

# CONSORTIUM AGREEMENT FOR IHI ACTION “[NAME OF IHI PROJECT]”

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THIS CONSORTIUM AGREEMENT DATED AS OF THE DATE OF LAST SIGNATURE AND EFFECTIVE AS OF THE EFFECTIVE DATE OF THE GRANT AGREEMENT IS MADE BETWEEN:

- (1) [.....], whose administrative offices are at [.....];
- (2) [.....], whose administrative offices are at [.....]; and
- (3) [.....], whose administrative offices are at [.....].

**WHEREAS:**

The Beneficiaries have submitted a proposal for the Action [*Insert name of project*] to IHI JU as part of the Innovative Health Joint Undertaking programme, a public-private partnership between the European Union, the European Coordination Committee of the Radiological, Electromedical and healthcare IT Industry (COCIR), the European Federation of Pharmaceutical Industries and Associations (EFPIA), EuropaBio, MedTech Europe, and Vaccines Europe.

The IHI JU has announced its intention to make the Grant in respect of the Action, subject to the terms of the Grant Agreement, and subject to the Beneficiaries entering into an agreement governing their collaboration (the “**Consortium Agreement**”).

Whereas, the IHI JU operates under the general rules of the Health Europe programme, as well as under the rules applicable to joint undertakings under Horizon Europe.

NOW, THEREFORE, the Parties hereto enter into the following Consortium Agreement:

## 1. DEFINITIONS

**“Access Rights”** means rights to use Results or Background under the terms and conditions laid down in the Grant Agreement and this Consortium Agreement.

**“Action”** also referred as **“Project”** means all the activities, including research activities, carried out by the Beneficiaries as detailed in Annex 1 of the Grant Agreement.

**“Action Objectives”** means the objectives of the Action as defined in Annex 1 of the Grant Agreement.

**“Action Share”** means the value of each Beneficiary’s total contribution (whether considered as eligible for IHI JU funding or not) to the Action as outlined in Annex 1 of the Grant Agreement;

**“Additional Data, Know- How or Information”** means any data, Know-How, or information useful or necessary to implement the Action but generated outside the Action after the Effective Date, provided by a Beneficiary for use in the Action, and excluding any Data Contributed as In-Kind. Additional Data, Know-How or Information are identified by the Beneficiaries in accordance with Clause 5.1.4 of this Consortium Agreement.

**“Advisory Agreement”** shall have the meaning set forth in Clause 11.1.4 of this Consortium Agreement.

**“Affiliated Entity”** means entities directly involved in the Action which are listed in Article 8 of the Grant Agreement and which have a legal or capital link to a Beneficiary (which is neither limited to the action nor established for the sole purpose of its implementation), which implement part of the Action, and which are allowed to charge costs directly to IHI JU.

**“Agreement on Background”** means Appendix 5 of this Consortium Agreement identifying Background.

**“Allocated Work”** means the activities allocated to a Beneficiary in accordance with Annex 1 of the Grant Agreement.

**“Anonymous”** means with regard to data that such data do not relate to an identified or identifiable natural person.

**“Anonymisation”** or **“Anonymised”** means that the concerned data do no longer relate to an identified or identifiable natural person. This means that Personal Data are rendered Anonymous in such a manner that the Data Subject is not or no longer identifiable (e.g. because all direct and indirect personal identifiers are removed from the data by for instance implementing technical measures so that such data can no longer be linked back to the initial Data Subject and the Data Subject can therefore not be re-identified).

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

**“Associated Partner”** means any legal entity cooperating with a Beneficiary and identified in Article 9.1 of Grant Agreement. Associated Partners do not receive IHI JU funding, and do not necessarily have a (capital or legal) link to a Beneficiary.

**“Background”** means any data, Databases, Know-How or information, whatever its form or nature, tangible or intangible, including any rights such as Intellectual Property rights, that are: (i) held by the Beneficiaries prior to their accession to the Grant Agreement, and (ii) identified

by the Beneficiaries in accordance with Clause 5.1.1 or 5.1.2 of this Consortium Agreement as needed for implementing the Action or for Exploiting its Results.

**[OPTIONAL: if needed for the Action specific definitions for certain subcategories of Background can be worked out on an as need basis An example is provided for below.]**

Background consists of (a) XX Background; (b) Software Background; (c) Background Databases and (d) Other Background, such categories defined as follows:

(a) **“XX Background”** means any Background which is [...];

(b) **“Software Background”** means any Background which is Software;

(c) **“Background Database”** means any Background which is a Database; and

(d) **“Other Background”** any Background other than (a), (b), or (c).]

**“Beneficiary”** means a legal entity who has signed the Grant Agreement with the IHI JU, either its main body or via a form of accession, and this Consortium Agreement, either by signing the main body of this Consortium Agreement or via a Form of Accession. There are two types of Beneficiaries in the Action, i.e.:

- Beneficiaries Not Receiving IHI JU Funding; and
- Beneficiaries Receiving IHI JU Funding.

**“Beneficiary Not Receiving IHI JU Funding”** means Beneficiaries belonging to any of the following categories, in each case to the extent not receiving IHI JU funding for the Action:

- Industrial Beneficiaries;
- Contributing Partners; and
- Other legal entities participating in the Action as a Beneficiary but not receiving funding for the Action (e.g. because they are established in a third country not associated to Horizon Europe).

**“Beneficiaries Receiving IHI JU Funding”** means any Beneficiary receiving IHI JU funding for the Action.

**“CDA”** shall have the meaning set forth in Clause 11.1.2 of this Consortium Agreement.

**[OPTIONAL: “Chairperson of the Executive Committee” shall have the meaning set forth in Clause 10.3.3.1 of this Consortium Agreement.]**

**“Chairperson of the General Assembly”** shall have the meaning set forth in Clause 10.5.3.1 of this Consortium Agreement.

**“Chairperson of the Steering Committee”** shall have the meaning set forth in Clause 10.4.3.1 of this Consortium Agreement.

**“Communication”** means any communication, other than a Dissemination, concerning the Project.

**“Communication Guidelines”** mean the guidelines to be adhered to when making a Communication, as more particularly set out in Appendix 7.

**“Confidential Information”** means any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed. If information has been identified as confidential only orally, it will be considered to be Confidential Information only if such confidentiality is confirmed in writing within thirty (30) Days of the oral disclosure. Notwithstanding the foregoing, Personal Data will always be considered as Confidential Information.

**“Consortium”** means the group of Beneficiaries that are parties to this Consortium Agreement.

**“Consortium Agreement”** means this consortium agreement and all of its appendices, together with any amendments validly agreed in writing amongst the Beneficiaries.

**“Contributing Partner”** means any legal entity other than a member of the IHI JU, or a constituent entity of a member or an affiliated entity of either, that supports the IHI JU objectives in its specific area of research and whose application has been approved in accordance with Article 9 of the JUs Regulation and which is participating in the Action as a Beneficiary.

**“Controlled License Terms”** means, in relation to Software and Database Platform Frameworks (as defined in the definition of Database) only, terms imposed by a Third Party in any license that require that the use, copying, modification and/or distribution of Software or Database Platform Framework and/or of any copyright work that is a modified version of or is a derivative work of such Software or Database Platform Framework (in each case, **“Derivative Software/Database Platform”**) be subject, in whole or in part, to one or more of the following:

- a) that the Source Code be made available as of right to any third party on request, whether royalty-free or not;
- b) that permission to create modified versions or derivative works of the Software, Database Platform Framework, or Derivative Software/Database Platform be granted to any third party;
- c) that a royalty-free license relating to the Software, Database Platform Framework or Derivative Software/Database Platform be granted to any third party.

For the sake of clarity, terms in any license that merely permit (but do not require any of) these things are not Controlled License Terms.

**“Coordinator”** means the Beneficiary in charge of the grant administration, to whom are assigned the specific tasks identified in Article 7(b) of the Grant Agreement. The Coordinator’s roles and responsibilities are further defined in Clause 10.1 of this Consortium Agreement. For the avoidance of doubt, these responsibilities do not include the responsibilities of the Project Leader as further defined Clause 10.2 of this Consortium Agreement.

**“Database”** means (i) collection of data, images, works or other independent elements, arranged in a systematic or methodical manner, and individually accessible by electronic means or by any other means, whatever the medium, that have been the subject of a constitution, a matching, and / or an annotation, and / or an interpretation, and/or curation and / or other form of added value or by technical means allowing and / or facilitating said annotation; and (ii) database management systems managing and controlling access to such data, images, works or other independent elements (also referred to herein as **“Database Platform Framework”**), and includes (iii) the associated Database Documentation.

**“Database Documentation”** means documentation in written text and illustrations in relation to a Database and provides a description of what a particular database does or shall do, how it operates and how it is supposed to be used. It includes the respective database manuals and documentation for using the API.

**“Data Contributed as In-Kind”** means data and/or information, useful or necessary to implement the Action but generated outside the Action after the Effective Date, and provided by a Beneficiary Not Receiving IHI JU Funding for use in the Action against an in-kind value agreed with the IHI JU. Data Contributed as In-Kind are identified by the Beneficiaries in accordance with Clause 6.2.1 of this Consortium Agreement.

**“Data Management Plan”** means the Deliverable developed in the Project in line with Annex 1 of the Grant Agreement, that amongst others may describe how Personal Data are Processed, and/or how data will be collected, harmonized, standardized, quality controlled, stored, accessed, managed and/or otherwise used, both during and after the Project. The Data Management Plan may also include, subject to the provisions set out in this Consortium Agreement (including the provisions on Access Rights), the (minimum) terms & conditions for the contribution to and access and use of data the case being via a database or platform within the Project. Once available, the Data Management Plan (and any future updates thereof) will become an integral part of this Consortium Agreement (Appendix 14).

**“Data Subject”** means an identified or identifiable natural person. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

**“Data Protection Legislation”** shall have the meaning set forth in Appendix 3.

**“Days”** means calendar days, as the case may be, unless otherwise specified.

**“Defaulting Beneficiary”** means a Beneficiary in breach of any obligation(s) under the Grant Agreement and/or this Consortium Agreement.

**“Deliverables”** means a distinct output of the Action meaningful in terms of the Action Objectives and constituted by a report, a document, a technical diagram, Software, etc.

**“Direct Exploitation”** shall have the meaning set forth in the definition of Exploitation.

**“Disclosing Beneficiary”** shall have the meaning set forth in Clause 9.1 of this Consortium Agreement.

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

**“Donor”** means the natural person to whom the Human Samples refer.

**“Effect of the Action”** means effects generated/produced by activities inside the Action. Effects of the Action exclude effects generated/produced by activities outside of the Action — be it before the Action starts, during its course or after it ends.<sup>1</sup>

**“EFPIA”** means the European Federation of Pharmaceutical Industries and Associations.

**“Eligible Costs”** means those eligible costs incurred by a Beneficiary in carrying out its Allocated Work; the nature of such costs is more particularly detailed in Article 6 of the Grant Agreement.

**[OPTIONAL: “Ethics Advisory Board”** shall have the meaning set forth in Clause 10.9 of this Consortium Agreement.]

**“Excluded Beneficiary”** shall have the meaning set forth in Clause 13.3.3 of this Consortium Agreement.

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<sup>1</sup> For more information on the concept and scope of “Results”, see (i) the webinars published by the European Commission which can be found at <https://ec.europa.eu/research/participants/docs/h2020-funding-guide/other/event210609.htm>; and (ii) the Annotated Model Grant Agreement for EU Funding Programmes 2021-2027 which can be found at [https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/aga\\_en.pdf](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/aga_en.pdf) (annotations to Article 16, page 112).



[**OPTIONAL:** “Executive Committee” shall have the meaning set forth in Clause 10.3 of this Consortium Agreement.]

“**Exploitation**” means the use of Results in further research and innovation activities other than those covered by the Action, including among other things, commercial exploitation such as developing, creating, manufacturing and marketing a product or process, creating and providing a service, or in standardisation activities. For the avoidance of doubt, “Exploitation” can be divided into (i) Research Use and (ii) Direct Exploitation.

(i) “**Research Use**” means the use of Results for all purposes other than for implementing the Action or for Direct Exploitation. For the avoidance of a doubt, such use includes but is not limited to the use of Results as a tool in research, development & innovation activities, including but not limited to use as a tool to support clinical research and trials on a product, and in standardization activities linked to such product.

For the avoidance of doubt, the field of Research Use includes use of Results, without limitation:

(a) for pharmaceuticals and vaccines, in:

- all pre-clinical research and development activities,
- all human clinical studies on compounds which were not Results of this Action (to the extent Results are used in such activities, e.g. as a tool),
- all activities relating to developing the ability to commercialize any drug substance or drug product (including process development work),
- all activities relating to seeking, obtaining and/or maintaining any regulatory approvals from regulatory authorities or for the purposes of a medicinal product assessment (as provided for in the applicable local legislation).

(b) for medical devices, medical technologies and imaging techniques, in:

- all pre-clinical research and development activities,
- all clinical studies or data obtained in order to determine the utility of a particular medical device which was not a Result of the Action,
- the use of Results as a tool in all research & development steps taken (including use in tests) for development of a Beneficiary’s own medical device, medical technologies and imaging techniques with a view to ultimately making available to the market such medical device, medical technologies and imaging techniques,
- all activities relating to developing the ability to commercialize any drug substance or drug product (including process development work) in combination with a medical device,
- all tools used in the evaluation of design options for their suitability for commercialization,
- all activities relating to seeking, obtaining and/or maintaining any regulatory approvals from regulatory authorities for new and existing commercial products or for the purposes of registration of a medical device (as provided for in the applicable local legislation).

To illustrate the distinction between Research Use and Direct Exploitation, an example of Research Use is the application of Results (like an animal model or a biomarker) as a

tool for research and clinical research in the discovery, development or commercialisation of pharmaceutical products by for-profit institutions and organisations. However, the commercialization of such biomarker itself as a diagnostic kit would be Direct Exploitation.

(ii) **“Direct Exploitation”** means use for all direct commercialization purposes. For the avoidance of doubt, such use includes directly (i) providing commercial services with (or using) Results, sales of Results (or products incorporating such Results, for instance commercialisation of a diagnostic kit containing a biomarker to the extent the biomarker was a Result), or marketing for commercial services on, or sales of, Results, (ii) developing a Result (for instance clinical trial on an asset which is a Result) with a view to directly commercialize such Result (or products incorporating such Result), and (iii) manufacturing a Result (or products incorporating such Result), with a view to directly commercialize such Result (or products incorporating such Result).

**“Extended Affiliate”** means any legal entity that is under the direct or indirect control of a Beneficiary or is under the same direct or indirect control as that Beneficiary, or is directly or indirectly controlling that Beneficiary. Control may take any of the following forms:

- a) the direct or indirect holding of more than fifty percent (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.

However, the following relationships between legal entities shall not in themselves constitute controlling relationships:

- (i) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than fifty percent (50%) of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
- (ii) the legal entities concerned are owned or supervised by the same public body.

**“Fair and Reasonable Conditions”** means the appropriate conditions, including possible (a) Financial Terms, or (b) Royalty-Free Conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the Results or Background to which Access Rights are requested and/or the scope, duration or other characteristics of the Exploitation (Research Use and/or Direct Exploitation) envisaged.

**“Financial Terms”** means, with respect to Fair and Reasonable Conditions for certain Access Rights, those financial terms applicable to the envisaged grant of Access Rights.

