Consortium Agreement

DESCA
MODEL CONSORTIUM
AGREEMENT

PRostate cancer **A**wareness and **I**nitiatives for **S**creening
in the **E**uropean **U**nion (PRAISE-U_

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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 European Commission's General Model Grant Agreement and its Annexes, and is made on the effective date of the Grant Agreement (22 March 2023), hereinafter referred to as the Effective Date

BETWEEN:

(1) STICHTING EUROPEAN UROLOGICAL FOUNDATION (EAU), established in Mr. E.N. van Kleffensstraat 5, 6842 CV Arnhem, Netherlands ("**the Coordinator**");

(2) ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM (EMC), established in 'Dr Molewaterplein 40, Rotterdam 3015 GD, Netherlands;

(3) STICHTING EUROPESE STUDIE PROSTAATKANKER SCREENING (ERSPCF), established in Schaarweide 5, Reeuwijk 2811 JM, Netherlands;

(4) REGION MIDTJYLLAND (CDR), established in Skottenborg 26, Viborg 8800, Denmark;

(5) USTAV ZDRAVOTNICKYCH INFORMACI A STATISTIKY CESKE REPUBLIKY (UZIS), established in Palackeho Namesti 4, Praha 12801, Czechia;

(6) UNIVERSITAIR MEDISCH CENTRUM UTRECHT (UMCU), established in Heidelberglaan 100, Utrecht 3584 CX, Netherlands;

(7) EUROPEAN CANCER ORGANISATION (ECO), established in Rue De La Science 41, Bruxelles 1040, Belgium;

(8) DOLNOSLASKIE CENTRUM ONKOLOGII, PULMONOLOGII I HEMATOLOGII (DCOPiH), established in Ul. Pl. Ludwika Hirszfelda, 12 000, 53-413, Wroclaw, Poland;

(9) NARODOWY INSTYTUT ZDROWIA PUBLICZNEGO PZH – PANSTWOWY INSTYTUT BADAWCZY (NIZP), established in Chocimska 24, Warszawa 00791, Poland;

(10) CONSELLERIA DE SANIDADE DE GALICIA (CSG), established in Edificio Administravito San Lazaro sn, Santiago de Compostela 15781, Spain;

(11) ALTHAIA XARXA ASSISTENCIEL UNIVERSITARIA DE MANRESA FUNDACIO PRIVADA (ALT), established in Calle Doctor Joan Soler 1 – 3, Manresa, Barcelona 08243, Spain;

(12) VASTRA GOTALANDSREGIONEN (VGR), established in Regionens Hus, Vanersborg 462 80, Sweden;

(13) REGION SKANE (SKA), established in Region Skane, Kristianstad 291 89, Sweden;

(14) NACIONALINIS VEZIO INSTITUTAS (NCI), established in Santariskiu Str, 1, Vilnius 08660, Lithuania;

(15) GENT UNIVERSITY (UGENT), public institution with legal personality, having its administrative offices in Belgium, B-9000 Gent, Sint-Pietersnieuwstraat 25; company registration number 0248.015.142; duly represented by prof. dr. Rik van de Walle, Rector, who entrusts the execution of the present Agreement to prof. dr. Lieven Annemans, Department of Public Health and Primary Care hereinafter referred to as "UGENT";

(16) HEALTH SERVICE EXECUTIVE (HSE), established in Limetree Avenue, Millenium Park, Nass, County Kildare, Ireland;

(17) EESTI UROLOOGIDE SELTS (EUS), established in L Puusepa TN 8, Tartu 51014, Estonia;

(18) UNIVERSITY COLLEGE DUBLIN, NATIONAL UNIVERSITY OF IRELAND, DUBLIN (UCD), established in Belfield, Dublin 4, Ireland;

(19) STICHTING WONCA EUROPE (WONCA), established in Poljanski Nasip 58, Ljubljana 1000, Slovenia;

(20) MOVEMBER FOUNDATION EV (MOV), established in Leopoldstr 11 A, Munchen 80802, Germany;

Each Party at (1) to (20) hereinafter individually referred to as a "**Beneficiar**y" and jointly referred to as "**Beneficiaries**"

(21) INTERNATIONAL AGENCY FOR RESEARCH ON CANCER (IARC) the cancer research agency of the World Health Organization (WHO), whose offices are at 25 avenue Tony Garnier, CS 90627, 69366 LYON CEDEX 07, France;

(22)EUROPEAN SOCIETY OF UROGENITAL RADIOLOGY (ESUR), whose administrative offices are at Landstrasser Hauptstrasse 27, Eingang Weyrgasse 9 / Tür 15, 1030, Vienna, Austria;

(23) EUROPA UOMA (Europa UOMO), whose administrative offices are atLeopoldstraat 34 000, 2000, Antwerpen, Belgium; and

(24)THE CZECH UROLOGICAL SOCIETY (EUS), whose administrative offices are atSokolská 490/31, 120 00, Praha 2, Czechia;

Each Party at (21) to (24) hereinafter individually referred to as a "**Associated Partner**" and jointly referred to as "**Associated Partners**"

Hereinafter Beneficiaries and Associated Partner(s), are jointly or individually referred to as "**Parties**" or a "**Party**"

relating to the Action entitled

PRostate cancer Awareness and Initiative for Screening in the European Union

in short

PRAISE-U

hereinafter referred to as "**Project**"

WHEREAS:

The Parties, having considerable experience in the field concerned, have submitted a proposal for the Project to the Granting Authority as part of Horizon Europe – the Framework Programme for Research and Innovation (2021-2027).

