achieve decisions through a consensus approach. This approach entails discussion that aims to achieve consensus among Members in order to promptly resolve the issues at hand. Even if a unanimous decision cannot be reached, a group discussion where everyone's opinions are heard and regarded shall take place, resulting in establishing the best solution that the Consortium Body can achieve at a given time.

6.3.3.1 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.

- 6.3.3.2 Each Member of a Consortium Body present or represented in the meeting shall have one vote.
- 6.3.3.3 Decisions shall be taken by a majority of two-thirds (2/3) of the votes cast.

## 6.3.4 Minutes of meetings

- 6.3.4.1 The Coordinator shall produce written minutes of each meeting which shall be the formal record of all decisions taken. The Coordinator shall send the draft minutes to all Members within one month of the meeting.
- 6.3.4.2 The minutes shall be considered as accepted if, within 7 calendar days from sending, no Member has sent an objection in writing to the Coordinator with respect to the accuracy of the draft of the minutes.
- 6.3.4.3 The Coordinator shall safeguard the accepted minutes and send them to all the Members of the Consortium Body.

## 6.4 Specific operational procedures for the Consortium Bodies

## 6.4.1 Steering Committee (SC)

In addition to the rules described in Section 6.3, the following rules apply:

#### 6.4.1.1 Members

The Steering Committee shall consist of the Work Package Leaders, Project Management Team, and representatives of the European Commission (hereinafter SC Members). When required, other experts will be invited to specific Steering Committee meetings.

The Scientific Coordinator shall chair all meetings of the Steering Committee.

#### 6.4.1.2 Tasks

- The Steering Committee shall monitor the effective and efficient implementation of the Joint Action and accept action plans on specific issues, where needed;
- It shall discuss all issues, which bear on the implementation of the JA, both in the realm of scientific issues as well as administrative issues;
- The Steering Committee will be regularly updated and consulted on: the progress of the JA and its WPs, activities of the coordinator at policy level, synergies and activities carried out by the horizontal WPs 1-3, timely preparation of the final report, as well as regular updating on financial expenditure of the JA by WPs and individual partners, where problematic.

## 6.4.2 General Assembly (Joint Action Meeting)

In addition to the rules described in Section 6.3, the following rules apply:

- 6.4.2.1 Members of the General Assembly Joint Action (JA) meetings consisting of representatives of all Parties, Affiliated Entities and the PMT, as well as representatives of the European Commission.
- 6.4.2.2 The Coordinator shall chair all meetings of the General Assembly, unless decided otherwise by the General Assembly.

## 6.4.2.3 Tasks

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

The following decisions shall be taken by the General 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

#### Evolution of the consortium

- 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

## Appointments

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

- External Expert Advisory Board Members

In the case of abolished tasks as a result of a decision of the General Assembly, Members shall rearrange the tasks of the Parties concerned. Such rearrangement shall take into consideration any prior legitimate commitments which cannot be cancelled.

The Parties agree to abide by all decisions of the General Assembly.

This does not prevent the Parties from submitting a dispute for resolution in accordance with the provisions of settlement of disputes in Section 11.8 of this Consortium Agreement.

The Associated Partner(s) is/are excluded from voting on and vetoing the following decisions of the General Assembly. Regarding unanimity or majority decisions, only Members with voting rights regarding the item are taken into account.

## 6.4.2.4 General Assembly meetings

General Assembly meetings will be held to discuss progress on Joint Action objectives with the entire OriON consortium. WP 1 will present the technical status of the Joint Action as well as the most recent financial status. WP 2 and 3 will present the progress of the Dissemination and Evaluation strategies. The core WPs will present the progress of their specific tasks and deliverables.

## 6.4.3 Project Management Team (PMT)

In addition to the rules in Section 6.3, the following rules apply:

#### 6.4.3.1 Members

The Project Management Team shall consist of the Scientific Coordinator, Project Manager, Financial Officer, Secretariat and researchers.

#### 6.4.3.2 Tasks

- The Project Management Team shall discuss and resolve daily management issues.
- It shall act as liaison between all Parties and the Agency.
- The Project Management Team shall communicate with the WP Leaders, Parties and potential Associated Partners via a variety of methods. These include, but are not limited to: e-mail, telephone, tele-, web- and videoconference, face to face meetings. Emphasis will be put on regular bilateral web-conferences between the PMT and individual WPs, as well as online SC meetings.