**“Force Majeure”** means any situation or event that (a) prevents a Beneficiary from fulfilling its obligations under this Consortium Agreement, (b) was an unforeseeable, exceptional situation and beyond that Beneficiary’s control, (c) was not due to error or negligence on the part of the Beneficiary (or on the part of other Participants 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 shall apply in any interpretation of whether specific circumstances shall constitute an event of Force Majeure.

**“Form of Accession”** means the template which any Third Party contemplating to become a Beneficiary must sign before acceding to this Consortium Agreement as a Beneficiary, as more particularly set out in Clause 16.2 of this Consortium Agreement.

**“General Assembly”** means the governance body responsible for the determination of policies, strategic direction and decision making in relation to the overall management of the Action as further defined in Clause 10.5 of this Consortium Agreement.

**“Grant”** means the IHI JU’s financial contribution to the Action as determined by the Grant Agreement.

**“Grant Agreement”** means Grant Agreement No. [REDACTED] (including its annexes and any amendments thereto) entered into between the Beneficiaries and the IHI JU for the undertaking by the Beneficiaries of the Action.

**“Horizon Europe Regulation”** means Regulation (EU) 2021/695 of 28 April 2021 establishing Horizon Europe.

**“Human Sample”** means any human tissue or human biological material of a Donor, including any portion of an organ, any tissue, skin, bone, muscle, connective tissue, blood, cerebrospinal fluid, cells, gametes, or sub-cellular structures such as DNA, and/or any copy of such Donor’s human tissue or human biological material (such as stem cells, cell lines or xenograft tissues which are genetically identical to the initially collected human materials of a Donor); and any human biological product, including, but not limited to, hair, nail clippings, teeth, urine, faeces, breast milk, and sweat but excluding derivatives and/or non-human progeny (for example a viral or bacterial strain obtained from any human biological material of the Donor).

**“IHI”** means the Innovative Health Initiative.

**“IHI JU”** means the IHI Joint Undertaking, a European Union body established by Council Regulation (EU) No. 2021/2085 of 19 November 2021.

**“In Kind Contributions to Additional Activities”** or **“IKAA”** means contributions by the private members of the IHI JU, their constituent entities or the affiliated entities of either, consisting of the costs incurred by them in implementing additional activities less any contribution to those costs from the IHI JU and from the participating states of the IHI JU where 'additional activities' are activities that do not receive financial support from the IHI JU or any other Union funding programme but (i) contribute to its objectives; (ii) are set out in the annual additional activities plan (the IKAA Plan) annexed to the IHI JU work programme, or alternatively, in a plan for additional activities included in relevant project proposals; (iii) are carried out in the Union or in countries associated with Horizon Europe (irrespective of the country of establishment of the entity incurring the related costs). Additional activities can be either Programme specific or Project specific: Programme-specific additional activities contribute to the uptake of results from IHI JU, IMI2 JU, IMI JU projects or have a significant added value for the Union; Project-specific additional activities contribute towards the achievement of objectives of the IHI JU funded projects, or the dissemination, sustainability or exploitation of IHI JU project results.

**“IKAA Output”** means any tangible or intangible output of performing the additional activities referred to in the definition of IKAA, such as data, Know-How or information, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including Intellectual Property rights.

**[OPTIONAL: “Imaging Equipment”** means imaging equipment (such as MR, CT or ultrasound systems, post processing reading stations...), labelled or not and used for investigational purposes.]

**“Indemnitees”** shall have the meaning set forth in Clause 12.2.1 of this Consortium Agreement.

**“Indemnitor”** shall have the meaning set forth in Clause 12.2.1 of this Consortium Agreement.

**“Industrial Beneficiary”** means a Beneficiary which is, or which affiliated entity is, a member of the European Coordination Committee of the Radiological, Electromedical and healthcare IT Industry (COCIR), the European Federation of Pharmaceutical Industries and Associations (EFPIA), EuropaBio, MedTech Europe, or Vaccines Europe.

**“Intellectual Property”** means knowledge in the broadest sense, encompassing e.g. inventions, Software, Databases and micro-organisms, whether or not they are protected by legal instruments such as patents, as referred to in Commission Recommendation C(2008) 1329 of 10.4.2018 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to that recommendation. For the avoidance of doubt and without limitation, Know-How, patent rights, copyrights, database rights, and trade secrets constitute Intellectual Property.

**“Joint Owners”** shall have the meaning set forth in Clause 6.1.3 of this Consortium Agreement.

**“JUs Regulation”** means Regulation (EU) No 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe.

**“Know-How”** means any unpatented technical information (including, without limitation, information relating to inventions, discoveries, concepts, methodologies, models, research, development and testing procedures, the results of experiments, tests and trials, manufacturing processes, techniques and specifications, quality control data, analyses, reports and submissions) that is not in the public domain.

**[OPTIONAL: “LIPAC”** means the legal and intellectual property advisory committee as set out in Clause 10.7 of this Consortium Agreement.]

**“Loss”** or collectively **“Losses”** shall have the meaning set forth in Clause 12.2.1 of this Consortium Agreement.

**“Mandate”** shall have the meaning set forth in Clause 11 of this Consortium Agreement.

**“Materials”** means all types of tangible chemical, biological and/or physical materials and any type of equipment and hardware.

**“Mitigation Plan”** shall have the meaning set forth in Clause 13.3.2 of this Consortium Agreement.

**“Open Access”** means online access, provided free of charge to the end-user, to Research Outputs resulting from the Action, in accordance with Articles 14 and 39(3) of the Horizon Europe Regulation.

**“Participant”** means any entity participating in the Action as a Beneficiary, an Affiliated Entity, an Associated Partner, a Third Party giving in-kind contributions, a Sub-Contractor, or a recipient of financial support to Third Parties.

**“Personal Data”** means any information relating to a Data Subject, including data extracted from Human Samples, if and to the extent they refer or can be referred to an identified or identifiable Donor. Data (including data extracted from Human Samples) that are Anonymized are no longer considered to be Personal Data. Data that are Anonymous are not Personal Data.

**“Process”** or **“Processing”** means, if referred to Personal Data, any operation or set of operations which is performed on Personal Data or sets of Personal Data whether or not by automated means, such as the obtaining, collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure, by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

**“Project”** shall have the meaning set forth in the definition of **“Action”**.

**“Project Leader”** means the Industrial Beneficiary which is i.a. in charge of the overall scientific and Project leadership as further defined in Clause 10.2 of this Consortium Agreement.

**“Project Management Office”** or **“PMO”** means the project management office as set out in Clause 10.6 of this Consortium Agreement.

**“Providing Beneficiary”** shall have the meaning set forth in Clause 8.1.1 of this Consortium Agreement relating to the transfer of Materials.

**“Pseudonymisation”** means processing Personal Data in such a manner that the Personal Data can no longer be attributed to a specific Data Subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organizational measures to ensure that the Personal Data cannot be attributed to an identified or identifiable natural person.

**“Receiving Beneficiary”** shall have the meaning set forth in Clause 9.1 of this Consortium Agreement relating to Confidential Information.

**“Recipient Beneficiary”** shall have the meaning set forth in Clause 8.1.1 of this Consortium Agreement relating to the transfer of Materials.

**“Representative”** means the person chosen by a Beneficiary to represent it on one of the governing bodies of the Consortium as described in Clause 10 of this Consortium Agreement.

**“Results”** means any tangible or intangible Effect of the Action, such as data, new Databases, new Software, Know-How or information, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including Intellectual Property rights. For the avoidance of doubt, “Results” can be subdivided into (i) Action Objective Results and (ii) Sideground Results, but excludes any IKAA Output.

(i) **“Action Objective Results”** means any Results generated during the term of the Action and in the performance of the activities set out in Annex 1 of the Grant Agreement and which are inside the scope of the Action Objectives.

*[OPTIONAL: if needed for the Action specific definitions for certain subcategories of Results can be worked out on an as need basis. An example is provided for below.]*

Action Objective Results consists of (a) XX Results; (b) Software Results; (c) Database Results, (d) Imaging Results, and (e) Other Results, such categories defined as follows:)

(a) **“XX Results”** means any Action Objective Result which are ... ;

(b) **“Software Results”** means any Action Objective Results which is a Software.  
*[Note: depending on how the Access Rights on Software Results are approached, certain key deliverables such as predictive models/algorithms, empty database platform, etc. can be excluded from Software Results and included in a specific category of Results with customized Access Rights.]*

(c) **“Database Results”** means any Action Objective Result which is a Database.

(d) **“Imaging Results”** means any Action Objective Results which are XX.

(e) **“Other Results”** any Action Objective Results other than (a), (b), (c), or (d).

(ii) **“Sideground Results”** means any Results generated during the term of the Action and under the performance of the activities set out in Annex 1 of the Grant Agreement, but which are outside the Action Objectives.

**“Research Outputs”** means Results generated by the Action to which access can be given in the form of scientific publications, data or other engineered outcomes and processes such as Software, algorithms, protocols and electronic notebooks.

**“Research Use”** shall have the meaning set forth in the definition of Exploitation.

**“Retiring Beneficiary”** shall have the meaning set forth in Clause 13.3.2 of this Consortium Agreement.

**“Royalty-Free Conditions”** means, for the envisaged grant of Access Rights, free of charge or any other payment.

[**OPTIONAL: “Scientific Advisory Board” or “SAB”** shall be further defined in Clause 10.8 of this Consortium Agreement.]

**“Software”** means a software program – other than a Database - being 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. A Software shall constitute its corresponding (i) Software Documentation, (ii) Object Code and (iii) Source Code.

- (i) **“Object Code”** means Software in machine-readable compiled and/or executable form including, but not limited to, binary code form and in form of machine-readable libraries used for linking procedures and functions to other Software.
- (ii) **“Source Code”** means Software in human-readable form normally used to make modifications to it, including but not limited to comments and procedural code such as job control language and scripts to control compilation and installation.
- (iii) **“Software Documentation”** means documentation in written text and illustrations in relation to a Software and provides a description of what a particular software does or shall do, how it operates and how it is supposed to be used. It includes the respective software manuals and documentation for using the API.

**“Steering Committee”** shall have the meaning set forth in Clause 10.4 of this Consortium Agreement.

**“Sub-Contractor”** means a Third Party which has entered into an agreement on business conditions with one or more Beneficiaries, in order to carry out at least part of such Beneficiary’s Allocated Work in accordance with Article 9.3 of the Grant Agreement.

**“Terminated Beneficiary”** means any Beneficiary whose participation to the Action is terminated pursuant to Article 32 of the Grant Agreement.

**“Third Party”** means a legal entity or person which is not a party to the Grant Agreement, including a legal entity or person only providing resources to a Beneficiary.

**“Third Party Claims”** shall have the meaning set forth in Clause 12.2.1 of this Consortium Agreement.

**“Work Package” or “WP”** means a sub-division of the Action as described in Annex 1 of the Grant Agreement.

**“Work Package Leader(s)”** means the leader(s) of a Work Package. Each WP will have two co-leaders which jointly constitute the Work Package Leaders for purposes of this Consortium Agreement: one of the group of Industrial Beneficiaries and one of the group of Beneficiaries which are not Industrial Beneficiaries.

## **2. PURPOSE & INDEPENDENT CONTRACTING PARTIES**

- 2.1 The purpose of this Consortium Agreement is to specify the Beneficiaries’ collaboration in relation to the Action in accordance with the provisions of the Grant Agreement, by supplementing the contractual provisions of the Grant Agreement to more specifically detail the rights and obligations of the Beneficiaries amongst each other in relation to,

inter alia, financial aspects, performance of the Action, Intellectual Property rights, Material transfer, confidentiality, project management and governance, and liability and indemnification.

- 2.2 This Consortium Agreement is not intended, and nothing contained herein shall be deemed, to create any partnership, agency or joint venture amongst the Beneficiaries or any of the Beneficiaries, nor to establish any other legal entity amongst any or all of the Beneficiaries. Although the term “consortium” is used throughout this agreement, based on the terminology used in the Grant Agreement, the Beneficiaries expressly agree they do not constitute a “consortium” as defined in the Belgian Companies and Association Code.
- 2.3 No Beneficiary shall enter into or have authority to enter into any engagement or make any representation or warranty on behalf of any of the other Beneficiaries or otherwise bind or oblige any other Beneficiary hereto. Each Beneficiary agrees to perform under this Consortium Agreement solely as independent contracting parties.
- 2.4 Each Beneficiary remains to be permitted to carry out any independent projects which are related to the subject matter of this Action. Results, Background, and Confidential Information of the other Beneficiaries may be used by such Beneficiary for the purposes of such other projects insofar and to the extent permitted by this Consortium Agreement.

### **3. FINANCIAL PROVISIONS**

- 3.1 The Action is funded by the Grant [*OPTIONAL: add if relevant for the Action:* and the contribution (in kind and/or in cash) from the Industrial Beneficiaries]. The indicative budget of the Action is specified in Annexes 1 and 2 to the Grant Agreement.
- 3.2 Each Beneficiary eligible to receive IHI JU funding shall maintain financial records in relation to its activities within the Action, including its Affiliated Entities, Associated Partners and Sub-Contractors, according to the Grant Agreement.
- 3.3 The Coordinator shall give each Beneficiary eligible to receive IHI JU funding a minimum of forty-five (45) Days prior written notice of the deadline to produce additional prefinancing or periodic reports as prescribed in the Grant Agreement and each of these Beneficiaries shall be responsible for the preparation and obtaining of a certificate on the financial statements as may be required by the Grant Agreement. The Coordinator must receive these reports timely, with respect to the additional prefinancing and period reports, in order to enable him to meet the sixty (60) Days (after the end of the relevant reporting period) timeline for submission to IHI JU.
- 3.4 The Beneficiaries eligible to receive IHI JU funding agree that their respective entitlements to the Grant shall depend on: (a) the extent to which they shall be able to properly authenticate costs incurred, as Eligible Costs, and (b) the manner in which all Beneficiaries agree how the Action should proceed and the consequent allocation of costs amongst Beneficiaries eligible to receive IHI JU funding [*OPTIONAL: add if relevant for the Action:*, and (c) a go/no go-decision to proceed to the next stage in the Action as outlined in Annex 1 to the Grant Agreement]. Neither the Coordinator nor any of the other Beneficiaries shall be in any way liable or responsible for any justification of costs by a Beneficiary towards the IHI JU.
- 3.5 A Beneficiary that spends less than its allocated share of the budget as set out in Annex 1 of the Grant Agreement or – in case of reimbursement via unit costs - implements less units than foreseen in in Annex 1 of the Grant Agreement 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 Annex 1 of the Grant Agreement will be funded only in respect of duly justified Eligible Costs up to an amount not exceeding that share.