The Parties wish to specify or supplement binding commitments among themselves in addition to the provisions of the specific Grant Agreement to be signed by the Beneficiaries and the Granting Authority (hereinafter “Grant Agreement”).

The Parties are aware that this Consortium Agreement is based upon the DESCA model consortium agreement (version for use with Associated Partners AP1, July 2022)

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

1 Definitions

1.1 Definitions

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

1.2 Additional Definitions

“Consortium Body”

Consortium Body means any management body described in Section 6 (Governance Structure) of this Consortium Agreement.

“Consortium Plan”

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 General Assembly.

“Granting Authority”

means the body awarding the grant for the Project.

“Defaulting Party”

Defaulting Party means a Party which the General Assembly has declared to be in breach of this Consortium Agreement and/or the Grant Agreement as specified in Section 4.3 of this Consortium Agreement.

“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.

“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.

2 Purpose

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

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.

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 Beneficiary, or
- the Grant Agreement is terminated, or
- a Beneficiary’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.

If an Associated Partner´s participation in the Project is terminated, its participation in this Consortium Agreement may be terminated subject to the provisions surviving the expiration or termination under this Consortium Agreement (Section 3.3 and Section 4.2).

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 for a period of five (5) years.

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 General 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. However, the Parties do not undertake that any research will lead to any particular (scientific) results.

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 for Associated Partners

For the avoidance of doubt, the Associated Partners do not sign the Grant Agreement and do not receive funding from the Granting Authority and therefore do not have a right to charge costs or claim contributions from the Granting Authority. Each Associated Partner must ensure its own funding for the implementation of the Project and has provided assurance of this to the Coordinator (for example by way of a letter of intent) regarding its financial capacity for the implementation of Project tasks and obligations arising from the Consortium Agreement. However, certain terms and conditions of the Grant Agreement and its Annexes are applicable to the Associated Partners. The Coordinator will share a copy of the signed Grant Agreement and information on any amendments with the Associated Partners.

Each Associated Partner hereby commits to implement the Project tasks attributed to it in Annex 1 of the Grant Agreement.

In addition, each Associated Partners hereby commits especially to the following articles of the Grant Agreement and related regulations of Annex 5:

- Proper implementation of the action (Article 11)
- Conflicts of interest (Article 12)

- Confidentiality and security (Article 13)
- Ethics and values (Article 14)
- Visibility (Article 17.2)
- Specific rules for carrying out the action (Article 18)
- Information obligations (Article 19)
- Record-keeping (Article 20)

The Associated Partners support the Beneficiaries regarding their exploitation, dissemination and Open Science obligations and commit(s) to contribute to the technical and continuous reporting during and after the implementation of the Project.

Furthermore, each Associated Partner hereby explicitly agree to cooperate with and grant access to bodies according to Article 25 of the Grant Agreement (the Granting Authority, the European Anti-Fraud Office (OLAF), the European Public Prosecutor's Office (EPPO), the European Court of Auditors (ECA)), so that these bodies can carry out checks, reviews, audits and investigations on each Associated Partner.

Any Associated Partner from a non-EU country undertakes to comply additionally with any other obligation arising from Art. 10.1 (data protection) of the Grant Agreement.

In case of termination or being declared a Defaulting Party, an Associated Partner shall, within the limits specified in Section 5.2 of this Consortium Agreement, bear any reasonable and justifiable costs occurring to the other Parties for performing this Associated Partners tasks and the costs for additional efforts necessary to implement the Project.

Moreover, an Associated Partner is obliged to indemnify the other Parties for any claim of the Granting Authority against them which is caused by such Associated Partner´s actions or omissions during Grant Agreement preparation, Project implementation or after Project end. Regarding such claims each Associated Partner´s special liability is limited to: (i) in respect of IARC: [redacted] (equal to the budget of the beneficiary with the lowest budget in the consortium (VGR) and equal to [redacted] of the total project budget).

Should an Associated Partner be obliged to sign a separate agreement concerning its funding for the Project, it is the responsibility of that Associated Partner to ensure such agreement is not in conflict with this Consortium Agreement.

For the avoidance of doubt, the provisions of this Article 4.2 shall be without prejudice to the provisions of Article 11.9.

4.3 Breach

In the event that the General 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 General 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 substantial and is not remedied within that period or is not capable of remedy, the General 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, but which shall be in accordance with the provisions of Chapter 5 of the Grant Agreement (Consequences of Non-Compliance).

4.4 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 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.

4.5 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* 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.

4.6 Specific responsibilities regarding ethical practice

Each Party shall ensure that its work on the Project complies fully with all applicable national, local, government and international laws, regulations and guidelines which are effective during the period of the Consortium Agreement, including those governing health and safety, data protection, and where relevant, the use of human subjects and good clinical practice such as defined by the guidelines of the International Council on Harmonization of Good Clinical Practice and the most recent version of the Declaration of Helsinki. In this regard, each Party shall maintain the confidentiality, in accordance with Cection 10 of this Consortium Agreement, of all materials and data relating to the use of patients, which is created or used in the course of the Project.

No Party shall undertake any aspect of the Project (including clinical intervention) that requires ethical approval until such time as that Party is satisfied that all relevant consents, insurances, regulatory approvals and a favourable opinion from an appropriate ethics committee has been obtained.

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,

- 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 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, except in case of breach of confidentiality.

A Party's general aggregate liability towards the other Parties collectively shall be limited to the Beneficiary's share of the total costs of the Project as identified in Annex 2 of the Grant Agreement and in case of Associated Partners, limited to: (i) in respect of IARC: [redacted] (equal to the budget of the beneficiary with the lowest budget in the consortium (VGR) and equal to [redacted] of the total project budget).