Key documents to be produced include: Project Policy, Financial Policy, Consortium Agreement and Final Technical and Financial Report.

#### 6.5 Coordinator

6.5.1 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.

## 6.5.2 In particular, the Coordinator shall:

- Monitor that the action is implemented properly (see Article 7 and Article 11 of the Grant Agreement);
- Act as the intermediary for all communications between the Parties and the Granting Authority (in particular, providing the Granting Authority with the information described in Article 7 of the Grant Agreement), unless the GA specifies otherwise;
- Request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;
- Submit the deliverables and reports to the Granting Authority (see Articles 7 and 21 of the Grant Agreement);
- Ensure that all payments are made to the other Parties without unjustified delay (see Article 7 and Article 22 of the Grant Agreement);
- Inform the Granting Authority of the amounts paid to each Party, when required in the Grant Agreement (see Articles 22 and 32) or requested by the Agency, or in the context of ex post Audits.
- 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.
- If the Coordinator fails in its coordination tasks, the General Assembly may propose to the Granting Authority to change the Coordinator.

6.5.3 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, or unless it is expressly agreed in written form.

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

# **Section 7: Financial provisions**

Section 7 of the Consortium Agreement does not apply to Associated Partners.

## 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 Beneficiary 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 Beneficiary shall be solely responsible for justifying its costs (and those of its Affiliated Entities, if any) with respect to the Project towards the Granting Authority. Neither the Coordinator nor any of the other Beneficiaries shall be in any way liable or responsible for such justification of costs towards the Granting Authority.

## 7.1.3 Funding principles

A Beneficiary 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 Beneficiary 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, unless otherwise decided within the Joint Action and agreed upon by the Granting Authority.

## 7.1.4 Excess payments

A Beneficiary has received excess payment

- if the payment received from the Coordinator exceeds the amount declared or
- if a Beneficiary 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 Beneficiary has received excess payment, the Beneficiary 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 Beneficiary is in substantial breach of the Consortium Agreement.

Amounts which are not refunded by a breaching Beneficiary and which are not due to the Granting Authority, shall be apportioned by the Coordinator to the remaining Beneficiaries pro rata according to their share of total

costs of the Project as identified in the Consortium Budget, until recovery from the breaching Beneficiary is possible. The Steering Committee decides on any legal actions to be taken against the breaching Beneficiary.

The circumstances under which this Article shall apply, are the following:

- 1. Circumstances, described in Articles 22 of the Grant Agreement, the Coordinator will inform each Party about the recovery of undue amounts.
- 2. Each Party's responsibility in case of recovery of undue amounts is limited to its own debts. Undue amounts paid by the Granting Authority for costs declared by an Affiliated entity will be considered as amounts unduly paid to the Party concerned. Parties will be fully liable for repaying the debts of their Affiliated entities.

The Coordinator will inform each such Party about the procedure of the recovery of the amounts:

- 1. with detailed information about the reasons for the recovery and the amount due;
- 2. with a debit note with the terms and the date of the payment.

#### 7.1.5 Revenue

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

## 7.1.6 Financial Consequences of the termination of the participation of a Beneficiary

A Beneficiary 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 Beneficiary declared to be 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 Beneficiaries in order to perform the leaving Beneficiary's task and necessary additional efforts to fulfil them as a consequence of the Beneficiary leaving the consortium.

The Beneficiaries must ensure that all their obligations under Grant Agreement and under this agreement also apply to their Affiliated Entities. Breaches by Affiliated Entities will be handled in the same manner as breaches by Beneficiaries. Recoveries of undue amounts will be handled through Beneficiaries.

## 7.2 Payments

7.2.1 Payments to Beneficiaries are the exclusive task of the Coordinator

In particular, the Coordinator shall:

- notify the Beneficiary 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 Beneficiary 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 Mutual Insurance Mechanism and for the final payment.

#### 7.2.2 Payment schedule

The transfer of the initial pre-financing, the additional pre-financings (if any) and interim payments to Beneficiaries will be handled in accordance with Article 22.1. and Article 7 of the Grant Agreement following this payment schedule:

Funding of costs included in the Consortium Plan will be paid by the Coordinator to the Beneficiaries after receipt of payments from the Granting Authority in separate instalments as agreed below:

50 % on receipt of Advance Payment (pre-payment)

Interim payment

Payment of the balance, on the basis of the request for payment of the balance

Funding for costs accepted by the Granting Authority will be paid by the Coordinator to the Beneficiary concerned.