- 3.6 The Coordinator will receive directly the Grant from the IHI JU and undertakes to transfer, in accordance with the Grant Agreement **[OPTIONAL: add if relevant for the Action:, and the go/no go decisions outlined in Annex 1 of the Grant Agreement]**, the appropriate sums to the respective Beneficiaries eligible to receive IHI JU funding without unjustified delay **[OPTIONAL: include different distribution keys if appropriate for the Action, e.g; XX% on receipt of pre-financing, XX% on achievement of milestone Y, etc.]**. The Coordinator will notify each of the Beneficiaries eligible to receive IHI JU funding promptly of the date and amount transferred to its respective bank account and shall give the relevant references. The Coordinator shall hold such funds in trust for the benefit of the other Beneficiaries eligible to receive IHI JU funding until such time such funds are transferred to the Beneficiaries eligible to receive IHI JU funding. 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 IHI JU for the mutual insurance mechanism (as provided for in the Grant Agreement) and for the final payment.
- 3.7 Without prejudice to the provisions of Clauses 4 and 12 of this Consortium Agreement and subject to the provisions of Clause 17 of this Consortium Agreement as well as the provisions of the Grant Agreement, the Coordinator can withhold any payment if a Beneficiary eligible to receive IHI JU funding is late in submitting or refuses to provide Deliverables as required under the Grant Agreement and this Consortium Agreement. In any case, the Action's Steering Committee and General Assembly will be informed of the decision.
- 3.8 Bank account details of each Beneficiary eligible to receive IHI JU funding shall be provided to the Coordinator within thirty (30) Days of each such Beneficiary's signature of this Consortium Agreement.
- 3.9 A Beneficiary receiving IHI JU funding has received excess IHI JU funding payment (i) if the IHI JU funding payment it received from the Coordinator exceeds the Eligible Costs it declared; or (ii) if it has received IHI JU funding payments from the Coordinator but, within the last year of the Project, its Eligible Costs fall significantly behind the costs it would be entitled to according to Annex 1 of the Grant Agreement. **[OPTIONAL: The Beneficiaries agree that "significantly" as used in the previous sentence shall mean XX.]**

In case a Beneficiary receiving IHI JU funding has received excess payment, such Beneficiary has to inform the Coordinator and return the relevant amount to the Coordinator without undue delay. In case no refund takes place within thirty (30) days upon request for return of excess payment from the Coordinator, the Beneficiary is in material breach of this Consortium Agreement.

**[OPTIONAL: the following clause can be inserted to distribute risks in case a Beneficiary spends much less of its pre-financing/interim payments than foreseen in the initial budget, and does not repay such sums.** Amounts which are not refunded by a Beneficiary in material breach of this Consortium Agreement, and which are not due to the IHI JU (and for which therefore the Mutual Insurance Mechanism as set forth in Article 22 of the Grant Agreement does not intervene), shall be apportioned by the Coordinator to the remaining Beneficiaries Receiving IHI JU Funding pro rata according to their share of total costs of the Project as identified in Annex 1 of the Grant Agreement, until recovery from the breaching Beneficiary is possible.]



- 3.10 In case a Beneficiary earns any revenue that is deductible according to the Grant Agreement from the total funding as set out in Annex 1 of the Grant Agreement, 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 Annex 1 of the Grant Agreement, the Beneficiary shall reimburse the funding reduction suffered by other Beneficiaries.
- 3.11 A Beneficiary leaving the consortium shall refund to the Coordinator any IHI JU funding it has received except the amount of Eligible Costs accepted by the IHI JU.
- 3.12 In addition, a Defaulting Beneficiary shall 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 General Assembly should agree on a procedure regarding additional costs which are not covered by the Defaulting Beneficiary or the mutual insurance mechanism (as provided for in the Grant Agreement).
- 3.13 For the avoidance of doubt, the provisions of this Clause 3 shall apply in relation to any proportion of a Beneficiary Allocated Work which such Beneficiary shall have properly, in accordance with the Grant Agreement and/or this Consortium Agreement, sub-contracted to a Sub-Contractor, as if such Beneficiary had undertaken such proportion on its own account.

#### **4. IMPLEMENTATION OF THE ACTION**

- 4.1 Each Beneficiary shall carry out the tasks specifically allotted to it in the Action, both in relation to the completion of each such Beneficiary's Allocated Work, and in relation to all other undertakings and obligations pursuant to the Grant Agreement and this Consortium Agreement. Each Beneficiary shall maintain and allocate sufficient resources required to carry out such tasks in a timely manner.
- 4.2 If necessary to implement the Action, the Beneficiaries may assign the implementation of certain Action tasks described in Annex 1 of the Grant Agreement to Sub-Contractors. Sub-contracting may cover only a limited part of the Action. Other than to the extent provided in this Consortium Agreement, or as may be otherwise expressly permitted under the Grant Agreement, no Beneficiary shall be entitled to sub-contract any part of its Allocated Work to a Sub-Contractor.
- 4.3 Each Beneficiary shall be responsible for the compliance by its Affiliated Entities, Extended Affiliates, Associated Partners, and Sub-Contractors with the terms of this Consortium Agreement and the Grant Agreement. Where reference to Allocated Work to be performed by a Beneficiary is made in Annex 1 of the Grant Agreement, it shall be understood as referring to Allocated Work to be performed by the Beneficiary or any of its Affiliated Entities, Extended Affiliates, Associated Partners, or its Sub-Contractors, without such Affiliated Entities, Extended Affiliates, Associated Partners, and/or Sub-Contractors becoming Beneficiaries.
- 4.4 Each Beneficiary acknowledges that any delay in the Deliverables of a Beneficiary due to delays in obtaining the necessary data from another Beneficiary to undertake the allocated tasks (without prejudice to the latter's liability to the other Beneficiaries) will be considered a justified delay and as such it is an exception to any liability of the Beneficiary so delayed in connection with its timely performance of its task in the Project.

- 4.5 Each Beneficiary shall promptly, provide or forward to the Coordinator all data, information or material which the Coordinator is reasonably required to collect, pursuant to the provisions of this Consortium Agreement or under the Grant Agreement.
- 4.6 Each Beneficiary will use reasonable endeavours to carry out its Allocated Work but does not give any warranty or make any representation that its Allocated Work will lead to any particular result, nor does it guarantee a successful outcome of the Project.
- 4.7 The Beneficiaries shall perform their obligations and exercise their rights under this Consortium Agreement and the Grant Agreement in accordance with all applicable laws and regulations, and ethical guidelines.
- 4.8 Unless otherwise required or prohibited by law, the Beneficiaries each warrant, to the best of their knowledge, that in relation to the performance of this Consortium Agreement:
- a) they do not employ, engage or otherwise use any child labour in circumstances such that the tasks performed by any such child labour could reasonably be foreseen to cause either physical or emotional impairment to the development of such child;
  - b) they do not use forced labour in any form (prison, indentured, bonded or otherwise) and its employees are not required to lodge papers or deposits on starting work;
  - c) they provide a safe and healthy workplace, presenting no immediate hazards to its employees. Any housing provided by the Beneficiaries to their employees is safe for habitation. The Beneficiaries provide access to clean water, food, and emergency healthcare to their employees in the event of accidents or incidents in the workplace;
  - d) they do not discriminate against any employees on any ground (including race, sexual orientation, religion, disability or gender);
  - e) they do not engage in or support the use of corporal punishment, mental, physical, sexual or verbal abuse and do not use cruel or abusive disciplinary practices in the workplace;
  - f) they comply with the laws on working hours and employment rights in the countries in which they operate;
  - g) they are respectful of their employees' right to join and form independent trade unions and freedom of association; and
  - h) they pay each employee at least the minimum wage or a fair representation of the prevailing industry or academic wage (as applicable) according to applicable standards of the countries in which the Beneficiary operates (whichever is the higher) and provide each employee with all legally mandated benefits.

The Beneficiaries are responsible for controlling their own supply chain and they shall encourage compliance with ethical standards and human rights by any subsequent supply of goods and services that are used by the Beneficiaries when performing their obligations under this Consortium Agreement.

- 4.9 **[OPTIONAL: Insert in case laboratory animal work is part of the Action:]** All work involving the use of animals in laboratory research will be performed in accordance with all applicable laws, regulations and ethical guidelines, as outlined in Appendix 2 **[OPTIONAL: and following consultation with the Ethics Advisory Board]**.

- 4.10 **[OPTIONAL: Insert in case clinical trials are part of the Action:]** In Actions involving clinical trials, the agreements governing such trials will form the subject of a separate agreement between the relevant Beneficiaries or Third Parties and shall contain provisions which, at a minimum, provide protection for study subjects and Personal Data consistent with the terms of this Consortium Agreement and shall not conflict with the terms of this Consortium Agreement.<sup>2</sup>

**Processing of Personal Data, use and transfer of data, and Human Samples**

- 4.11 **Personal Data.** The Beneficiaries must Process Personal Data under and pursuant to this Consortium Agreement and the Grant Agreement in compliance with their respective obligations under applicable EU and national laws on data protection (including, the General Data Protection Regulation (Regulation (EU) 2016/679)).
- 4.12 **Personal Data – representation and warranty.** Each Beneficiary represents and warrants (i) that any Personal Data required for use in the Project or generated during the Project that are Processed by it will be Processed in accordance with all relevant laws and regulations regarding the Processing of Personal Data and (ii) that any applicable authorisation from relevant supervisory authorities and informed consents of the Data Subjects – in so far needed under applicable law- required for performing the Action or to conduct Research Use pursuant to the provisions of the Consortium Agreement (or otherwise determined in an agreement between the data provider(s) and the data receiver(s)), will be obtained prior to the commencement of the respective part of the Allocated Work respectively the envisaged Research Use. When Processing Personal Data under or pursuant to the Grant Agreement and/or this Consortium Agreement, the relevant Beneficiaries will comply with the terms and conditions as set out in Appendix 3.
- 4.13 **Human Samples.** The Beneficiaries must use Human Samples under and pursuant to this Consortium Agreement and the Grant Agreement in compliance with their respective obligations under applicable international and national laws and regulations.
- 4.14 **Human Samples - representation and warranty.** Each Beneficiary represents and warrants that any Human Samples required for use in the Project that are obtained, handled or used by it (i) will be obtained, handled or used in accordance with all relevant laws and regulations (and where applicable, local ethical guidelines) regarding the collection, use, transport and subsequent disposal of Human Samples and (ii) that any ethics committee approvals and Donor informed consents – in so far needed - required for performing the Action or to conduct Research Use pursuant to the provisions of the Consortium Agreement (or otherwise determined in a bilateral agreement between the Human Sample provider and the Human Sample receiver), will be obtained prior to the commencement of the respective part of the Allocated Work respectively the envisaged Research Use. When processing Personal Data in relation to Human Samples under or pursuant to the Grant Agreement and/or this Consortium Agreement, the relevant Beneficiaries will comply with the terms and conditions as set out in Appendix 3.
- 4.15 **Data agreements.** The relevant Beneficiaries may need to enter into appropriate additional agreements (e.g. data processing and/or data transfer agreements), to implement, regulate and facilitate appropriate provisions on the transfer and

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<sup>2</sup> For the avoidance of doubt, the Beneficiaries involved in such separate agreements may agree on different arrangements governing the clinical trials as the ones provided for in this Consortium Agreement (for instance with respect to liability), but these arrangements should only be applicable as between such Beneficiaries and cannot affect the rights and obligations of the other Beneficiaries under this Consortium Agreement.

processing of data (including Personal Data) in relation to the Project, including the case being data transfers of data to a database/platform or biobank within the Project. The draft of such additional agreements shall in such case be initiated by the Beneficiary providing the data to another Beneficiary/Third Party (data receiver), regardless of the status of the Beneficiary providing the data per applicable Data Protection Legislation, before the transfer or processing of such data actually occurs, unless agreed otherwise in writing and beforehand between the data provider and data receiver or otherwise covered in the Data Management Plan. Such agreements may not contain provisions contradicting this Consortium Agreement (including the provisions of Appendix 3 to the extent and in so far applicable) or limiting any usage rights already granted under this Consortium Agreement, and are subject to applicable Data Protection Legislation.

- 4.16 **Data Transfer Records.** Notwithstanding Clause 4.15 of this Consortium Agreement, to the extent that in accordance with this Consortium Agreement and/or the Grant Agreement data that (i) are not and do not contain Personal Data, (ii) are Anonymous, and/or (iii) are fully Anonymized, need to be transferred from one Beneficiary (including through its Extended Affiliates, Associated Partners, and/or Sub-Contractors) ("**Providing Data Beneficiary**") to another Beneficiary ("**Recipient Data Beneficiary**"), such transfer can be done within the framework and in compliance with the provisions of the Consortium Agreement, without the need to conclude additional agreements to facilitate such transfer. However, the Providing Data Beneficiary is entitled to require the use of the data transfer record forms in Appendix 4 to record the transfer of such data. Each Recipient Data Beneficiary shall be furthermore bound by the following provisions and shall be responsible for ensuring that its Extended Affiliates, Associated Partners, and/or Sub-Contractors comply with such provisions:

4.16.1 The data will be accessed and used in compliance with all applicable laws and regulations and pursuant to and in compliance with the terms and conditions (including the Access Rights granted) under this Consortium Agreement.

4.16.2 The transfer of the data itself does not modify the acknowledgment and/or allocation of Intellectual Property rights of Clauses 5, 6 and 7 of this Consortium Agreement. This transfer shall only be the consequence of honoring the rights (e.g., ownership, licenses or Access Rights) that both the Providing Data Beneficiary and the Recipient Data Beneficiary shall have on the relevant Background and Results according to Clauses 5, 6 and 7 of this Consortium Agreement.

4.16.3 The data shall not be transferred or made available by the Recipient Data Beneficiary to any individual other than those allowed under this Consortium Agreement and/or Grant Agreement.

4.16.4 The Receiving Data Beneficiary shall return to the Providing Data Beneficiary or destroy at the Providing Data Beneficiary's request all data of the Providing Data Beneficiary which are in its possession, power or control or in the possession, power or control of its personnel, other individuals under the supervision and control of the Receiving Data Beneficiary, Extended Affiliates, Associated Partners, and/or Sub-Contractors who have received such data from the Receiving Data Beneficiary pursuant to this Consortium Agreement, whenever requested to do so by the Providing Data Beneficiary, and where such data is not required by the Receiving Data Beneficiary for the use or exercise of its rights (including Access Rights) or licenses under this Consortium Agreement. The return or destruction of the data will not affect the Receiving Data Beneficiary's

obligation to observe the confidentiality and non-use restrictions in respect of the Providing Data Beneficiary's Confidential Information set out in this Consortium Agreement.

4.16.5 Unless otherwise provided in this Consortium Agreement, all data are transferred with no warranties, express or implied, of merchantability or fitness for a particular purpose or otherwise. In particular, no Providing Data Beneficiary represents or warrants that the use of the data will not infringe or violate any patent or proprietary rights of Third Parties.

4.17 **Anonymization of Personal Data.** To the extent a Beneficiary introduces to the Action Anonymized data and thereby enables other Beneficiaries or Third Parties to access and process such data within the Action, at least the following will apply:

- a) The introducing Beneficiary represents and warrants that any such data which initially contain Personal Data have been Anonymized before they are transferred to the data receiver;
- b) Where Anonymized data includes health-related data or information, the following provisions shall apply:
  - (i) For patients in the United States, if and so far the Health Insurance Portability and Accountability Act ("HIPAA") applies, the introducing Beneficiary shall de-identify all Personal Data in accordance with the applicable HIPAA standards (45 C.F.R. §164.514 HIPAA) as amended from time to time and as applicable
  - (ii) For patients outside the United States, unless otherwise agreed under the Action, all Personal Data shall by or on behalf of the introducing Beneficiary be Anonymized in accordance the guidance on Anonymization issued by the European Data Protection Board (EDPB), or any succeeding guidelines.