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.

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.

Each Party will notify the General 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 General 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 authorisation, provided that the Party has used its reasonable efforts to fulfil its tasks and to apply for any necessary license or authorisation properly and in time.

Each Party will notify the General 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 General Assembly.

For the avoidance of doubt each Party shall adhere to all applicable export control laws and regulations, including (only in respect of a Party which is established in a member state of the European Union) Regulation (EU) 2021/821 of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items. Each Party shall inform each other if goods, software or technology to be transferred pursuant to this Consortium Agreement are affected by export control laws and regulations. The export of goods, software or technology to third parties outside the European Union may be subject to an export license provided by the relevant authority.

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.

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.

6.2 Members

The General Assembly shall consist of one representative of each Party (hereinafter referred to as "**Member**").

Each Member shall be deemed to be duly authorised to deliberate, negotiate and decide on all matters listed in Section 6.3.7 of this Consortium Agreement.

The Coordinator shall chair all meetings of the General Assembly, unless decided otherwise by the General Assembly.

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

This does not prevent the Parties from exercising their veto rights, according to Section 6.3.5, or 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 (6.3.7) and therefore are not counted towards any respective quorum:

- Financial changes to the Consortium Plan
- Distribution of EU contribution among the Beneficiaries
- Proposals for changes to Annex 2 of the Grant Agreement to be agreed by the Granting Authority
- Decisions related to Section 7.1.4 of this Consortium Agreement

Regarding unanimity or majority decisions, only Members with voting rights regarding the item are taken into account (e.g. Section 6.3.2.5).

6.3 Operational procedures for the General Assembly:

6.3.1 Representation in meetings

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.

6.3.2 Preparation and organisation of meetings

6.3.2.1 Convening meetings:

The chairperson shall convene ordinary meetings of the General Assembly at least once every six months and shall also convene extraordinary meetings at any time upon written request of any Member.

6.3.2.2 Notice of a meeting

The chairperson shall give written notice of a meeting to each Member as soon as possible and no later than 14 calendar days preceding an ordinary meeting and 7 calendar days preceding an extraordinary meeting.

6.3.2.3 Sending the agenda:

The chairperson shall prepare and send each Member an agenda no later than 14 calendar days preceding the meeting, or 7 calendar days before an extraordinary meeting.

6.3.2.4 Adding agenda items:

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

Any Member may add an item to the original agenda by written notice to all of the other Members no later than 7 calendar days preceding the meeting and 2 days preceding an extraordinary meeting.

6.3.2.5

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

6.3.2.6

Meetings of the General Assembly may also be held by tele- or videoconference or other telecommunication means.

6.3.2.7

Decisions will only be binding once the relevant part of the minutes has been accepted according to Section 6.3.6.2.

6.3.3 Decisions without a meeting

Any decision may also be taken without a meeting if

a) the Coordinator circulates to all Members of the General Assembly a suggested decision with a deadline for responses of at least 7 calendar days after receipt by a Party and

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

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

A veto according to Section 6.3.5 may be submitted up to 10 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.

6.3.4 Voting rules and quorum

6.3.4.1

The General Assembly 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 General Assembly 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.

6.3.4.2

Each Member present or represented in the meeting shall have one vote. Associated Partners are excluded from certain decisions of the General Assembly according to Section 6.2.

A Party which the General Assembly has declared according to Section 4.3 to be a Defaulting Party may not vote.

6.3.4.3

Decisions shall be taken by a majority of two-thirds (2/3) of the votes cast.

6.3.5 Veto rights

6.3.5.1

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 the General Assembly may exercise a veto with respect to the corresponding decision or relevant part of the decision.

6.3.5.2

When the decision is foreseen on the original agenda, a Party may only veto such a decision during the meeting.

6.3.5.3

When a decision has been taken on a new item added to the agenda before or during the meeting, a Party may veto such decision during the meeting or within 15 calendar days after receipt of the draft minutes of the meeting.

6.3.5.4

When a decision has been taken without a meeting a Party may veto such decision within 10 calendar days after receipt of the written notice by the chairperson of the outcome of the vote.

6.3.5.5

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

6.3.5.6

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.

6.3.5.7

A Party requesting to leave the consortium may not veto decisions relating thereto. That Party's right of veto will be reinstated in the event that it withdraws its request to leave the consortium, or such request is not permitted by the General Assembly in accordance with Article 6.3.7.

6.3.6 Minutes of meetings

6.3.6.1

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

6.3.6.2

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

6.3.6.3

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

6.3.7 Decisions of the General Assembly

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
- Modifications or withdrawal of Background in Attachment 1 (Background Included)
- Additions to Attachment 3 (List of Third Parties for simplified transfer according to Section 8.3.2)
- Additions to Attachment 4 (Identified entities under the same control)

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 4.2, Section 7.1.4)

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.

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 certification) and specific requested documents to the Granting Authority
- preparing the meetings, proposing decisions and preparing the agenda of General Assembly meetings, chairing the meetings, preparing the minutes of the meetings and monitoring the implementation of decisions taken at meetings
- transmitting promptly documents and information connected with the Project to any other Party 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
- providing a copy of the Grant Agreement and its Annexes to the Associated Partners.

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 General 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 Scientific Advisory Board and Ethical Advisory Board

A Scientific Advisory Board (SAB) will be appointed and steered by the General Assembly to provide critical and constructive input. An Ethical Advisory Board (EAB) will also be appointed to provide input on ethical issues related to the Project, such as data privacy and protection and informed consent and also ethical approaches to screening studies.