The Coordinator is entitled to withhold any payments due to a Beneficiary identified by the General Assembly to be in breach of its obligations under this Consortium Agreement or the Grant Agreement or to a Beneficiary which has not yet signed this Consortium Agreement. The Coordinator is equally entitled to withhold payments to a Beneficiary, in accordance with circumstances, described in Article 22.2 and 22.4 of the Grant Agreement or when this is suggested by or agreed with the Granting Authority. The Coordinator will inform each such Beneficiary about the reasons for withholding funds and release terms.

The Coordinator is entitled to recover any payments already paid to a Beneficiary declared as 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 Beneficiary when this is suggested by or agreed with the Granting Authority.

## 7.3 Financial reporting

Beneficiaries shall certify that the information provided in their financial reports to the Granting Authority (via the Coordinator) is full, reliable and true. They shall also certify that the costs incurred are eligible in accordance with Article 6 of the Grant Agreement.

In addition to the Periodic and Final report which will be submitted to the Granting Authority after M12 and M24, there will also be 2 internal interim financial reports (IIFR 1 and 2). Internal interim financial reports should be sent to the Coordinator via the 4PM software by each Party within 1 month after the related reporting period.

Detailed instructions and guidelines of the Periodic, Final and interim reporting through 4PM platform will be set out in the Financial Policy.

Nr. of report	Reporting period	Due date
IIFR 1 to COO	M1-M6 (January 2024 – June 2024)	M7 (July 2024)
Periodic Report to the Granting Authority	<b>M1-M12</b> (January 2024 – December 2024)	<b>M14</b> (February 2025)
IIFR 2 to COO	M13-M18 (January 2025 – June 2025)	M19 (July 2025)
Final report to the Granting Authority	<b>M13-M24</b> (January 2025 – December 2025)	<b>M26</b> (February 2026)

Beneficiaries should submit all reports according to the instructions set in the Grant Agreement and Financial Policy.

## **Section 8: Results**

## 8.1 Ownership of results

Results are owned by the Party (or its Affiliated Entity) generating it.

## 8.2 Joint Ownership

Joint ownership is governed by Grant Agreement Article 16.4 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 activities on a royalty-free basis, and without requiring the prior consent of the other joint owner(s), and
- each of the joint owners shall be entitled to otherwise Exploit the jointly owned Results and to grant non-exclusive licences to third parties (without any right to sub-license), if the other joint owners are given:
  - 1. at least 45 calendar days advance notice with a right for the other joint owners to object hereto at the latest 15 days after receipt of such notice; and
  - 2. If no objection is made within the time limit stated above, the permission is given by the other joint owners who each shall receive Fair and Reasonable compensation considering each joint owner's relative contribution to the jointly owned Results.

However, the joint owners shall, as soon as possible after the creation of the joint Results enter into a Joint Ownership Management Agreement to agree on all protection measures, ownership percentages and the division of related costs in advance.

## 8.3 Transfer of Results

#### 8.3.1

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, subsection "Transfer of ownership". It must however ensure that its obligation under the Grant Agreement and this Consortium Agreement also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

Each Party may identify specific third parties it intends to transfer the ownership of its Results to in Attachment (3) of this Consortium Agreement. 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.

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 under the Consortium Agreement and the Grant Agreement will not be affected by such transfer. Any addition to Attachment (3) after signature of this Consortium Agreement requires a decision of the General Assembly.

The Parties recognise 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.

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

#### 8.3.2

Unless otherwise agreed in writing for specifically-identified Third Parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a Party that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other Parties that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any Party concerned to assess the effects on its access rights.

Unless otherwise agreed in writing for specifically-identified Third Parties, any Party may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its Access rights. In this case, the transfer may not take place until agreement has been reached between the Parties concerned.

## 8.3.3

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

## 8.4.1

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.

## 8.4.2 Dissemination of own (including jointly owned) Results

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.

The Parties acknowledge their common interest in publishing Results to obtain recognition within the scientific community and to advance the state of scientific knowledge in their scientific field.

It is contemplated that the Results will jointly be published whenever applicable, notably in the respect of the fact that one such Result is jointly-owned; however, the Parties each separately reserve the right to publish their own Results and Background. Authorship on joint publications will be based on academic standards and customs.