## **5. INTELLECTUAL PROPERTY – BACKGROUND, ADDITIONAL DATA, KNOW-HOW OR INFORMATION**

### **5.1 IDENTIFICATION OF BACKGROUND, ADDITIONAL DATA, KNOW-HOW OR INFORMATION**

5.1.1 Beneficiaries shall identify and agree the Background in writing in Appendix 5 of this Consortium Agreement. Such Appendix shall be deemed the "**Agreement on Background**" pursuant to Annex 5 of the Grant Agreement. If Background is subject to rights of a Third Party, the contributing Beneficiary must ensure that it is able to comply with its obligations under the Grant Agreement and this Consortium Agreement.

Pursuant to the Grant Agreement where the call conditions restrict control due to strategic interests reasons, Background that is subject to control or other restrictions by a country (or entity from a country) which is not one of the eligible countries or target countries set out in the call conditions and that impact the Exploitation of the Results (i.e. would make the Exploitation of the Results subject to control or restrictions) must not be used and must be explicitly excluded from it in the Agreement on Background — unless otherwise agreed with the IHI JU.

5.1.2 After its signature of or accession to the Grant Agreement and during the Action, each Beneficiary may identify additional Background. The Beneficiary shall add such additional Background to the list provided for in Appendix 5 and circulate

the updated list to the other Beneficiaries and **[Insert appropriate governance body, such as the PMO]**. Providing additional Background in the Background appendix shall constitute an amendment to this Consortium Agreement.

- 5.1.3 The Background identified in accordance with Clauses 5.1.1 and 5.1.2 of this Consortium Agreement shall be subject to the Access Rights pursuant to Clauses 7.2.1 (Access Rights to Background for implementation), 7.3.1 (Access Rights to Background needed for Research Use of Own Results) 7.3.2 (Access Rights to Background reasonably required for Research Use of Results owned by other Beneficiaries), 7.4.1 (Access Rights to Background for Direct Exploitation of Own Results), and 7.4.2 (Access Rights to Background for Direct Exploitation of Results) of this Consortium Agreement. For the avoidance of a doubt, anything which is not identified pursuant to Clauses 5.1.1 and 5.1.2 of this Consortium Agreement shall not constitute Background and shall not be subject to said Access Rights.
- 5.1.4 A Beneficiary may contribute Additional Data, Know-How or Information whatever its form or nature, tangible or intangible, including any rights such as Intellectual Property rights, that it lawfully acquires control of following the date it acceded to the Grant Agreement and which could be useful to carry out the Action. Such Additional Data, Know-How or Information shall be identified by filling-in the form set out in Appendix 5 of this Consortium Agreement and returning such form to the other Beneficiaries and **[Insert appropriate governance body, such as the PMO]**. Such data, information and Know-How, if contributed and identified, is not formally Background but shall be subject to the same Access Rights as those granted between the Beneficiaries (and their Extended Affiliates) for Background.
- 5.1.5 When identifying Background pursuant to Clauses 5.1.1 and 5.1.2 of this Consortium Agreement or Additional Data, Know-How or Information pursuant to Clause 5.1.4 of this Consortium Agreement, the Beneficiary shall at the same time identify in Appendix 5 any obligation to others pertaining to such Background or such Additional Data, Know-How or Information that he is aware of and that could prevent or restrict the enjoyment of Access Rights granted under this Consortium Agreement.
- 5.1.6 **[OPTIONAL: include if relevant for the Action.** Software Background/and or Background Databases obtained from Third Parties can be introduced under Controlled License Terms in the Action only to the extent the Beneficiaries approve unanimously such introduction under Controlled License Terms into the Action. Such approval shall be obtained either pursuant to Clause 5.1.1 of this Consortium Agreement or, in case the Controlled License Terms are not included in Appendix 5 at the time of signature of this Consortium Agreement, pursuant to an express written (email suffice) approval following a notification by the contributing Beneficiary specifying the Controlled License Terms and how they affect the Access Rights under this Consortium Agreement.]

## 5.2 OWNERSHIP AND TRANSFER OF BACKGROUND AND ADDITIONAL DATA, KNOW-HOW OR INFORMATION

- 5.2.1 Each Beneficiary shall remain the exclusive owner of its Background and Additional Data, Know-How or Information. Participation in the Action shall not affect such ownership rights in its Background and Additional Data, Know-How

or Information, without prejudice to any rights and obligations under this Consortium Agreement and the Grant Agreement.

- 5.2.2 Each Beneficiary remains free to license, transfer or otherwise dispose of its ownership rights in Background and Additional Data, Know-How or Information, provided that the Access Rights to such Background and Additional Data, Know-How or Information as provided for in this Consortium Agreement and the Grant Agreement can remain to be granted.
- 5.2.3 Where a Beneficiary transfers its ownership rights in Background and Additional Data, Know-How or Information, it must pass on its obligations specified under the Grant Agreement and this Consortium Agreement regarding the Background and Additional Data, Know-How or Information to the transferee, including the obligation to pass those obligations on to any subsequent transferee. If a Beneficiary grants licenses on the Background and/or Additional Data, Know-How or Information it owns or lawfully holds, it must ensure that Access Rights granted to others as defined in the Grant Agreement and this Consortium Agreement can be preserved and that obligations to grant Access Rights to others can be fulfilled.

## **6. INTELLECTUAL PROPERTY – RESULTS**

### **6.1 OWNERSHIP OF RESULTS**

- 6.1.1 Each Beneficiary shall own the Results it has generated.
- 6.1.2 Such Beneficiary shall ensure that any rights of its employees or any other parties in relation to such Results can be exercised in a manner compatible with the Beneficiary's obligations under the Grant Agreement and this Consortium Agreement. This includes that each Beneficiary shall enter or have entered into appropriate (employment) agreements with its employees, agents and personnel, and have directed its Extended Affiliates, Associated Partners and Sub-Contractors, if any, to enter or have entered into agreements with their employees, agents and personnel, providing that each such employee, agent or personnel transfers the full ownership to any Results to such Beneficiary (as the case may be through such Extended Affiliates, Associated Partners and Sub-Contractors), unless this is already provided for automatically under applicable law.

In case such terms cannot be agreed under applicable national laws, regulations and policies, the relevant Beneficiary shall ensure that only employees, agents, researchers and personnel, including PhD students, who have signed agreements or forms, legally permitted under applicable laws and regulations, clearly stating that such persons agree to be bound by the terms and conditions of this Consortium Agreement or otherwise leading to equivalent legally binding terms are allowed to participate in the implementation of the Action.

If obtaining these rights is impossible, the Beneficiary cannot use the relevant Extended Affiliates, Associated Partners and Sub-Contractors and their

respective employees, agents, researchers and personnel to generate the Results.

- 6.1.3 Two or more Beneficiaries shall own Results jointly (“**Joint Owners**”) if:
- a) they have jointly generated such Results, and
  - b) it is not possible to:
    - (i) establish the respective contribution of each Beneficiary, or
    - (ii) separate such Results when applying for, obtaining or maintaining their protection.

Joint Owners shall agree in writing on the allocation and terms of exercise of their joint ownership in a joint ownership agreement defining their respective rights and obligations with respect to the jointly owned Results, in the absence of which the relevant joint ownership sections of this Consortium Agreement shall serve as the joint ownership agreement between them.

Unless otherwise agreed in the joint ownership agreement pursuant to Clause 6.1.3 of this Consortium Agreement, in the case of joint ownership of Results, each Joint Owner is granted a non-exclusive, world-wide, fully paid up, royalty-free, perpetual, irrevocable license to use the jointly owned Results for Research Use, including the right to grant non-exclusive sub-licenses to its Extended Affiliates, and to contractors, licensees and collaborators carrying out Research Use on behalf and for the benefit of the Joint Owner without the need to inform the other Joint Owners.

**[Include either OPTION 1 or OPTION 2 below: OPTION 1:** Each Joint Owner and its Affiliated Entities shall have a license to use for Direct Exploitation the jointly owned Results, including the right to grant non-exclusive licenses to Third Parties subject to the following conditions

- (a) prior notice of at least forty-five (45) Days must be given to any other Joint Owner(s); and,
- (b) fair and reasonable compensation must be provided to the other Joint Owners, to be agreed in writing on a case-by-case basis prior to the start of the Direct Exploitation.]

**[OPTION 2:** each Joint Owner is granted a non-exclusive, world-wide, fully paid up, royalty-free, perpetual, irrevocable license to use the jointly owned Results for Direct Exploitation, including the right to grant non-exclusive sub-licenses to its Extended Affiliates, and to contractors, licensees and collaborators carrying out Direct Exploitation on behalf and for the benefit of the Joint Owner without the need to inform the other Joint Owners.

- 6.1.4 The owning Beneficiaries must indicate their presumed ownership of any Results in the Results ownership list in the final periodic report, as the case may be taking into account any ownership transfers pursuant to Clause 6.3 of this Consortium Agreement. Such list shall be based on the template made available for Horizon Europe projects and be adopted by the General Assembly. The Beneficiaries explicitly agree such list shall only have indicative value and shall not prevail over the terms of this Consortium Agreement and the Grant Agreement.

## 6.2 DATA CONTRIBUTED AS IN-KIND



- 6.2.1 A Beneficiary may contribute Data Contributed as In-Kind if so agreed with the IHI JU. Beneficiaries shall identify any Data Contributed as In-Kind in writing in Appendix 6 of the Consortium Agreement.
- 6.2.2 Data Contributed as In-Kind is not considered Background. Data Contributed as In-Kind shall be considered Results, and more specifically [**add applicable Result sub-type**], and the provisions applicable to such Results in this Consortium Agreement shall apply to such Data Contributed as In-Kind. They shall continue to be owned by the Beneficiary introducing them into the Action and shall be considered Confidential Information of such Beneficiary (whether or not marked as such).

### 6.3 TRANSFER OF OWNERSHIP AND GRANTING OF LICENSE ON RESULTS

- 6.3.1 Subject to Clauses 6.3.2 to 6.3.6 of this Consortium Agreement, each Beneficiary remains free to transfer its ownership rights in the Results it owns provided that this does not affect compliance with its obligations under the Grant Agreement and this Consortium Agreement. Such Beneficiary shall ensure that its obligations under the Grant Agreement and this Consortium Agreement with respect to such Results shall also apply to the new owner and that the latter has the obligation to pass them on in any subsequent transfer.

- 6.3.2 [OPTIONAL: include either OPTION 1 or OPTION 2 if relevant for the Action:

OPTION 1: Beneficiaries may agree here that ownership of certain Results, once said Results have been generated, shall be transferred from the initial owning Beneficiary(-ies) to another Beneficiary. If so wished, the following wording is suggested: Notwithstanding Clause 6.1.1 of this Consortium Agreement, any [Describe specific Result sub-type] Results are initially owned by the Beneficiary(-ies) who generated such Results. However, immediately following generation of the [Describe specific Result sub-type] Results, each such owning Beneficiary automatically and in full transfers to the [Short name specific Beneficiary] any of its ownership rights, title and interest in the respective [Describe specific Result sub-type] Results. In consideration of this assignment of ownership upon creation, the following conditions as outlined below apply: [\_\_\_\_].]

[OPTION 2: Beneficiaries may agree here that where Results have been generated by one or more Beneficiary(-ies) as a result of a cash contribution from another Beneficiary, these Results would be transferred to the cash funding Beneficiary: Results generated by Beneficiary(-ies) having received a cash contribution from another Beneficiary shall be initially owned by the Beneficiary(-ies) who generated such Results. However, immediately following generation of such Results, each such owning Beneficiary automatically and in full transfers to the cash contributing Beneficiary any of its ownership rights, title and interest in the respective Results. The cash contribution shall be the unique and full compensation for the transfer of such Results.]

- 6.3.3 [OPTIONAL: include in case any of the options above have been included. Except for any transfers pursuant to Clause 6.3.2 of this Consortium Agreement,] Subject to Clause 6.3.4 of this Consortium Agreement and unless agreed otherwise (in writing) for specifically-identified Third Parties or unless impossible under applicable laws, a Beneficiary that intends to transfer ownership of Results must give at least forty-five (45) Days' notice to the other Beneficiaries

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 Beneficiary concerned to assess the effects on its Access Rights.

Subject to Clause 6.3.4 of this Consortium Agreement and unless agreed otherwise (in writing) for specifically-identified Third Parties, any other Beneficiary may object within thirty (30) Days of receiving the notification if it can show that the transfer would adversely affect its Access Rights. In this case, the transfer may not take place until an agreement has been reached between the Beneficiaries concerned.

6.3.4 Notwithstanding the above, a Beneficiary may, without the consent of the other Beneficiaries but provided that the transferee agrees in writing to be bound by the Grant Agreement and this Consortium Agreement, transfer its Results to any of the following:

- a) Any Extended Affiliate,
- b) any purchaser of all or a substantial amount of its relevant assets, and
- c) any successor entity resulting from the merger with or consolidation of such a Beneficiary.

In addition, in the case of b) and c) above other Beneficiaries will be informed of the transfer of the respective Results within a reasonable time following the effective date of such transfer.

6.3.5 Each Party hereby waives any (additional) rights it may have under the Grant Agreement to prior notification and to object to any transfer of Results to the extent such transfer takes place in compliance with Clauses 6.3.1 to 6.3.4 of this Consortium Agreement.

6.3.6 Beneficiaries may grant licenses to their Results or otherwise give the right to exploit them, including on an exclusive basis, if this does not affect compliance with their obligations under the Grant Agreement and this Consortium Agreement, provided that exclusive licenses to Results may be granted only if all the other Beneficiaries concerned have waived their Access Rights.

6.3.7 [Optional: Include if the call conditions for the Action provided for the right for the IHI JU to object to transfers or licensing: The IHI JU may object to transfers or exclusive licensing of Results under the conditions laid down in Annex 5 of the Grant Agreement.]

## 6.4 PROTECTION OF RESULTS

### 6.4.1 General Commitment to protect Results

In accordance with Annex 5 of the Grant Agreement, Beneficiaries Receiving IHI JU Funding must adequately protect their Results — for an appropriate period and with appropriate territorial coverage — if protection is possible and justified, taking into account all relevant considerations, including the prospects for commercial exploitation, the legitimate interests of the other Beneficiaries and any other legitimate interests.

#### 6.4.2 Patents - Inventorship, assignment and inventor remuneration

6.4.2.1 Subject to other conflicting regulations under applicable law, the inventorship of any invention under this Consortium Agreement shall be determined by the owning Beneficiary in accordance with applicable patent laws and practices.

6.4.2.2 Each Beneficiary will claim any patentable Result from its own inventors according to the applicable legal requirements of inventorship and inventor remuneration. Each Beneficiary shall be solely responsible for any potential compensation due to any of its employees, agents, Extended Affiliates, Associated Partners or Sub-Contractors in relation to any of its Results, including without limitation any potential remuneration due by operation of law to any of its employees, agents, Extended Affiliates, Associated Partners, or Sub-Contractors (or their respective employees) on account of commercialization or any other activity of any of its Result.

6.4.2.3 **[OPTIONAL: Include if ownership assignments are agreed in Clause 6.3:** In the event that the Beneficiary which has generated the Results is not the owning Beneficiary per Clause 6.3 of this Consortium Agreement, such generating Beneficiary shall, subject to any applicable laws and at the owning Beneficiary's request:

a) cause its own and its Extended Affiliates, Associated Partners and Sub-Contractors' employees and agents to execute and deliver to the owning Beneficiary all such documents and do all such things as may be reasonably required by the owning Beneficiary to confirm the vesting of any and all the rights into the invention to the owning Beneficiary;

b) cause its own and its Extended Affiliates, Associated Partners and Sub-Contractors' employees and agents to assist the owning Beneficiary in prosecuting such patent applications and execute and deliver any and all instruments necessary to make, file and prosecute all such applications, at the owning Beneficiary's costs.]