The Coordinator will ensure that a non-disclosure agreement is executed between all Parties and each SAB and EAB member.

Its terms shall be not less stringent than those stipulated in this Consortium Agreement, and it shall be concluded no later than 30 days after their nomination or before any confidential information will be exchanged/disclosed, whichever date is earlier.

By way of exception to Section 6.4.4 above, the Parties hereby mandate the Coordinator to execute, in their name and on their behalf, a non-disclosure agreement (hereafter "NDA") with each member of the SAB and EAB, in order to protect Confidential Information disclosed by any of the Parties to any member of the SAB or EAB as relevant. The NDA for the SAB/EAB members is enclosed in Attachment 5 (which will also form the basis of the NDA with each member of the SAB/EAB). The mandate of the Coordinator comprises solely the execution of the NDA on substantially the same terms as that set out in Attachment 5. Notwithstanding the foregoing wording, in respect of Ghent University, the NDA thus executed in its name by the Coordinator shall be confirmed in writing by its legal representative.

The Coordinator shall write the minutes of the SAB meetings and submit them to the General Assembly. The SAB and EAB members shall be allowed to participate in General Assembly meetings upon invitation but have not any voting rights.

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 budget table at Attachment 6 to this Agreement (tab 2 – internal budget),
- 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.

The amounts payable as set out in tab 2 (internal budget) of the budget table at Attachment 6 to this Agreement include the maximum amounts which will be payable, in terms of share of financial contribution of the Granting Authority as distributed to each Beneficiary by the Coordinator and the share of funding to be contributed by each Beneficiary.

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.

7.1.4 Excess payments

A Beneficiary has received excess payment

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

b) 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 General Assembly decides on any legal actions to be taken against the breaching Beneficiary according to Section 6.3.7.

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. However, the Parties shall use reasonable endeavours to mitigate such additional costs). The General Assembly should agree on a procedure regarding additional costs which are not covered by the Defaulting Party or the Mutual Insurance Mechanism.

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;

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

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

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 without undue delay and in conformity with the provisions of the Grant Agreement. Costs accepted by the Granting Authority will be paid 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 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.

8 Results

8.1 Ownership of Results

Results are owned by the Party that generates them.

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:

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

In case of joint ownership, each of the joint owners shall be entitled to Exploit the joint Results as it sees fit, and to grant non-exclusive licenses, without obtaining any consent from, paying compensation to, or otherwise accounting to any other joint owner, unless otherwise agreed between the joint owners.

The joint owners shall agree on all protection measures and the division of related cost 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, sub-section “Transfer of ownership”. In the case of jointly owned Results, no such transfer of ownership may occur without the other joint owners’ explicit written consent.

8.3.2

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.

8.3.3

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 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.

8.3.4

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.

8.3.5

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

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

8.4.2.1

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 14 calendar days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.

8.4.2.2

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.

8.4.2.3

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. Where the objection is raised under Article 8.4.2.2.(c) the objecting Party shall identify what Confidential Information is required to be deleted and the publishing Party shall revise the publication to prevent undesired disclosure of the objecting Party’s Confidential Information.

8.4.2.4

The objecting Party can request a publication delay of not more than 90 calendar days from the time it raises such an objection. After the expiry of such agreed delay period the publication is permitted, provided that the objections of the objecting Party have been addressed.

8.4.3 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.

8.4.4 Cooperation obligations

The Parties undertake to cooperate to allow the timely submission, examination, publication and defense 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.

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

9.2 General Principles

9.2.1

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.

9.2.2

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

9.2.3

Access Rights 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 Project shall be granted on a royalty-free basis, unless otherwise agreed for Background in Attachment 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 a royalty-free basis. Access Rights to Results if required by a Party which is an academic institution shall also be granted on a royalty-free basis (a) solely for non-commercial teaching or patient care by that academic institution; and (b) with the academic institution having no right to sub-licence or assign such Access Rights; and (c) subject to the obligations of confidentiality under Article 10 and with such Access Rights terminating automatically in the event that such academic organization is no longer a Beneficiary or Associated Partner to the Consortium.

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 twenty-four 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 Access Rights for entities under the same control

Access Rights for entities under the same control as Parties to this Agreement (including any such entities as identified in Attachment 4 (Identified entities under the same control) to this Consortium Agreement) must be requested by the entity under the same control 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 entity under the same control. Access Rights to an entity under the same control shall be granted on Fair and Reasonable conditions and upon written bilateral agreement.

Entities under the same control which obtain Access Rights in return fulfil all confidentiality obligations accepted by the Parties under the Grant Agreement or this Consortium Agreement as if such entities were Parties.

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

Access Rights granted to any entity under the same control are subject to the continuation of the Access Rights of the Party with whom it is under the same control, and shall automatically terminate upon termination of the Access Rights granted to such Party.

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

Further arrangements with entities under the same control 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. For the avoidance of doubt, neither the Grant Agreement nor this Consortium Agreement shall be construed as creating any obligation on any Party to grant any other Party any Access Rights not expressly permitted or otherwise granted in writing by the owning Party.

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 General Assembly to terminate its participation in the consortium.

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.

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

For the avoidance of doubt, the general provisions for Access Rights provided for in this Section 9 are applicable also to Software.

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 respective Software documentation in any particular form or detail, but only as available from the Party granting the Access Rights.

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 a period of 5 years after the final payment of the Granting Authority (the Coordinator notifies the Associated Partner(s) about the date of the final payment):

- 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 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 provided that 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 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;
- 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 10.7 hereunder.