Prior notice of any planned publication or communication of joint results (as well as a provided copy of such proposed abstract or publication manuscript (and a reasonably detailed description of any such oral presentation or other public disclosure) to all the Parties concerned via the Coordinator) 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.

## An objection is justified if

- a) the protection of the objecting Party's Results or Background would be adversely affected
- b) the objecting Party 's legitimate interests in relation to the Results or Background would be significantly harmed
- c) the publication contains Confidential Information of the objecting Party.

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

Parties who fail to answer within fifteen (15) calendar days will be considered to have given their consent.

Provided that all reasonable modifications have been implemented, none of the Parties concerned may withhold its consent to publication or communication for a period longer than two (2) months from the date such publication or communication was first notified to the Parties.

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.

## 8.4.3 Information on EU FUNDING – Obligation and right to use the EU emblem

All dissemination connected to the Joint Action must acknowledge EU support and display the European flag (emblem) included in Art. 17.2 of the Grant Agreement and funding statement (translated into local languages, where appropriate).

All dissemination connected to the Joint Action must stipulate that they arise from the OriON Joint Action and include one of the appropriate Joint Action logos in a prominent place. The EU Emblem shall be at least as visible as the Logo of the Funded Project.

Publications should also include the following disclaimer:

"Funded by the European Union under Grant Agreement 101127673. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Health and Digital Executive Agency (HaDEA). Neither the European Union nor the granting authority can be held responsible for them."

8.4.4 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. The mere absence of an objection is not considered as an approval.

8.4.5 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.

8.4.6 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.

# **Section 9: Access Rights**

## 9.1 Background included

9.1.1 In Attachment 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 Attachment 1 shall not be the object of Access Right obligations regarding Background.

9.1.2 Any Party can propose to the Coordinator to modify its Background in Attachment 1. However, approval of the Steering Committee is needed should a Party wish to remove or modify Background in Attachment 1.

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

## 9.2 General Principles

- 9.2.1 Each Party shall implement its tasks in accordance with the Grant Agreement and shall bear sole responsibility for ensuring that its acts within the Joint Action do not knowingly infringe Third Party property rights.
- 9.2.2 Any Access Rights granted expressly exclude any rights to sublicense unless expressly stated otherwise.

- 9.2.3 Access Rights Needed for the performance of the work of a Party under the Joint Action shall be free of any administrative transfer costs.
- 9.2.4 Access Rights are granted on a non-exclusive basis.
- 9.2.5 Results and Background shall be used only for the purposes for which Access Rights to it have been granted.
- 9.2.6 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.
- 9.2.7 The requesting Party must show that the Access Rights are Needed.

## 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 Joint Action shall be granted on a royalty-free basis, unless otherwise agreed for Background in the Attachment 1.

## 9.4 Access Rights for Exploitation

- 9.4.1 Access Rights to Background if Needed for Exploitation of a Party's own Results, shall be granted on Fair and Reasonable conditions.
- 9.4.2 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 internal research activities and educational purposes shall be granted on a royalty-free basis.
- 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 9.7.1.2 of this Consortium Agreement after the termination of the requesting Party's participation in the Joint Action.

## 9.5 Access Rights for Affiliated entities

Affiliated entities shall have Access Rights under the same conditions as if they were a Party. For the avoidance of doubts, the provisions governing the granting of Access Rights to the Parties as set out in Sections 9.3 and 9.4 of this CA shall also apply to Affiliated entities.

Such Access Rights must be requested by the Affiliated entity from the Party that holds the Background or Results. Alternatively, the Party granting the Access Rights may individually agree with the Party requesting the Access Rights to have the Access Rights include the right to sublicense to the latter's Affiliated entities listed in Article 8 of the Grant Agreement. Access Rights to affiliated entities shall be granted on Fair and Reasonable conditions and upon written bilateral agreement.

Affiliated entities which obtain Access Rights in return fulfil all confidentiality and other obligations accepted by the Parties under the Grant Agreement or this Consortium Agreement as if such affiliated entities were Parties.

Access Rights may be refused to Affiliated entities if such granting is contrary to the legitimate interests of the Party which owns the Background or the Results.

Access Rights granted to any Affiliated entity are subject to the continuation of the Access Rights of the Party to which it is affiliated, and shall automatically terminate upon termination of the Access Rights granted to such Party.

Upon cessation of the status as an affiliated entity, any Access Rights granted to such former affiliated entity shall lapse.

Further arrangements with affiliated entities may be negotiated in separate agreements.