#### 6.5 COMMITMENT TO EXPLOITATION

##### 6.5.1 General Commitment to exploit Results for Beneficiaries Receiving IHI JU Funding

In accordance with Annex 5 of the Grant Agreement, Beneficiaries Receiving IHI JU Funding must – up to four (4) years after the end of the Action – use their best efforts<sup>3</sup> to Exploit their Results directly or have them Exploited indirectly via another entity, in particular through transfer or licensing. If, despite a Beneficiary's best efforts, the Results are not exploited within one (1) year after the end of the Action, such Beneficiary must (unless otherwise agreed in writing

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<sup>3</sup> According to the Annotated Model Grant Agreement for EU Funding Programmes, page 137, in exercising "best efforts" Beneficiaries must be proactive and take specific measures to try to ensure that their results are exploited (to the extent possible and justified)".

with the IHI JU) use the Horizon Results Platform to find interested parties to Exploit the Results.

For clarity, this Clause 6.5.1 does not apply to Beneficiaries Not Receiving IHI JU Funding.

#### 6.5.2 Additional Exploitation Obligations<sup>4</sup>

Other than as set forth in Clause 6.5.1 of this Consortium Agreement [OPTIONAL: add in case *this applies for the* Action and Section [ ] of Annex 1 of the Grant Agreement<sup>5</sup>], there are no additional exploitation obligations.

#### 6.5.3 [OPTIONAL: add in case of public health emergency and if specified in call conditions: Additional Exploitation Obligations in case of Public Health Emergency]

The Beneficiaries must (if requested by the IHI JU) grant for a limited period of time specified in the request, non-exclusive licenses — under Fair and Reasonable Conditions — to their Results to legal entities that need the Results to address the public emergency and commit to rapidly and broadly exploit the resulting products and services at Fair and Reasonable Conditions. This provision applies up to four (4) years after the end of the Action.]

### 6.6 DISSEMINATION OF RESULTS & COMMUNICATION

#### 6.6.1 General commitment on Dissemination

6.6.1.1 Each Beneficiary shall Disseminate its Results as soon as feasible, in a publicly available format, subject to any restrictions due to the protection of Intellectual Property, security rules, or legitimate interests (for instance, because the Results have not yet been protected, the Results concern trade secrets, or disclosing the Results would infringe on applicable Personal Data protection, security related, or other applicable obligations).

6.6.1.2 A Beneficiary may not Disseminate Results owned by another Beneficiary or any Background, Additional Data, Know-How or Information, or Confidential Information of such other Beneficiary, even if such Results, Background, Additional Data, Know-How or Information, or Confidential Information are amalgamated with such Beneficiary's Results, without the owning Beneficiary's prior written approval.

#### 6.6.2 Review and Approval Process

6.6.2.1 A Beneficiary may only Disseminate any of its own Results if it has circulated the proposed Dissemination to the other Beneficiaries by written notice at least sixty (60) Days prior to such Dissemination, and the below procedure has been followed.

6.6.2.2 Any Beneficiary may object to such a proposed Dissemination within thirty (30) Days of notification, if it can show its legitimate interest in relation to

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<sup>4</sup> To be confirmed based on Grant Agreement (including Annex 1 to the Grant Agreement) whether additional exploitation obligations apply.

<sup>5</sup> Parties negotiating the Consortium Agreement should cross-check the additional exploitation section in Annex 1 of the Grant Agreement to make sure its contents are acceptable from an intellectual property perspective.

its Results, Background or Additional Data, Know-How or Information, would be significantly harmed, such as for the reasons as detailed here below:

- a) where protection of the objecting Beneficiaries' own Results, Background or Additional Data, Know-How or Information would be adversely affected by the proposed Dissemination;
- b) where the proposed Dissemination contains Confidential Information from the objecting Beneficiary; or
- c) where other legitimate interests of the objecting Beneficiary in relation to its Results or Background would be significantly harmed.

If such objection is made, the publishing Beneficiary will:

- (i) in case of a) extend the review period and delay the proposed publication for a period determined by the objecting Beneficiary, which cannot exceed twelve (12) months to allow the objecting Beneficiary to evaluate the patentability and/or to file a patent application for the objecting Beneficiary's Results, Background or Additional Data, Know-How or Information; and/or otherwise modify the publication as requested for Intellectual Property reasons;
- (ii) in case of b) delay the Dissemination until the objecting Beneficiary's Confidential Information is removed from the proposed Dissemination;
- (iii) in case of c) enter into good faith discussions with the objecting Beneficiary on how to address the legitimate interests of the objecting Beneficiary, as the case may be, by amending the proposed Dissemination.

6.6.2.3 If no objection is received in writing within a twenty (20) Days' period from the date of notification of the proposed Dissemination, the Beneficiary seeking Dissemination shall send an e-mail reminder to those Beneficiaries who have not yet responded. If no objection is received in writing within the thirty (30) Days' period mentioned in Clause 6.6.2.2 of this Consortium Agreement, the Beneficiary seeking Dissemination will be free to proceed with the Dissemination as submitted to the other Beneficiaries to the extent such Dissemination does not include or refer to Results, Background, Additional Data, Know-How or Information, or any Confidential Information of any other Beneficiary.

6.6.2.4 Nothing in this Consortium Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Beneficiaries or any of their logos or trademarks without their prior written approval.

6.6.2.5 For the avoidance of doubt, the aforementioned Dissemination review procedure shall also apply in case Results are published in connection with a student submitting a thesis. All appropriate measures ensuring compliance with applicable requirements under Appendix 3 and ensuring confidentiality must be taken by the Beneficiary with which the student is associated to ensure protection of Confidential Information and/or patent

protection of the other Beneficiaries, which shall, where appropriate, require examiners external to the Beneficiary university to sign an agreement of non-disclosure prior to receipt of the thesis.

#### 6.6.3 Open Access to Scientific Publications

The Beneficiaries must ensure open access to peer-reviewed scientific publications relating to their Results in accordance with Annex 5 of the Grant Agreement. Beneficiaries must ensure that they (or the authors) retain sufficient Intellectual Property rights to comply with their open access requirements.

#### 6.6.4 Open Access to Research Outputs

The Beneficiaries must manage and ensure open access to Research Outputs in accordance with Annex 5 of the Grant Agreement.

*[OPTIONAL: In case of a public health emergency, consider to add additional provisions on the Grant Agreement requirement to deposit Research Outputs in a public repository and its alternative, the grant of non-exclusive licenses under Fair and Reasonable Conditions to Third Parties that need the Research Outputs to address the public health emergency. See also above on exploitation of resulting products and services.]*

#### 6.6.5 Communications

Each Beneficiary may make Communications provided that the subject matter, content and form of such Communication falls within the scope of the Communication Guidelines as set forth in Appendix 7.

#### 6.6.6 Visibility

In performing any Dissemination or Communication activity, each Beneficiary will comply with the rules on visibility of EU support as set forth in Article 17 of the Grant Agreement.

## 7. INTELLECTUAL PROPERTY – ACCESS RIGHTS

### 7.1 GENERAL PROVISIONS ON ACCESS RIGHTS

#### Request procedure

- 7.1.1 Unless otherwise specified in this Consortium Agreement, in order for a Beneficiary to exercise its Access Rights, these must be requested and established in writing.
- 7.1.2 Access Rights under Clauses 7.2.1 (Access Rights to Background for implementation) and 7.2.2 (Access Rights to Results for implementation) of this Consortium Agreement are hereby requested in writing by the Beneficiaries by means of signature of this Consortium Agreement. Such Access Rights are hereby granted by the respective Beneficiary by means of signature of this Consortium Agreement.
- 7.1.3 During the Action and after completion of the Action, Access Rights for Research Use pursuant to Clauses 7.3.1 (Access Rights to Background needed for Research Use of Own Results), 7.3.2(a) (Access Rights to Background reasonably required for Research Use of Action Objective Results owned by other Beneficiaries),

7.3.3 (Access Rights to Results of the other Beneficiaries for Research Use of Own Results), and 7.3.4(a) (Access Rights to Action Objective Results of the other Beneficiaries for Research Use) of this Consortium Agreement and which are provided under (i) Royalty-Free Conditions or (ii) pre-determined Fair and Reasonable Conditions under Clauses 7.3.1.2, 7.3.2.2, 7.3.3.2, or 7.3.4.1, respectively, of this Consortium Agreement are hereby requested in writing by the Beneficiaries by way of signature of this Consortium Agreement. Such Access Rights are hereby granted by the respective Beneficiary by means of signature of this Consortium Agreement.

- 7.1.4 During the Action and after completion of the Action, each Beneficiary shall request in writing Access Rights for Research Use which are provided on Fair and Reasonable Conditions other than Royalty-Free Conditions or pre-determined Fair and Reasonable Conditions. Such Access Rights shall become effective upon written agreement defining the Fair and Reasonable Conditions applicable. Request for Access Rights in accordance with this Clause 7.1.4 can be made until **[5][10][15][20]** years after completion of the Action. **[OPTIONAL: If different time limits apply for different categories of Access Rights, please specify it here]**. During the Action, request for Access Rights made in accordance with this Clause 7.1.4 shall be sent to **[Choose appropriate governance body]**.

#### **Scope of Access Rights**

- 7.1.5 All Access Rights pursuant to this Consortium Agreement shall be granted on a non-exclusive basis and are worldwide, perpetual and irrevocable. Access Rights need to be granted and exercised in accordance with this Consortium Agreement (including but not limited to Clauses 5, 6, 7, and 9 of this Consortium Agreement) and in a manner compliant with applicable laws and regulations. In particular, Access Rights to Personal Data need to be in accordance with the applicable informed consent forms (if any, and to the extent appropriate or required under applicable laws and regulations) and the provisions of this Consortium Agreement including those in Appendix 3. With regard to Personal Data only, Beneficiaries must ensure that the applicable informed consent forms (if any, and to the extent required under applicable laws and regulations) for Personal Data shared within the framework of the Project allow for the use of the Personal Data (including Research Use) in the field of the Project and/or a field compatible with the Project and permits cross-border transfers within the European Economic Area (“EEA”) (or such cross-border EEA transfers are otherwise permitted pursuant to applicable Data Protection Legislation) and/or outside the EEA, in which case additional safeguards and/or agreements and may need to be implemented between the data provider(s) and data receiver(s) in compliance with and pursuant to applicable Data Protection Legislation. In case additional agreements are needed to facilitate such (cross-border) transfer between Beneficiaries or with their Affiliated Entities, Extended Affiliates, Sub-Contractors and Associated Partners, these agreements shall be drafted and negotiated in good faith between the Beneficiaries concerned and this upon the data provider(s) or data receiver(s) first request, taking into account Clause 4.15 of this Consortium Agreement. In the case such transfer of Personal Data between Beneficiaries requires the conduct a data impact protection assessment and or a transfer impact assessment, these assessments will also be

conducted in good faith and as soon as reasonably feasible in order to expedite and facilitate such transfer (in case of a positive assessment).

- 7.1.6 **[OPTIONAL: Except as provided for in Clause 7.5 of this Consortium Agreement for Software, and]** unless as otherwise specified herein, Access Rights granted pursuant to this Consortium Agreement shall not include the right to sub-license such Access Rights. However, a Beneficiary who enjoys Access Rights pursuant to Clauses 7.2.1 (Access Rights to Background for implementation), 7.2.2 (Access Rights to Results for implementation), 7.3.1 (Access Rights to Background needed for Research Use of Own Results), 7.3.2(a) (Access Rights to Background reasonably required for Research Use of Action Objective Results owned by other Beneficiaries), 7.3.3 (Access Rights to Results of the other Beneficiaries for Research Use of Own Results), 7.3.4(a) (Access Rights to Action Objective Results of the other Beneficiaries for Research Use), 7.4.1 (Access Rights to Background for Direct Exploitation of Own Results), and 7.4.3 (Access Rights to Results for Direct Exploitation of Own Results) of this Consortium Agreement may authorize another legal entity, for instance an Extended Affiliate, to exercise those Access Rights on the Beneficiary's behalf, provided that the following conditions are fulfilled:
- a) the Beneficiary that enjoys Access Rights is liable for the acts of the other legal entity as if those acts had been performed by the Beneficiary; and
  - b) Access Rights granted to the other legal entity do not include the right to sub-license.
- 7.1.7 The Research Use Access Right includes that any Beneficiary, or its Extended Affiliates, licensees and designees, may refer to any Results or Background necessary to use such Results of another Beneficiary, in regulatory documentation relating to any product owned by such Beneficiary, or its Extended Affiliates, licensees and designees. Such regulatory documentation may include the marketing authorisation application, patient information leaflet, summary of product characteristics and equivalent documentation anywhere in the world. Prior to the submission of such Results or Background in such regulatory documentation, the submitting Beneficiary shall provide a written notice to the owning Beneficiary of its intent to make such submission to enable the owning Beneficiary to file for Intellectual Property protection covering such Results or Background (related to such Results). In such case the submission may be delayed by the owning Beneficiary for a reasonable period of time necessary to obtain such a protection.
- 7.1.8 **[OPTIONAL: Access Rights Table.** Appendix 8 summarizes the different types of Access Rights for the Action, and the conditions under which they are granted under this Consortium Agreement.]
- 7.1.9 **Fair and Reasonable Conditions.** When certain Access Rights are granted under Fair and Reasonable Conditions which are not pre-determined in this Consortium Agreement, the Beneficiary requesting Access Rights and the Beneficiary granting Access Rights agree that in determining the actual Fair and Reasonable Conditions they will take into account they have collaborated in the Action to their mutual benefit, which should result in conditions which are more beneficial to the requesting Beneficiary than market conditions. Consequently,



Beneficiaries to the Action shall be offered conditions which are preferable to those offered to Third Parties.

**[OPTIONAL: include if relevant for the Action.]** General Provisions for Access Rights to Software and Databases

7.1.10 The provisions for Access Rights provided for in Clause 7 of this Consortium Agreement are applicable also to Software and Databases except if expressly provided otherwise in Clause 7.1.11 to 7.1.13 of this Consortium Agreement. [OPTIONAL: In addition, additional Access Rights to Software and Databases are foreseen in Clause 7.5 of this Consortium Agreement.]

#### **Software Background and Background Databases**

7.1.11 Beneficiaries' Access Rights to Software Background and Background Databases shall only be provided in Object Code, unless otherwise agreed between the Beneficiaries concerned or when needed for Implementation as provided for in Clause 7.2.3.1 of this Consortium Agreement.

7.1.12 The intended introduction of Software Background or Background Databases under Controlled License Terms in the Action requires the unanimous approval of the Beneficiaries to this Consortium Agreement to implement such introduction into the Action. To the extent so approved, Beneficiaries shall comply with possible limitations imposed by Controlled License Terms when exercising their Access Rights on such Software Background or Background Databases hereunder.