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 unauthorised disclosure, misappropriation or misuse of Confidential Information after it becomes aware of such unauthorised 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 or - in the case of an Associated Partner - with a reporting requirement from its national funding authority, 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 (subject always to the applicable law governing such disclosure).

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 for simplified transfer according to Section 8.3.2)
- Attachment 4 (Identified entities under the same control)
- Attachment 5 (NDA for External Expert Advisory Board agreed under Section 6)

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 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 4.3, 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 authorised 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 6.3.7 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 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 under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules.

The place of arbitration shall be Brussels if not otherwise agreed by the conflicting Parties.

The award of the arbitration will be final and binding upon the Parties.

Nothing in this Consortium Agreement shall limit the Parties' right to seek injunctive relief in any applicable competent court.

11.9 WHO Special Provisions for IARC

With regard to Party No.21, hereinafter “IARC”, as part of the World Health Organization (WHO) and the United Nations, an international organisation (IO) as defined under Art. 10.2 of the Grant Agreement, the provisions contained in this Section 11.9 prevail over any other provisions in this Consortium Agreement (which includes its core text, its Attachments and any other document referred to therein), and will survive the expiration or early termination of this Consortium Agreement.

11.9.1 Reference Law: Concerning IARC, any matter relating to the interpretation or application of this Consortium Agreement not covered by its terms shall be resolved by reference to the law of Belgium, supplemented, where appropriate, by the general principles governing the law of international organisations and the rules of general international law.

11.9.2 Privileges and Immunities - Disputes: Nothing in this Consortium Agreement shall be interpreted as a waiver of the privileges and immunities accorded to IARC, as part of WHO, by its constituent documents or international law. As such, IARC is not subject to any national or EU legislation, jurisdiction or enforcement measures. Any dispute relating to the interpretation or application of this Consortium Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the Parties or, in the absence of agreement, in accordance with the rules of arbitration of the International Chamber of Commerce. The Parties shall accept the arbitral award as final.

11.9.3 Regulatory Framework: Notwithstanding anything to the contrary in this Consortium Agreement, all of IARC’s actions, obligations, and undertakings within and for the purpose of the Project shall be conducted, pursuant to the terms of this Consortium Agreement, subject always to IARC/WHO’s statute, regulations, rules, policies and procedures, as adopted by its governing bodies (the “IARC/WHO Regulatory Framework”).

11.9.4 Data Protection: Where required and applicable, IARC shall ensure an appropriate protection of personal data in accordance with the IARC/WHO Regulatory Framework. Specifically, in lieu of the applicable data protection regulations or legislation referred to in Section 4.5 of this Consortium Agreement, IARC complies with the Personal Data Protection and Privacy Principles for UN System Organizations, UN-HCLM 2018 (the “UN Principles”), adopted by the UN High-Level Committee on Management at its 36th Meeting on 11 October 2018, the WHO Personal Data Protection Policy and the IARC Data Protection Policy.

11.9.5 Audits: With regard to IARC, the “Agreement on the application of the verification clause to operations administered by the United Nations and financed or co-financed by the European Union” annexed to the “Financial and Administrative Framework Agreement” concluded by the Union, represented by the Commission, and the United Nations on 29.04.2003 (also referred to as the "FAFA" - to which WHO adhered on the 11.12.2003), as amended with effect from 01.01.2014, prevails over this Consortium Agreement with regard to any provisions dealing with the same issues.

12 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. The Parties agree that this Consortium Agreement may be executed by electronic signatures in separate counterparts, which shall be considered as equivalent to an original signature for all purposes and shall have the same force and effect as an original signature.