## 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 Access Rights granted to a Party leaving the consortium

## 9.7.2.1 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 Steering Committee to terminate its participation in the consortium.

## 9.7.1.2 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.

It may request Access Rights within the period of time specified in Section 9.4.3.

#### 9.7.2 Access Rights to be granted by any leaving Party

Any Party leaving the Joint Action 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 Joint Action.

## Section 10: Non-disclosure of information

10.1

All information in whatever form or mode of communication, which is disclosed by a Party or its Affiliated entity (the "Disclosing Party") to any other Party or its Affiliated entity (the "Recipient") in connection with the Joint Action 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 end of the Project:

- not to use Confidential Information otherwise than for the purpose for which it was disclosed;
- not to disclose Confidential Information to any third party other than its Affiliated entity without the prior consent of 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 Recipients 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 that the Recipient comply with the confidentiality obligations herein contained with respect to such copy for as long as the copy is retained.

10.3

The Recipient shall be responsible for the fulfilment of the above obligations on the part of their employees or third parties involved in the Joint Action and shall ensure that they remain so obliged, as far as legally possible, during and after the end of the Joint Action 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 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 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 completely independently of any such disclosure by the Disclosing Party; or
- the Confidential Information was already known to the Recipient 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 11.7 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 Joint Action as with its own confidential and/or proprietary information, but in no case less than reasonable care.

10.6

Each Party shall promptly advise the other Party in writing of any unauthorised disclosure, misappropriation or misuse of Confidential Information after it becomes aware of such unauthorised disclosure, misappropriation or misuse.

10.7

If any Party becomes aware that it will be required, or is likely to be required, to disclose Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, it shall, to the extent 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.

## **Section 11: Miscellaneous**

## 11.1 Attachments, inconsistencies and severability

This Consortium Agreement consists of this core text and

- Attachment 1 (Background included)
- Attachment 2 (Accession document)
- Attachment 3 (List of third parties and Affiliated Entities for simplified transfer according to Section 8.3.2)

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

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 which fulfils the purpose of the original provision.

## 11.2 No representation, partnership or agency

Except as otherwise provided in Section 6.5.3, 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 Notices and other communication

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

#### Formal notices:

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

#### Written notices:

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. Any change of persons or contact details shall be notified promptly by the respective Party to the Coordinator.

## 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 core text of this Consortium 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.

## 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 applicable EU law supplemented if necessary 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.

A dispute between any Parties of the Consortium agreement will be brought into attention of the Steering Committee which will act as a mediator and propose solutions to be agreed by the Parties. The Coordinator will

mediate disputes between SC members. Disputes between the Coordinator and any other Party shall primarily be settled through negotiation.

All disputes arising out of or in connection with this Consortium Agreement, which cannot be solved amicably and through mediation of the Steering Committee, shall be finally settled by the courts of Brussels, Belgium.

Nothing in this Consortium Agreement shall limit the Parties' right to seek injunctive relief in any applicable competent court. Article 43 of the Grant Agreement will be used for unsettled disputes related to the subject-matter referred to in paragraph 2, Article 43 of the Grant Agreement.

# **Section 12: Signatures**

## **AS WITNESS:**

The Parties have caused this Consortium Agreement to be duly signed by their authorised representatives in as many separate signature pages per Party as there are Parties, the day and year first above written.

The Parties agree that digital signatures (compliant to EU-Qualified Electronic Signature requirement) shall be treated as original signatures.

AS	WITNESS:
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1. NACIONALNI INSTITUT ZA JAVNO ZDRAVJE (NIJZ)	
Signature:	
Name:	
Title:	
Date:	

## **AS WITNESS:**

2. SCIENSANO (Sciensano)		
Signature:		
Name:		
Title:		
Date:		

AS	WITNESS:
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3. HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO (CIPH)		
Signature:		
Name:		
Title:		
Date:		

AS	WITNESS:
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4. MINISTRY OF HEALTH OF THE REPUBLIC OF CYPRUS (MoH CY)		
Signature:		
Name:		
Title:		
Date:		

AS	WITNESS:
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5. MINISTRY OF HEALTH OF THE REPUBLIC OF GREECE (MoH GR)					
Signature:					
Name:					
Title:					
Date:					
Date:					

AS	WITNESS:
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6. ORSZAGOS ONKOLOGIAI INTEZET (OOI)		
Signature:		
Name:		
Title:		
Date:		