#### **Software Results and Database Results**

7.1.13 Access Rights to Software Results and Database Results that are subject to Clause 7 of this Consortium Agreement shall comprise:

(i) where it concerns a functional software, an installable functional copy of the software with associated relevant user documentation; and

(ii) Access to the Object Code; and

(iii) where normal use of such an Object Code requires an API, access to the Object Code and such an API; and

(iv) if a Party can show that (a) the execution of its tasks under the Action or (b) the Research Use of Results, or (c) the Research Use or Direct Exploitation of its own Results, is technically impossible without Access Rights to the Source Code, access to the Source Code and Documentation to the extent needed. Such Access Rights to such Source Code and Documentation are agreed pursuant to this Consortium Agreement but will be recorded in writing separately between the relevant Beneficiaries.]

### **7.2 ACCESS RIGHTS FOR IMPLEMENTATION**

#### **7.2.1 Access Rights to Background for Implementation.**

7.2.1.1 During the Action, the Beneficiaries and their Affiliated Entities enjoy, unless prevented or restricted from doing so by obligations to others identified pursuant to Clauses 5.1.1 and 5.1.2 of this Consortium Agreement, Access Rights to the Background of the other Beneficiaries,

solely for the purpose and to the extent necessary for undertaking and completing the Action.

7.2.1.2 Such Access Rights are granted under Royalty-Free Conditions.

7.2.1.3 In accordance with Clause 7.1.2 of this Consortium Agreement, the Beneficiaries agree that the signature of this Consortium Agreement by the Beneficiaries shall constitute in itself a valid written request of Access Rights pursuant to Clause 7.2.1.1 of this Consortium Agreement for those Beneficiaries to enjoy these Access Rights. In addition, the signature of this Consortium Agreement shall at the same time constitute a valid approval of the owning Beneficiaries of such grant of Access Rights.

## 7.2.2 Access Rights to Results for Implementation

7.2.2.1 During the Action, the Beneficiaries enjoy Access Rights to the Results of the other Beneficiaries, solely for the purpose and to the extent necessary for undertaking and completing the Action.

7.2.2.2 Such Access Rights are granted under Royalty-Free Conditions.

7.2.2.3 In accordance with Clause 7.1.2 of this Consortium Agreement, the Beneficiaries agree that the signature of this Consortium Agreement by the Beneficiaries shall constitute in itself a valid written request of Access Rights pursuant to Clause 7.2.2.1 of this Consortium Agreement for those Beneficiaries and their Affiliated Entities to enjoy these Access Rights. In addition, the signature of this Consortium Agreement shall at the same time constitute a valid approval of the owning Beneficiaries of such grant of Access Rights.

## 7.2.3 [OPTIONAL: include if relevant for the Action. Additional Provisions for Access Rights to Software and Databases for Implementation.

7.2.3.1 In addition to the limited license provided for under Clauses 7.1.11 to 7.1.13 of this Consortium Agreement, Beneficiaries' Access Rights for Implementation to Software Background, Background Database, Software Results and Database Results for implementation shall additionally include relevant information, documentation and an installable copy as far as needed to be able to make functional use of the Software Background, Background Database, Software Results and Database Results for Implementation of the Action, and to allow a Beneficiary to carry out all of its tasks timely in the Action.]

## 7.3 ACCESS RIGHTS FOR EXPLOITATION: RESEARCH USE

### BACKGROUND

#### 7.3.1 Access Rights to Background needed for Research Use of Own Results

7.3.1.1 Subject to the provisions of this Consortium Agreement, in particular Clauses 5.1, 7.1, 8.1, 7.3.2(a), 7.4.1 and 9, during and after completion of the Action, Beneficiaries and their Extended Affiliates enjoy Access Rights to the Background of the other Beneficiaries, to the extent needed for the

purpose of Research Use of their own Results (or those of their Extended Affiliates).

7.3.1.2 Such Access Rights to Background of the other Beneficiaries to the extent needed for the purposes of Research Use of own Results are granted under Clause 7.3.1.1 of this Consortium Agreement on the following Fair and Reasonable Conditions: **[OPTION 1:]** [on Royalty-Free Conditions] **[OPTION 2:]** [on Fair and Reasonable Conditions other than Royalty-Free Conditions] **[Detail applicable terms.]** ***[Please indicate the option chosen and, if applicable, work out an appropriate arrangement for Option 2. Alternatively, the conditions can be agreed per type of Background as set out below:]***

(a) To XX Background: [on Royalty-Free Conditions/ Fair and Reasonable Conditions]

(b) To Software Background: [on Royalty-Free Conditions/ Fair and Reasonable Conditions]

(c) To Background Databases: [on Royalty-Free Conditions/ Fair and Reasonable Conditions]

(d) To Other Background: [on Royalty-Free Conditions/ Fair and Reasonable Conditions]

7.3.1.3 In accordance with Clause 7.1.3 of this Consortium Agreement, the Beneficiaries agree that the signature of this Consortium Agreement shall constitute in itself a valid request of Access Rights pursuant to Clause 7.3.1.1 of this Consortium Agreement for those Beneficiaries and their Extended Affiliates to enjoy these Access Rights to Background of the other Beneficiaries to the extent needed for Research Use of own Results both during and after completion of the Action. In addition, the signature of this Consortium Agreement shall at the same time constitute a valid approval of the owning Beneficiaries of such grant of Access Rights under Clause 7.3.1.1 of this Consortium Agreement, for which conditions pursuant to Clause 7.3.1.2 of this Consortium Agreement have been pre-agreed and are set out therein.

**7.3.2 Access Rights to Background reasonably required for Research Use of Results owned by other Beneficiaries**

**(a) for Research Use of Action Objective Results**

7.3.2.1 Subject to the provisions of this Consortium Agreement, in particular Clauses 5.1, 7.1, 8.1 and 9 during and after completion of the Action, Beneficiaries and their Extended Affiliates enjoy Access Rights to the Background of the other Beneficiaries, to the extent reasonably required for the purpose of the Research Use of Action Objective Results of the other Beneficiaries.

7.3.2.2 Such Access Rights to Background of the other Beneficiaries for the purposes of Research Use of Action Objective Results of the other Beneficiaries are granted under Clause 7.3.2.1 of this Consortium Agreement on the following Fair and Reasonable Conditions: **[OPTION 1:]** [on Royalty-Free Conditions] **[OPTION 2:]** [on Fair and Reasonable Conditions other than Royalty-Free Conditions] **[Detail applicable terms.]**

*[Please indicate the option chosen and, if applicable, work out an appropriate arrangement for Option 2. Alternatively, the conditions can be agreed per type of Background as set out below:]*

(a) To XX Background: [on Royalty-Free Conditions/ Fair and Reasonable Conditions]

(b) To Software Background: [on Royalty-Free Conditions/ Fair and Reasonable Conditions]

(c) To Background Databases: [on Royalty-Free Conditions/ Fair and Reasonable Conditions]

(d) To Other Background: [on Royalty-Free Conditions/ Fair and Reasonable Conditions]

7.3.2.3 In accordance with Clause 7.1.3 of this Consortium Agreement, the Beneficiaries agree that the signature of this Consortium Agreement shall constitute in itself a valid request of Access Rights pursuant to Clause 7.3.2.1 of this Consortium Agreement for those Beneficiaries and their Extended Affiliates to enjoy these Access Rights to Background of the other Beneficiaries to the extent reasonably required for Research Use of Action Objective Results of the other Beneficiaries both during and after completion of the Action. In addition, the signature of this Consortium Agreement shall at the same time constitute a valid approval of the owning Beneficiaries of such grant of Access Rights under Clause 7.3.2.1 of this Consortium Agreement, for which conditions pursuant to Clause 7.3.2.2 of this Consortium Agreement have been pre-agreed and are set out therein.

**(b) for Research Use of Sideground Results of the other Beneficiaries**

7.3.2.4 No Access Rights are granted to Beneficiaries to Background of the other Beneficiaries for Research Use of Sideground Results of the other Beneficiaries.

**RESULTS**

**7.3.3 Access Rights to Results of the other Beneficiaries for Research Use of Own Results.**

7.3.3.1 Subject to the provisions of this Consortium Agreement, in particular Clauses 7.1, 7.3.4(a), 8.1 and 9, during and after completion of the Action, Beneficiaries and their Extended Affiliates enjoy Access Rights to the Results of the other Beneficiaries, to the extent needed for the purpose of Research Use own Results (or those of their Extended Affiliates).

7.3.3.2 Such Access Rights to Results to the extent needed for the purposes of Research Use of own Results are granted on the following Fair and Reasonable Conditions: **[OPTION 1:]** [on Royalty-Free Conditions] **[Preferred Option]** **[OPTION 2:]** [on Fair and Reasonable Conditions other than Royalty-Free Conditions] *[Please indicate the option chosen and, if applicable, work out an appropriate arrangement for Option 2. Alternatively, the conditions can be agreed per type of Results as set out below:]*

**(A) In relation to own Action Objective Results**

(a) To XX Results: [on Royalty-Free Conditions **[Preferred Option]** / Fair and Reasonable Conditions]

(b) To Software Results: [on Royalty-Free Conditions **[Preferred Option]** / Fair and Reasonable Conditions]

(c) To Database Results: [on Royalty-Free Conditions **[Preferred Option]** / Fair and Reasonable Conditions]

(d) To Imaging Results: [on Royalty-Free Conditions **[Preferred Option]** / Fair and Reasonable Conditions]

(e) To Other Results: [on Royalty-Free Conditions **[Preferred Option]** / Fair and Reasonable Conditions]

**(B) In relation to own Sideground Results**

On Royalty-Free Conditions / Fair and Reasonable Conditions.

7.3.3.3 In accordance with Clause 7.1.3. of this Consortium Agreement, the Beneficiaries agree that the signature of this Consortium Agreement by the Beneficiaries shall constitute in itself a valid written request of Access Rights pursuant to Clause 7.3.3.1 of this Consortium Agreement for those Beneficiaries and their Extended Affiliates to enjoy these Access Rights. In addition, the signature of this Consortium Agreement shall at the same time constitute a valid approval of the owning Beneficiaries of such grant of Access Rights under Clause 7.3.3.1 of this Consortium Agreement for which conditions pursuant to Clause 7.3.3.2 of this Consortium Agreement have been pre-agreed and are set out therein.

**7.3.4 Access Rights to Results of the other Beneficiaries for Research Use**

**(a) To Action Objective Results**

7.3.4.1 Subject to the provisions of this Consortium Agreement, in particular Clauses 7.1, 8.1 and 9, during and after completion of the Action, Beneficiaries and their Extended Affiliates enjoy Access Rights to the Action Objective Results of the other Beneficiaries for Research Use.

7.3.4.2 Such Access Rights to Action Objective Results of the other Beneficiaries for the purposes of Research Use are granted on the following Fair and Reasonable Conditions: **[OPTION 1:]** [on Royalty-Free Conditions] **[Preferred Option]** **[OPTION 2:]** [on Fair and Reasonable Conditions other than Royalty-Free Conditions] ***[Please indicate the option chosen and, if applicable, work out an appropriate arrangement for Option 2. Alternatively, the conditions can be agreed per type of Results as set out below:]***

(a) To XX Results: [on Royalty-Free Conditions **[Preferred Option]** / Fair and Reasonable Conditions]

(b) To Software Results: [on Royalty-Free Conditions **[Preferred Option]** / Fair and Reasonable Conditions]

(c) To Database Results: [on Royalty-Free Conditions **[Preferred Option]** / Fair and Reasonable Conditions]

(d) To Imaging Results: [on Royalty-Free Conditions **[Preferred Option]** / Fair and Reasonable Conditions]

(e) To Other Results: [on Royalty-Free Conditions **[Preferred Option]** / Fair and Reasonable Conditions]

7.3.4.3 In accordance with Clause 7.1.3. of this Consortium Agreement, the Beneficiaries agree that the signature of this Consortium Agreement by the Beneficiaries shall constitute in itself a valid written request of Access Rights pursuant to Clause 7.3.4.1 of this Consortium Agreement for those Beneficiaries and their Extended Affiliates to enjoy these Access Rights. In addition, the signature of this Consortium Agreement shall at the same time constitute a valid approval of the owning Beneficiaries of such grant of Access Rights under Clause 7.3.4.1 of this Consortium Agreement for which conditions pursuant to Clause 7.3.4.2 of this Consortium Agreement have been pre-agreed and are set out therein.

#### **(b) To Sideground Results**

7.3.4.4 Subject to Clause 7.3.3 of this Consortium Agreement, no Access Rights are granted to Beneficiaries for Research Use of Sideground Results of the other Beneficiaries.

### **7.4 ACCESS RIGHTS FOR EXPLOITATION: DIRECT EXPLOITATION**

#### **7.4.1 Access Rights to Background for Direct Exploitation of Own Results**

7.4.1.1 Subject to the provisions of this Consortium Agreement, in particular Clauses 5.1, 7.1, 8.1 and 9, during and after completion of the Action, Beneficiaries and their Extended Affiliates enjoy Access Rights to the Background of the other Beneficiaries, to the extent needed for the purpose of Direct Exploitation of their own Results (or those of their Extended Affiliates).

7.4.1.2 Such Access Rights to Background of the other Beneficiaries for the purposes of Direct Exploitation of own Results are granted under Clause 7.4.1.1 of this Consortium Agreement on Fair and Reasonable Conditions.

#### **7.4.2 Access Rights to Background for Direct Exploitation of Results**

7.4.2.1 Subject to Clause 7.4.1.1 of this Consortium Agreement, Beneficiaries are not required to grant Access Rights to their Background reasonably required for Direct Exploitation of Results and may use, exploit, sublicense or otherwise commercialize their Background as they see fit, subject to the Access Rights granted pursuant to this Consortium Agreement.

#### **7.4.3 Access Rights to Results for Direct Exploitation of Own Results**

7.4.3.1 Subject to the provisions of this Consortium Agreement, in particular Clauses 7.1, 8.1 and 9, during and after completion of the Action, Beneficiaries and their Extended Affiliates enjoy Access Rights to the Results of the other Beneficiaries, to the extent needed for the purpose of Direct Exploitation of (i) their own Results (or those of their Extended Affiliates), and additionally (ii) products and assets they own or control.

Such rights, for clarity, shall not include the right to Directly Exploit the Results of the other Beneficiary on a standalone basis.

7.4.3.2 Such Access Rights for the purposes of Direct Exploitation of own Results are granted under Clause 7.4.3.1 of this Consortium Agreement on Fair and Reasonable Conditions, **[OPTIONAL:** but only to the extent that written notification about the existence of registered Intellectual Property in those Results is sent to the other Beneficiaries including sufficient details to enable the Beneficiaries to trace such registered Intellectual Property (e.g. application number, title, priority date, applicants and filing office),] which terms may be different whether it concerns Action Objective Results or Sideground Results. **[OPTIONAL:** Access Rights to such Results where said written notification is absent or is not provided within six (6) months after the end of the Project, and where such Results are needed for Direct Exploitation of a Beneficiary's own Results, shall be deemed requested and granted on Royalty-Free Conditions.]

7.4.3.3 **[OPTIONAL:** In case Access Rights for Direct Exploitation on a Result has been granted by the owning Beneficiary to a Third Party, and if another Beneficiary would request Access Rights on the same or substantially the same Result for Direct Exploitation of its own Results, those Access Rights shall not be granted on less favourable terms than those granted to such a Third Party.]

#### 7.4.4 Access Rights to Results for Direct Exploitation

7.4.4.1 Subject to Clause 7.4.3 of this Consortium Agreement, Beneficiaries are not required to grant to the other Beneficiaries any Access Rights for Direct Exploitation to their Results.