STICHTING EUROPEAN UROLOGICAL FOUNDATION

ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM

STICHTING EUROPESE STUDIE PROSTAATKANKER SCREENING

USTAV ZDRAVOTNICKYCH INFORMACI A STATISTIKY CESKE REPUBLIKY

UNIVERSITAIR MEDISCH CENTRUM UTRECHT

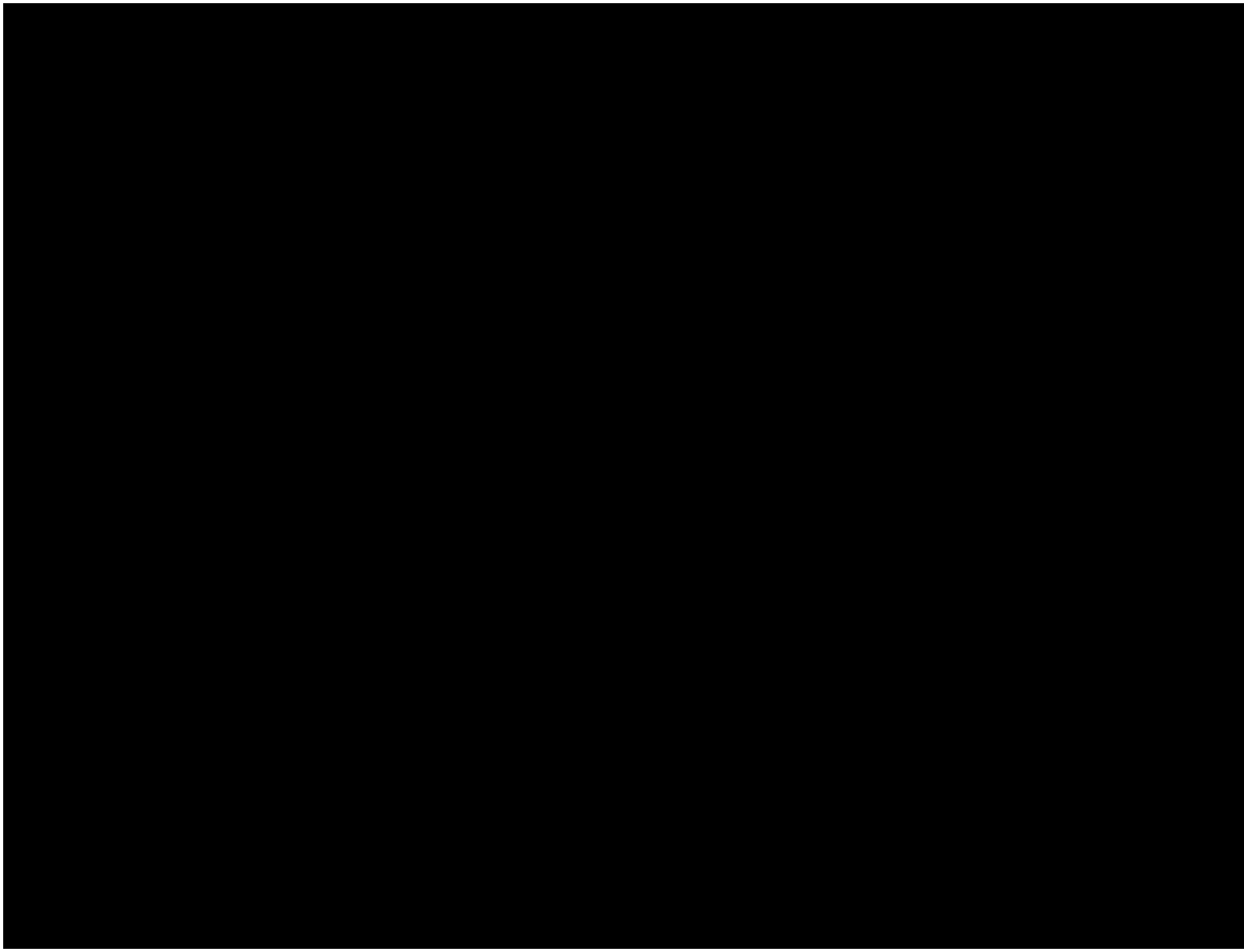
EUROPEAN CANCER ORGANISATION

DOLNOSLASKIE CENTRUM ONKOLOGII, PULMONOLOGII I HEMATOLOGII

NARODOWY INSTYTUT ZDROWIA PUBLICZNEGO PZH – PANSTWOWY INSTYTUT BADAWCZY

CONSELLERIA DE SANIDADE DE GALICIA

ALTHAIA XARXA ASSISTENCIEL UNIVERSITARIA DE MANRESA FUNDACIO PRIVADA



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HEALTH SERVICE EXECUTIVE

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UNIVERSITY COLLEGE DUBLIN, NATIONAL UNIVERSITY OF IRELAND, DUBLIN

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MOVEMBER FOUNDATION EV

INTERNATIONAL AGENCY FOR RESEARCH ON CANCER

EUROPEAN SOCIETY OF UROGENITAL RADIOLOGY

EUROPA UOMA

THE CZECH UROLOGICAL SOCIETY

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

PARTY 2

As to Erasmus Universitair Medisch Centrum Rotterdam it is agreed between the Parties that, to the best of their knowledge, 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 restrictions and/or conditions for implementation (Article 16.4 Grant Agreement and its Annex 5, Section “Access rights to results and background”, sub-section “Access rights to background and results for implementing the Action”)**	**Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section “Access rights to results and background”, sub-section “Access rights for exploiting the results”)**
Prostate cancer risk calculator	The risk calculator is freely available on the internet and will be used in the pilot studies	Exploitation is not allowed

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

PARTY 3

As to Stichting Europese Studie Prostaatkanker Screening (ERSPCF) it is agreed between the Parties that, to the best of their knowledge, 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 restrictions and/or conditions for implementation (Article 16.4 Grant Agreement and its Annex 5, Section “Access rights to results and background”, sub-section “Access rights to background**	**Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section “Access rights to results and background”, sub-section “Access rights for exploiting the results”)**

	and results for implementing the Action")	
ERSPC/ERSPC Foundation will bring in knowledge and knowhow on screening for prostate cancer.	No specific restrictions - as this input is based on knowledge and knowhow on screening for prostate cancer.	No specific restrictions - as this input is based on knowledge and knowhow on screening for prostate cancer.

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

PARTY 4

PARTY 5

PARTY 6

PARTY 7

PARTY 8

PARTY 9

PARTY 10

PARTY 11

PARTY 12

PARTY 13

PARTY 14

As to Universiteit Gent (UG) it is agreed between the Parties that, to the best of their knowledge, 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 restrictions and/or conditions for implementation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the Action")**	**Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights for exploiting the results")**

Expertise in health economic evaluation of screening programmes	No specific restrictions	No specific restrictions
Expertise in systematic literature review of cost-effectiveness studies (soft IP); not to be kept confidential	No specific restrictions	No specific restrictions

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

PARTY 15

PARTY 16

PARTY 17

PARTY 18

PARTY 19

PARTY 20

As to International Agency for Research on Cancer (IARC) it is agreed between the Parties that, to the best of their knowledge, 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 restrictions and/or conditions for implementation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the Action")**	**Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights for exploiting the results")**
Any data, materials, know-how, expertise, techniques and methods, and any other intellectual property rights of IARC that are necessary for the implementation of the Project	Access Rights will be granted to the extent IARC's Background is Needed for implementation of the Project, and to the extent that such Background is not subject to specific terms and conditions through existing agreements that may hinder or prohibit the	Any other use or exploitation of IARC's Background will be subject to a separate agreement to be negotiated in good faith with IARC.

	envisaged Access Rights. IARC's Background will be made available for the duration of, and for the purpose of research/ academic activities within the Project.	