AS	WITNESS:
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7. NATIONAL CANCER REGIST	RY BOARD (NCRI)		
Signature:			
Name:			
Title:			
Date:			

AS	WITNESS:
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8. ISTITUTO SUPERIORE DI SANITÀ (ISS)		
Signature:		
Name:		
Title:		
Date:		

	ITN	

9. NACIONALINIS VEZIO INSTITUTAS - NAT	ΓΙΟΝΑL CANCER INSTITUTE	(NCI)	
Signature:			
Name:			
Title:			
Date:			

AS	WITNESS:
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10. MINISTRY FOR HEALTH - GOVERNMENT OF MAL	TA (MFH)	
Signature:		
Name:		
Title:		
Date:		

AS	WITNESS:
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11. STICHTING INTEGRAAL KANKERCENTRUM NEDERLAND (IKNL)			
Signature:			
Name: Title:			
Date:			

AS	WITNESS:
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12. OSLO UNIVERSITETSSYKEHUS HF (OUS)		
Signature:		
Name:		
Title:		
Date:		

AS	WITNESS:
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13. THE MINISTRY OF HEALTH OF THE REPUBLIC OF POLAND (MZ)				
Signature:				
Name: Title:				
Data				
Date:				

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14. INSTITUTUL NATIONAL DE SANATATE PUBLICA (INSP)				
Signature:				
Name:				
Title:				
Date:				

AS	WITNESS:
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15. NÁRODNE CENTRUM ZDRAVOTNICKYCH INFORMACII (NCZI)				
Signature:				
Name: Title:				
Date:				

	۱FSS

16. FUNDACIÓN PA VALENCIANA (FISAI	E LA INVESTIGACIÓN	SANITARIA Y BIOM	ÉDICA DE LA COMUNITAT
Signature:			
Name:			
Title:			
Date:			

## **AS WITNESS:**

17. SOCIALSTYRELSEN (NBHW)		
Signature:		
Name:		
Title:		
Date:		

# **Attachment 1: Background included**

According to the Grant Agreement (Article 16.1) Background is defined as "data, know-how or information (...) that is (...) needed to implement the Action or exploit the results". Because of this need, Access Rights have to be granted in principle, but Parties must identify and agree amongst them on the Background for the Project. This is the purpose of this attachment.

#### PARTY 1

As to [NAME OF THE PARTY], it is agreed between the Parties that, to the best of their knowledge, [insert the relevant option here].

## [Option 1 start]

the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific limitations and/or conditions for implementation	Specific limitations and/or conditions for Exploitation
Not applicable	Not applicable	Not applicable

This represents the status at the time of signature of this Consortium Agreement.

## **Attachment 2: Accession document**

**ACCESSION** 

of a new Party to

**OriON Consortium Agreement, version September 2023** 

[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].

NACIONALNI INSTITUT ZA JAVNO ZDRAVJE (NIJZ)

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 authorised representatives.

[Date and Place]

[INSERT NAME OF THE NEW PARTY]

Signature(s)

Name(s)

Title(s)

[Date and Place]

NACIONALNI INSTITUT ZA JAVNO ZDRAVJE (NIJZ)

Signature(s)

Name(s)

Title(s)

# Attachment 3: List of third parties and Affiliated Entities for simplified transfer according to Section 8.3.2.

#### Affiliated Entities:

 ONKOLOŠKI INŠTITUT LJUBLJANA ZALOSKA CESTA 2 1000, LJUBLJANA Slovenia PIC 986222475

2. ILEKTRONIKI DIAKYVERNISI KOINONIKISASFALISIS

LIKOURGOU 10 po box: 000 10551, ATHINA Greece PIC 937198966

3. MINISTERO DELLA SALUTE

Via Giorgio Ribotta 5 00144, ROMA Italy PIC 999531942

4. CONSEJERIA DE SALUD Y CONSUMO DE LA JUNTA DE ANDALUCIA EDIF. ARENA 1. AVDA DE LA INNOVACION S//N 41020, Sevilla Spain PIC 950939307

 FUNDACION PUBLICA ANDALUZA PROGRESO Y SALUD M.P. AVENIDA AMERICO VESPUCIO 15 EDIF S2 41092, SEVILLA Spain PIC 998619463

6. SVERIGES KOMMUNER OCH REGIONER

HORNSGATAN 20 po box: 000 118 82, STOCKHOLM Sweden PIC 998829371