##### (a) Action Objective Results

Subject to Clause 7.4.3 of this Consortium Agreement, Beneficiaries are not required to grant any Access Rights to Action Objective Results for Direct Exploitation and no Access Rights are granted to Beneficiaries for Direct Exploitation of Action Objective Results.

**[OPTIONAL:** In case Access Rights for Direct Exploitation on a Result has been granted by the owning Beneficiary to a Third Party, and if another Beneficiary would request Access Rights on the same or substantially the same Result for Direct Exploitation of its own Results, those Access Rights shall not be granted on less favourable terms than those granted to such a Third Party.]

##### (b) Sideground Results

Subject to Clause 7.4.3 of this Consortium Agreement, Beneficiaries are not required to grant any Access Rights to Sideground Results for Direct Exploitation and no Access Rights are granted to Beneficiaries for Direct Exploitation of Sideground Results.

## 7.5 [OPTIONAL CLAUSE FOR PROJECTS INVOLVING SOFTWARE: ADDITIONAL ACCESS RIGHTS FOR SOFTWARE]

### 7.5.1 Additional Rights in relation to Software Background, needed for Research Use or Direct Exploitation of (own) Results.

7.5.1.1 **Software Background (Object Code and API).** For the avoidance of doubt, where a Beneficiary has Access Rights to Object Code or API that is Software Background (needed for Research Use or Direct Exploitation of (own) Results), such Access Rights to Software Background exclude the right to sub-license to any Third Parties except to Extended Affiliates and Third Party contractors working on behalf of the Beneficiary enjoying Access Rights. Such sub-licensing rights may, however, be negotiated between the Parties.

7.5.1.2 **Software Background (Source Code).** For the avoidance of doubt, where a Beneficiary has Access Rights to Source Code that is Software Background (needed for Research Use or Direct Exploitation of (own) Results), such Access Rights to Software Background exclude the right to sub-license to any Third Parties except to Extended Affiliates and Third Party contractors working on behalf of the Beneficiary enjoying Access Rights. Such sub-licensing rights may, however, be negotiated between the Parties.]

### 7.5.2 Additional Rights in relation to Software Results, for Research Use or Direct Exploitation of (own) Results [OPTIONAL: and/or of the Beneficiary's own products and assets.]

#### Object Code

7.5.2.1 **Rights of a Beneficiary to Software Results (Object Code).** Where a Beneficiary has Access Rights for Exploitation to Object Code and/or APIs that are Software Results, such Access Rights shall, in addition to the Access Rights for Research Use or Direct Exploitation foreseen in Clause 7 of this Consortium Agreement, as far as needed for the Exploitation of such Beneficiary's own Results [OPTIONAL: and/or of such Beneficiary's own products and assets], comprise the right:

- (i) to make an unlimited number of copies of Object Code and APIs; and
- (ii) to distribute, make available, communicate to the public, market, sell and offer for sale (including using services of a Third Party) such Object Code and APIs as part of or in connection with the own Results [OPTIONAL: and/or products, processes or services of such Beneficiary]; and
- (iii) to use the Object Code and API in research and development, and to create or market any product, process or service, and to use them to create or provide any service.

Provided however that any such products, processes or services of such Beneficiary has been developed by such Beneficiary in accordance with its rights for the Exploitation of Object Code and APIs for the Beneficiary's own Results [OPTIONAL: and/or of such Beneficiary's own products and assets.] *[revise as needed]*.



**7.5.2.2 Right to grant sub-licenses to Software Results to end-users (Object code).**

Access Rights to Object Code shall, as far as needed for the Research Use or Direct Exploitation of a Beneficiary's own Results [*OPTIONAL*: and/or such Beneficiary's own products and assets], comprise the right to grant to end-user customers buying/using the product/services, a sub-license to the extent as necessary for the normal use of the relevant product or service to use the Object Code or APIs alone or as part of or in connection with or integrated into products and services of such Beneficiary and, as far as needed:

(i) to maintain such product/service;

(ii) to create for its own end-use interacting interoperable software in accordance with the Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs

**Source Code**

**7.5.2.3 Rights of a Beneficiary to Software Result (Source Code).** Where, in accordance with Clauses 7.3.3 and 7.4.3 of this Consortium Agreement, a Beneficiary has Access Rights for Research Use or Direct Exploitation of such Beneficiary's own Results to Source Code that is a Software Result, then such Access Rights shall comprise a worldwide right to perform, to make or have made copies, to modify or have modified, to develop, to adapt Source Code for research, to create/market a product/process and to create/provide a service against Fair and Reasonable Conditions. Such rights on the Source Code, however, do not include the right to grant a sub-license to any third parties other than Extended Affiliates or Third Party contractors working on behalf of such Beneficiary.

**7.5.2.4 Right to grant sub-licenses to end-users (Source Code).** Access Rights to Source Code of Software Results under Clauses 7.3.3 and 7.4.3 of this Consortium Agreement for the Research Use or Direct Exploitation of a Beneficiary's own Results [*OPTIONAL*: and/or the Beneficiary's own products and assets] shall include the right to sub-license Source Code solely for purpose of error correction, maintenance and/or support of the Software Result [*OPTIONAL*]; but only if agreed upon such right to sub-license and upon the related conditions with the granting Beneficiary].

**Formalities**

**7.5.2.5 Specific formalities for the above referred end-user sublicences.** Each permitted end-user sub-license granted on Software Results according to the provisions of Clause 7 of this Consortium Agreement shall be made by a written agreement between the Beneficiary granting the sublicense and the Third Party receiving the sublicense, specifying and protecting the proprietary rights of the originating Beneficiary concerned.

**7.6 ACCESS RIGHTS FOR NEW AND DEPARTING BENEFICIARIES**

7.6.1 Beneficiaries joining during the Action in accordance with the provisions of Clause 16 of this Consortium Agreement will be granted the Access Rights as provided for in Clauses 7.1 to 7.4 of this Consortium Agreement [*OPTIONAL*: refer to Clause 7.5 as well if included] hereof as from the date of their signature

of the Form of Accession as described in Appendix 13 of this Consortium Agreement.

7.6.1.1 For Beneficiaries leaving the Action in accordance with the provisions of Clause 13.3 of this Consortium Agreement the following provisions will apply:

7.6.1.1.1 with the exception of the cases where the participation of a Beneficiary is terminated by reason of breach in accordance with the provisions of Clause 13.4 of this Consortium Agreement, the Access Rights accrued up to the date of termination and the obligations to grant Access Rights pursuant to the Grant Agreement and this Consortium Agreement shall continue in full force and effect.

7.6.1.1.2 Defaulting Beneficiaries shall be obliged to continue to grant Access Rights pursuant to the Grant Agreement and this Consortium Agreement, but the Access Rights granted to the Defaulting Beneficiary pursuant to this Consortium Agreement shall cease immediately upon termination of the participation of such Defaulting Beneficiary as a Beneficiary to this Consortium Agreement, or the Grant Agreement, if earlier.

## 7.7 ACCESS RIGHTS FOR THIRD PARTIES

7.7.1 Except if otherwise foreseen (e.g. with respect to Extended Affiliates), no Access Rights to Background or Results are granted to Third Parties pursuant this Consortium Agreement. Any grant of Access Rights to Third Parties shall be on the basis of a separate agreement to be entered into between the owner of respective Background or Results and the requesting Third Parties. Such grant of Access Rights shall be up to the owning Beneficiary's discretion.

## 8. MATERIAL TRANSFER OBLIGATIONS

### 8.1 MATERIAL TRANSFER FOR THE PERFORMANCE OF THE ACTION

8.1.1 If any Materials are transferred for the performance of the Action from one Beneficiary (including through its Extended Affiliates, Associated Partners, and/or Sub-Contractors) ("**Providing Beneficiary**") to another Beneficiary ("**Recipient Beneficiary**"), or to its Extended Affiliates, Associated Partners, and/or Sub-Contractors, each Recipient Beneficiary shall be bound by the following provisions and shall be responsible for ensuring that its Extended Affiliates, Associated Partners, and/or Sub-Contractors comply with such provisions:

8.1.1.1 The Providing Beneficiary is entitled to require the use of one of the material transfer record forms in Appendix 9.

8.1.1.2 The Recipient Beneficiary needs to have all the required authorisations under all applicable laws and regulations to perform the Allocated Work using the Materials.

- 8.1.1.3 The Materials shall be used in full compliance with all applicable laws and regulations.
- 8.1.1.4 The Materials shall be used solely for performance of the Action in accordance with this Consortium Agreement. The Materials will under no circumstances be administered to humans, unless this is specifically required in Annex 1 of the Grant Agreement. The Materials or animals treated therewith shall under no circumstances be used as food for humans or animals.
- 8.1.1.5 Title to any Material shall remain with the Providing Beneficiary at all times.
- 8.1.1.6 The Materials shall not be analysed, copied, modified, used to create any derivative works, or reverse engineered by the Recipient Beneficiary except as necessary for the purpose of the Action.
- 8.1.1.7 [**OPTIONAL: include in case relevant for the Action:** In the case the Material is Imaging Equipment, the Recipient Beneficiary represents and warrants in addition that it shall:
  - 8.1.1.7.1 Notify forthwith the Providing Beneficiary of defects and malfunctions of the Imaging Equipment;
  - 8.1.1.7.2 Give the Providing Beneficiary reasonable access to the Imaging Equipment;
  - 8.1.1.7.3 Not repair or otherwise maintain the Imaging Equipment, or permit others to do so.]
- 8.1.2 The Materials shall not be transferred or made available by the Recipient Beneficiary to any individual other than those under the supervision and control of the Recipient Beneficiary, its Extended Affiliates, Associated Partners, and/or Sub-Contractors. Upon completion of the Action, or the expiry or termination of this Consortium Agreement, any unused Materials will, at the discretion of the Providing Beneficiary, be either returned to the Providing Beneficiary or disposed of/destroyed in accordance with all applicable laws and regulations and subject to providing the Providing Beneficiary with a written confirmation of such disposal or destruction.
- 8.1.3 All Materials are transferred with no warranties, express or implied, of merchantability or fitness for a particular purpose or otherwise. In particular, no Providing Beneficiary represents or warrants that the use of the Materials will not infringe or violate any patent or proprietary rights of Third Parties.
- 8.1.4 The Materials are to be used with caution and prudence in any experimental work, since not all of the characteristics are necessarily known. The Recipient Beneficiary using the Materials shall bear all risk to it and/or any other risks resulting, directly or indirectly, from its use, application, storage or disposal/destruction of the Materials.
- 8.1.5 In case that a Beneficiary requires more stringent clauses in order to protect its Materials to be transferred under the Action, the relevant Beneficiaries may agree on supplemental terms applicable to the transfer of such Materials, which

can be attached as an addendum to the relevant material transfer record form in Appendix 9.

- 8.1.6 This Consortium Agreement shall not be construed by the Recipient Beneficiary, its Extended Affiliates, Associated Partners, and/or Sub-Contractors as an assignment by the Providing Beneficiary of its ownership rights in the Material.

## 8.2 MATERIAL TRANSFER FOR RESEARCH USE

- 8.2.1 If any Materials are transferred for Research Use from the Providing Beneficiary to a Recipient Beneficiary, or to its Extended Affiliates, Associated Partners, and/or Sub-Contractors, on request of the Providing Beneficiary, a material transfer agreement may be established between the Providing Beneficiary and Receiving Beneficiary to implement appropriate provisions. Such a material transfer agreement may not contain provisions contradicting this Consortium Agreement or limiting any usage rights already granted under this Consortium Agreement. If no separate material transfer agreement has been agreed, then the above provisions for use of Materials for the performance of the Action shall apply *mutatis mutandis* for the Research Use of such Materials.

## 8.3 [OPTIONAL: SPECIFIC PROVISIONS ON THE TRANSFER OF HUMAN SAMPLES]

- 8.3.1 include specific provisions on the transfer of human samples here if required for the Action, which may also include country-specific requirements such as for instance on traceability.]

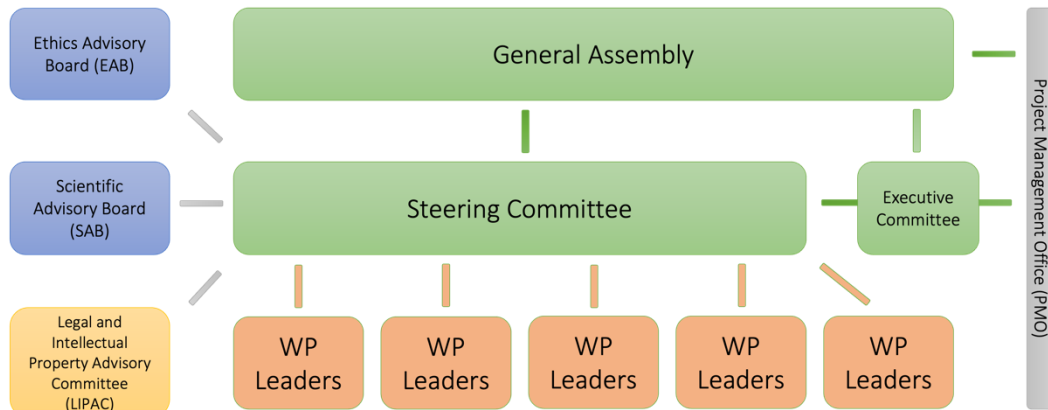
## 9. CONFIDENTIALITY

- 9.1 During implementation of the Action and for [seven (7) years] after the completion of the Action, any Beneficiary (the “**Receiving Beneficiary**”) must keep confidential any Confidential Information that is disclosed by or on behalf of another Beneficiary (the “**Disclosing Beneficiary**”) during the course of the Action.
- 9.2 No Confidential Information of the Disclosing Beneficiary may be used by the Receiving Beneficiary for any purpose other than the performance of the Receiving Beneficiary’s obligations or the exercise of the Receiving Beneficiary’s rights under this Consortium Agreement or the Grant Agreement.
- 9.3 A Receiving Beneficiary may disclose Confidential Information of a Disclosing Beneficiary to its personnel, other individuals under the supervision and control of such Receiving Beneficiary, and its Extended Affiliates, Associated Partners, Sub-Contractors involved in the Action and/or other Third Parties only if they: (i) need to know the Confidential Information in order for the Receiving Beneficiary to exercise its rights or to perform its obligations under this Consortium Agreement or the Grant Agreement, and (ii) are bound by obligations of confidentiality at least equivalent to those set forth herein. The Receiving Beneficiary must use all reasonable endeavours to ensure that persons and/or entities receiving Confidential Information from it do not further disclose such Confidential Information except as is otherwise permitted herein. The Receiving Beneficiary shall be responsible to the Disclosing Beneficiary for any use of the Confidential Information of the Disclosing Beneficiary by any such personnel, Extended Affiliates, Associated Partners, Sub-Contractors and Third Parties, which violates the terms of this Consortium Agreement.
- 9.4 The confidentiality obligations under this Clause 9 do not apply if:

- 9.4.1 the Disclosing Beneficiary agrees in writing that it no longer considers the Confidential Information as protected by the terms of this Clause 9;
  - 9.4.2 the Confidential Information was already known by the Receiving Beneficiary or any of its Extended Affiliates, Associated Partners, and/or Sub-Contractors or is given to such parties by a Third Party without obligation of confidentiality to the extent such Third Party was not bound by any obligation of confidentiality with respect to such Confidential Information;
  - 9.4.3 the Receiving Beneficiary proves that the information was developed independently by the Receiving Beneficiary or its Extended Affiliate, Associated Partners, and/or Sub-Contractors without the use of Confidential Information;
  - 9.4.4 the Confidential Information is, at the time of disclosure, or becomes after such disclosure generally and publicly available, without any breach by the Receiving Beneficiary of its confidentiality obligations hereunder or any applicable law (including Data Protection Legislation) in this regard.
- 9.5 Disclosure of Confidential Information shall be permitted if the Receiving Beneficiary is required to do so by or in connection with any laws, regulations or legal processing, or court of competent jurisdiction, provided that such disclosure is subject to all applicable governmental, regulatory or judicial protection available and immediate written notice of such requirement is given to the Disclosing Beneficiary with a view to agreeing the timing and the content of such disclosure. The same shall apply in case a disclosure of Confidential Information to a patent office or equivalent government agency or department required for the purposes of obtaining patent protection, provided, that the Beneficiary opting for patent or similar protection must give prior written notice to the Disclosing Beneficiary and agree the timing and the content of such disclosure with the Disclosing Beneficiary.
- 9.6 The Receiving Beneficiary shall return to the Disclosing Beneficiary all documents or other materials containing any of the Disclosing Beneficiary's Confidential Information, which are in its possession, power or control or in the possession, power or control of its personnel, other individuals under the supervision and control of the Receiving Beneficiary, Extended Affiliates, Associated Partners, and/or Sub-Contractors involved in the Action who have received such Confidential Information from the Receiving Beneficiary pursuant to this Clause 9, whenever requested to do so by the Disclosing Beneficiary, and where such Confidential Information is not required by the Receiving Beneficiary for the use or exercise of (i) Access Rights for completing the Action or (ii) other rights or licenses under this Consortium Agreement. The return or destruction of Confidential Information will not affect the Receiving Beneficiary's obligation to observe the confidentiality and non-use restrictions in respect of the Disclosing Beneficiary's Confidential Information set out in this Consortium Agreement. The Beneficiary shall be entitled to keep one (1) copy of the Confidential Information in a secure place for the purpose of evidence. The provisions of this Clause 9.6 shall not apply to copies of electronically exchanged Confidential Information made as a matter of routine information technology backup and to Confidential Information or copies thereof which must be stored by the Receiving Beneficiary according to provisions of mandatory law.