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

PARTY 21

PARTY 22

PARTY 23

PARTY 24

As to EPSRC it is agreed between the Parties that, to the best of their knowledge, 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 restrictions and/or conditions for implementation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the Action")**	**Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights for exploiting the results")**
ERSPC/ERSPC Foundation will bring in knowledge and knowhow on screening for prostate cancer.	No specific restrictions - as this input is based on knowledge and knowhow on screening for prostate cancer.	No specific restrictions - as this input is based on knowledge and knowhow on screening for prostate cancer.

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

Attachment 2: Accession document

ACCESSION

of a new Party to

PRAISE-U 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 made 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]

[INSERT NAME OF THE COORDINATOR]

Signature(s)

Name(s)

Title(s)

Attachment 3: List of third parties for simplified transfer according to Section 8.3.2.

[to be completed if relevant/required]

Attachment 4: Identified entities under the same control according to Section 9.5

[to be completed if relevant/required]

Attachment 5: NDA for Scientific Advisory Board / Ethics Advisory Board agreed under Section 6

THIS NON DISCLOSURE AGREEMENT (this "**Agreement**") is made and entered into as of the [insert date] (the "**Effective Date**"), by and between:

[X] Consortium Members, as defined below and listed in Exhibit 1;

and

[insert Recipient's name and Recipient's address] ("**Recipient**")

WHEREAS,

(A) The parties intend to disclose/receive confidential information for the purpose of facilitating discussions between the Consortium Members and the Recipient;

(B) The Consortium Members have formed a consortium under the Innovative Medicines Initiative 2 ("**IMI**") for the purpose of establishing the project called PRAISE-U (the "**Action**") and are parties to the PRAISE-U Consortium Agreement, as defined below, supported by the IMI2 Joint Undertaking;

(C) The Consortium Members have authorized [name of authorized company or institution] (the "**Mandate Holder**") to execute this Agreement on behalf of the Consortium Members.

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, the parties hereto agree as follows:

1. DEFINITIONS

- "**Affiliate**" shall mean any legal entity that is under the direct or indirect control of a party, under the same direct or indirect control as a party, or is directly or indirectly controlling a party, control taking any of the following forms: (a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity; (b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.
- "**Confidential Information**" shall mean any and all information that is disclosed on or after the Effective Date whether orally or in written, electronic or other tangible form by any of the Consortium Members (each referred to as a "**Disclosing Party**" and collectively as the "**Disclosing Parties**") to any Recipient that relates to the Action.
- "**Consortium Members**" shall mean the parties to the Innovative Medicines Initiative Consortium Agreement for PRAISE-U effective as of *[…]* ("*[X]* **Consortium Agreement**") as listed at Exhibit 1.

2. PURPOSE OF DISCLOSURE

The Confidential Information is being disclosed to the Recipient for the purpose of facilitating discussions between Consortium Members and the Recipient:

- in order to engage in discussions regarding the provision of providing independent advice to *[insert the applicable:* "the *[specify committee]* committee of the Action"; *or* "the various committees in the Action" or "the consortium of the Action as such";
- in order to engage in discussions regarding the accession of the Recipient to the Action consortium in compliance with the Consortium Agreement;
- in order to engage in discussions regarding a collaboration between the Action consortium and the Recipient;

(the "**Purpose**").

3. MAINTENANCE OF CONFIDENTIALITY: NON-USE OBLIGATIONS

3.1 Each Disclosing Party's Confidential Information shall be kept confidential by the Recipient and, except as otherwise permitted herein, shall not be disclosed by the Recipient to any third party without first obtaining the Disclosing Party's prior written consent to such disclosure. The Recipient shall protect the Confidential Information in the same manner it protects its own confidential information of a similar nature, which shall be at least a reasonable standard of care. Recipient may disclose the Confidential Information only to its officers, employees, consultants and/or Affiliates on a need-to-know basis, provided that the Recipient will have executed or shall execute appropriate written agreements with its employees, consultants and Affiliates sufficient to enable compliance with all the provisions of this Agreement with respect to the Confidential Information. The Recipient shall be liable for any damage caused by or resulting from any unauthorized disclosure of the Confidential Information by the Recipient's employees, consultants or Affiliates.

3.2 The Confidential Information shall not be utilized by the Recipient, except for the Purpose permitted herein, without first obtaining the Disclosing Party's prior written consent to such use.

4. EXCLUDED INFORMATION

4.1 Confidential Information shall not include any information which:

- at the time of disclosure is in the public domain;
- after disclosure becomes part of the public domain, except through breach of this Agreement by Recipient;
- Recipient can demonstrate by reasonable proof was in Recipient's or any of its Affiliates' possession prior to the time of disclosure by a Disclosing Party hereunder, and was not acquired directly or indirectly from a Disclosing Party;
- Recipient can demonstrate by reasonable proof was developed by or on behalf of Recipient or its Affiliates independent of and without reference to the Confidential Information; or

- becomes available to Recipient or its Affiliates from a third party who did not acquire such information directly or indirectly from a Disclosing Party and who is not otherwise prohibited from disclosing such information.

4.2 Confidential Information shall not be deemed to be or have become public knowledge merely because any part of such Confidential Information is embodied in general disclosures or because individual features, components or combinations thereof are known or become known to the public.

5. NOTIFICATION OF MANDATORY DISCLOSURE

5.1 Recipient may disclose that portion of Confidential Information that is required by law to be disclosed, provided that, to the extent practicable, the Disclosing Party is first given advance notice of the required disclosure and an adequate opportunity to seek appropriate legal relief to prevent such disclosure or limit use and further disclosure of the Confidential Information. Recipient shall cooperate with the Disclosing Party in seeking an appropriate relief or remedy and shall use reasonable efforts to secure confidential treatment of any Confidential Information disclosed.

5.2 If, in the absence of such legal relief or other remedy, the Recipient is nonetheless required to disclose any part of the Confidential Information, the Recipient may disclose such Confidential Information without liability hereunder, provided that the Recipient shall furnish only such portion of the Confidential Information which the Recipient is legally required to disclose. For the avoidance of any doubt, if the Recipient is required to disclose Confidential Information pursuant to the Recipient's obligations under the provisions of the Freedom of Information Act 2000 or any equivalent law or regulation in any other applicable jurisdiction, the Recipient shall in all instances seek to apply the exemptions under that Act.

6. TERM

This Agreement shall come into effect on the effective date. It may be terminated with respect to further disclosures upon thirty (30) days' prior written notice. This Agreement shall cover Confidential Information disclosed within a period of two (2) years from the effective date. After such period, the obligations accrued under this Agreement shall survive for a period of seven (7) years after disclosure of the Confidential Information, unless otherwise prescribed by local applicable law or regulations.

7. NO OTHER OBLIGATION; NO LICENSE

This Agreement shall not be construed, by implication or otherwise, as an obligation to enter into any further agreement relating to the Confidential Information or as the grant of a license or other ownership rights other than to use the Confidential Information for the Purpose. Confidential Information disclosed by a Disclosing Party to the Recipient, as well as any right which could result from such Confidential Information, remains the exclusive property of that Disclosing Party. Recipient shall not reverse-compile, reverse-assemble or reverse-engineer the Confidential Information or any part of it.

8. NO REPRESENTATION OR WARRANTY

A Disclosing Party makes no representations or warranties either express or implied with respect to the Confidential Information and specifically disclaims any implied warranty of non-infringement or merchantability, satisfactory quality or fitness for purpose.

9. RETURN OF CONFIDENTIAL INFORMATION

At the request of the Disclosing Party or, at the latest, on completion of the Purpose, and in the absence of any further written agreement between the parties, the Recipient shall cease all use of the Confidential Information and shall promptly return to each Disclosing Party all of its Confidential Information which is in tangible form, except that the Recipient shall be permitted to retain one (1) copy of the Confidential Information so that any continuing obligations may be determined. The return of the Confidential Information will not affect Recipient's obligation to observe the confidentiality and non-use obligations set out in this Agreement. The provisions of this clause 9 shall not apply to copies of electronically exchanged Confidential Information or copies thereof which must be stored by the Recipient according to the provisions of mandatory applicable law.

10. NO PUBLICITY

Subject to clause 5, the parties shall not directly or indirectly cause or permit (a) the oral or written release of any public statement referring to the existence or terms of this Agreement, or (b) any use of the other parties' name, logo or trademarks, without the other parties' prior written consent.

11. RIGHTS OF THIRD PARTIES

Each Consortium Member shall have a right to enforce the terms of this Agreement.

12. ASSIGNMENT

This Agreement shall not be assigned by the Recipient without the prior written consent of the Disclosing Parties, whose consent may be withheld at the Disclosing Parties' sole discretion, and any purported assignment without such consent shall be void; provided, however, the Recipient may without such consent assign this Agreement in connection with the sale or transfer of all or substantially all of its business or in connection with a merger or other consolidation with another entity.

13. SEVERABILITY

If any provision of this Agreement is found to be invalid, illegal or unenforceable by a court of competent jurisdiction, the validity, legality and enforceability of the remaining provisions shall in no way be affected or impaired thereby. The parties shall in this case replace the invalid,

illegal or unenforceable provision with a provision that is as close as possible to the economic effect of the invalid, illegal or unenforceable provision.

14. ENTIRE AGREEMENT; AMENDMENTS; WAIVER

This Agreement contains the entire understanding between the parties hereto with respect to the subject matter contained herein and supersedes all prior written or oral communications, negotiations, understandings or agreements of any kind with respect to such subject matter. No amendment or modification of this Agreement shall be effective except by a written instrument referring to this Agreement and signed by authorized representatives of both parties. Failure by a party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor operate as a waiver in other instances.

15. GOVERNING LAW; DISPUTE RESOLUTION; HEADINGS

This Agreement shall be governed by and construed in accordance with the laws of Belgium, without giving effect to any of its conflict of laws principles. Exclusive place of jurisdiction shall be Brussels. The headings in this Agreement are for convenience of reference only and shall not affect its interpretation.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in *[insert number of necessary duplicates]* in their own name and in case of the Mandate Holder in addition in the name and on behalf of their respective Consortium Members as their duly authorized representative.

(**Mandate Holder**) *name of authorized company or institution;*

_____	_____
Name:	Name:
Function:	Function:
Place: _____	Place: _____
Date: _____	Date: _____

For acknowledgment:

Ghent University:

Place & Date: _____

Signature of the Rector (Ghent University): _____

[Add further signature lines for further signatures on behalf of signing entities, if requested by such signing entities]

ATTACHMENT 6: BUDGETARY TABLE AS REFERRED TO AT SECTION 7.1.1

Note that this table includes two tabs – the first is for adjusted budget (GAP) and the second is for internal budget allocation

PRAISE-U_overview_
budget_adjustments v