## 10. PROJECT MANAGEMENT AND GOVERNANCE STRUCTURE

*[This is an example of how project governance can be structured and can be used for guidance. It can be adapted according to the size of the consortium and specific requirements of the Project, but always reflecting the public-private partnership philosophy.]*



### 10.1 COORDINATOR

#### 10.1.1 Appointment

**[Beneficiary X]** is appointed as Coordinator. The Coordinator shall act through a designated Representative.

#### 10.1.2 Responsibilities

10.1.2.1 The Coordinator is and shall be a central point of contact between the Beneficiaries and the IHI JU in particular regarding the management of the Grant.

10.1.2.2 The Coordinator will perform certain duties as part of the general management of the Action, as provided for in the Grant Agreement (for instance, its Article 7(b)). The Coordinator shall act in close collaboration with the Project Leader. In particular, the Coordinator shall be responsible for:

- a) coordinating and managing of the Grant;
- b) central point of contact for IHI JU for its administration, meaning that the Coordinator shall be responsible for
  - receiving all payments made by the IHI JU;
  - distributing the IHI JU funding to Beneficiaries eligible to receive IHI JU funding;
  - ensuring that all the appropriate payments are made to the Beneficiaries eligible to receive IHI JU funding without unjustified delay;
  - keeping accurate accounts of the amounts of, and distribution of, IHI JU funding to Beneficiaries eligible to receive IHI JU funding;
  - informing the IHI JU of the distribution of IHI JU funding, the amounts and the dates of such transfer to Beneficiaries eligible to receive IHI JU funding;

- c) after consultation with the Project Leader monitoring that the Action is implemented properly;
- d) acting as the intermediary for all communications between the Beneficiaries and IHI JU (unless the Grant Agreement or the IHI JU instructs otherwise), in particular those relating to the administration and management of the Grant and the submission of prefinancing guarantees to the IHI JU. This includes communications taking place through the EU's Funding and Tender Portal. However, for communications relating to a specific Beneficiary (other than with respect to Deliverables agreed upon in the relevant WPs and the submission of reports and guarantees provided by such Beneficiary to the Coordinator), the Coordinator shall request the views of the specific Beneficiary and, except in the case it is a Defaulting Beneficiary, incorporate the input of such a Beneficiary in the relevant communication.
- e) request and review together with the Project Leader, any documents or information required by IHI JU and verifying their completeness and correctness before submission to IHI JU;
- f) including the individual financial statements from each Beneficiary receiving JU funding to verify consistency with the Actions tasks and in requested format;
- g) verifying that other requested documents than the financial statements are submitted by the Beneficiary and in requested format;
- h) verifying that the technical information submitted by a Beneficiary concerns its Action tasks as described in Annex 1 of the Grant Agreement;
- i) submitting reports on the Deliverables and other requested reports to the IHI JU following prior review by the Project Leader.

10.1.3 Except as stated in Clause 11 of this Consortium Agreement, the Coordinator shall neither be entitled to act or to make legally binding declarations, on behalf of any other Beneficiary nor to enlarge their role beyond the one described herein and in the Grant Agreement, without the prior written consent of the Beneficiaries.

10.1.4 If one or more of the Beneficiaries is late in submitting Deliverables, or any other information or material required under the Grant Agreement or under this Consortium Agreement, the Coordinator shall submit the other Beneficiaries' Deliverables to the IHI JU without the contribution of the Defaulting Beneficiaries and report the delay of these Beneficiaries to the IHI JU after approval by the Project Leader.

10.1.5 The Coordinator shall forward any information, report or other correspondence referred to in Clause 10.1.4 of this Consortium Agreement promptly to IHI JU.

## 10.2 PROJECT LEADER

#### 10.2.1 Appointment

**[Beneficiary Y]** is appointed as Project Leader. The Project Leader shall act through a designated Representative.

#### 10.2.2 Responsibilities

The Project Leader is in charge of the overall scientific and Action related governance and will perform a number of duties as part of the general management of the Action and will act in close collaboration with the Coordinator. In particular, the Project Leader shall be responsible for:

- a) Ensuring strong scientific coordination and collaboration between all Beneficiaries;
- b) reviewing the Deliverables and reports before submission by the Coordinator to the IHI JU;
- c) being informed on and collaborate with the Coordinator on its monitoring activities and the adoption of appropriate internal measures to ensure the Beneficiaries are on track with their obligations as well as with respect to budget, time, Deliverables and high scientific quality, under the Grant Agreement and/or this Consortium Agreement;
- d) advising the Coordinator on the allocation and distribution of the IHI JU financial contribution among Beneficiaries eligible to receive IHI JU funding, in accordance with the Grant Agreement and this Consortium Agreement;
- e) acting as the key contact and intermediary for all scientific and Action governance issues including external communications, other than the ones entrusted directly to the Coordinator (e.g. with bodies like EFPIA or other industry associations and their internal working groups); overseeing the technical, financial, technological (innovation impact) and ethical aspects; this shall be done jointly with the Coordinator;
- f) coordinating the drafting and negotiation of legal agreements which are needed for implementing the Action, in collaboration with the Beneficiaries;
- g) working with Beneficiaries to prepare and negotiate any non-disclosure agreements that may be required, unless covered by the Mandate pursuant to Clause 11 of this Consortium Agreement.

10.2.3 Except as stated in Clause 11 of this Consortium Agreement, the Project Leader shall neither be entitled to act or to make legally binding declarations, on behalf of any other Beneficiary nor to enlarge its role beyond the one described herein and in the Grant Agreement, without the prior written consent of the Beneficiaries.

10.2.4 The Project Leader and the Coordinator shall jointly agree on withholding any payment if a Beneficiary eligible to receive IHI JU funding is late in submitting or refuses to provide Deliverables as required under the Grant Agreement and this Consortium Agreement.

10.2.5 Other than where expressly provided in this Consortium Agreement, any information, Deliverables, report or other correspondence which a Beneficiary or the Consortium, pursuant to the provisions of this Consortium Agreement or of the Grant Agreement are required to communicate to the IHI JU, shall first be



approved by the Project Leader who will send such approved information, report or other correspondence to the Coordinator.

### 10.3 [OPTIONAL: EXECUTIVE COMMITTEE:

[Complex and large projects may establish a Executive Committee to facilitate the effective execution of the Action.]

#### 10.3.1 Members

The Executive Committee can be made up of the Representative appointed as Project Leader, the Representative appointed as Coordinator together with the representative from the Project Management Office (the latter non-voting).

#### 10.3.2 Responsibilities

[Decide which of the listed responsibilities of the Steering Committee that should be given to the Executive Committee. Most likely, the Executive Committee shall be responsible for the preparation of decisions with respect to policies and decision making in relation to the overall management of the Project, the day-to-day operations and the initial mediation of any disputes between the Beneficiaries relating to the execution of the Project. It will ensure the smooth operation of the Action and guarantee that all efforts are focused towards the objectives.]

#### 10.3.3 Meetings

10.3.3.1 The Project Leader shall act as the chairperson of the Executive Committee (the “Chairperson of the Executive Committee”) and shall

- a) be responsible for the convening of meetings, preparation and distribution of the agenda and minutes for meetings of the Executive Committee; and
- b) chair meetings of the Executive Committee.

10.3.3.2 Where the Chairperson of the Executive Committee cannot attend an Executive Committee meeting, the Representative of the Project Management Office or the Coordinator shall chair the meeting for the purposes of such meeting.

10.3.3.3 For circulation procedures Clause 10.5.5 of this Consortium Agreement shall apply *mutatis mutandis*, except for the voting rules, for which Clause 10.3.4 shall apply *mutatis mutandis*.

10.3.3.4 Minutes of the meetings of the Executive Committee will be prepared by the Chairperson of the Executive Committee (or replacement) and made available to each of the members of the Executive Committee within fourteen (14) Days after each meeting.

10.3.3.5 Minutes of the meetings of the Executive Committee shall be considered as accepted by the members of the Executive Committee if, within two (2) weeks from receipt, no member of the Executive Committee who was present at the relevant meeting has objected in a traceable form to the Chairperson of the Executive Committee. Requests for amendments will be considered by the Chairperson of the Executive Committee and if

approved will be sent to all members of the Executive Committee. The minutes may be shared with the Steering Committee after acceptance.

10.3.3.6 Any member of the Executive Committee may participate in meetings of the Executive Committee by telephone-conference, video-conference or any other technology that enables everyone participating in the meeting to communicate interactively and simultaneously with each other.

10.3.3.7 Any experts or qualified persons may be invited by any member of the Executive Committee to attend meetings of the Executive Committee with a role of non-voting advisor. Prior to their first participation in a meeting of the Executive Committee or their first receipt of Confidential Information, any Third Party expert or qualified person shall first enter into an Advisory Agreement with the Project Leader, on behalf of the Beneficiaries, in accordance with Clause 11.1.4 of this Consortium Agreement. This requirement to enter into an Advisory Agreement shall not apply to the extent such expert or qualified person is (i) an employee, agent, consultant, or Sub-Contractor of a Beneficiary which is under confidentiality obligations at least equivalent to the confidentiality obligations provided herein and which is required to assign any Intellectual Property to such Beneficiary in order for the latter to comply with its obligations under this Consortium Agreement; or (ii) a representative of a governmental or administrative agency under confidentiality obligations imposed by law or regulations.

#### 10.3.4 Decisions

10.3.4.1 In order for an Executive Committee meeting to be quorate **[seventy five (75) percent]** of its members need to attend, as well as the Representatives of the Project Leader and the Coordinator. **[Depending on size and structures]**

10.3.4.2 Where a Executive Committee meeting shall be inquorate, the Chairperson of the Executive Committee shall reconvene its members at a date no later than three (3) weeks from the date of the original meeting, and shall advise the members accordingly by notice in writing.

10.3.4.3 Decisions will be taken by **[simple majority/unanimity]**. The Project Leader shall have a casting vote.

10.3.4.4 Decisions of which the subject matter has not been duly announced in the agenda of a meeting may only be taken if no member of the Executive Committee objects; absent members of the Executive Committee shall have the opportunity to object subsequently to these decisions within a reasonable period of time to be specified by the Chairperson of the Executive Committee.]

### 10.4 STEERING COMMITTEE

#### 10.4.1 Members

The Consortium shall have a Steering Committee. The Steering Committee shall be made up of the Project Leader, the Coordinator, the Work Package Leaders (i.e. two (2) per Work

Package), and a representative of the Project Management Office (the latter if established shall have no voting rights).

#### 10.4.2 Responsibilities

10.4.2.1 The Steering Committee shall be responsible for the overall execution of the Action, alignment across all Work Packages, decision making and the initial finding of amicable solutions for any disputes between the Beneficiaries relating to the execution of the Action. It will ensure the smooth operation of the Action and guarantee that all efforts are focused towards the Action Objectives and Deliverables. This will be achieved by regular meetings, at least every second month and thorough reviews of progress reports. It will also ensure that all Beneficiaries are regularly updated on the scientific progress.

10.4.2.2 The Steering Committee shall undertake, and decide on, the following matters, provided such matters and their implementation are in compliance with the terms of the Grant Agreement:

- a) monitor progress against Action Objectives and budget;
- b) ensure effective communication external and between WPs with regard to Project progress, best practice and harmonisation and validation across teams using project communication and management tools to ensure operational consistency and efficiency;
- c) ensure alignment of activities between the WPs and progress towards common goal of success in the Project;
- d) recommend changes to Allocated Work, budget allocation, risk mitigation plans and potential changes in Project direction for endorsement by the General Assembly;
- e) during the Action period, receive and coordinate all written requests, if required, for Access Rights to Background and/or Results which a Beneficiary may wish to make, and forwarding, as appropriate, to the concerned Beneficiaries;
- f) encourage the organisation of regular meetings between the WP members and the whole Consortium to ensure true collaboration between the Beneficiaries, adequate flow of information within the Consortium and clarification of any potential overlaps and interdependencies;
- g) prepare Project activity reports, periodic reports (including financial statements), risk management procedures, quality assurance plans, prior to submission to the IHI JU;
- h) mediate conflicts which cannot be handled within the individual Work Packages and finding amicable solutions for any unresolved disputes between the Beneficiaries relating to the execution of the Action;
- i) decide upon measures in the framework of controls to ensure the effective day-to-day coordination and monitoring of the progress of the technical work affecting the Action as a whole;
- j) without limitation to any of the foregoing responsibilities, proper management and administration of the Action and implementation of

the provisions contained in the Grant Agreement and in this Consortium Agreement.

10.4.2.3 The Steering Committee will be supported by the Project Management Office.

#### 10.4.3 Meetings

10.4.3.1 A Representative of the Project Leader shall act as the chairperson of the Steering Committee (the “**Chairperson of the Steering Committee**”) and shall

- a) with assistance from the Project Management Office be responsible for the convening of meetings, preparation and distribution of the agenda and minutes for meetings of the Steering Committee; and
- b) chair meetings of the Steering Committee.

10.4.3.2 Where the Chairperson of the Steering Committee cannot attend a Steering Committee meeting, the representative of the Project Management Office or the Coordinator shall chair the meeting for the purposes of such meeting.

10.4.3.3 The Chairperson of the Steering Committee convenes the meetings, at least every **[second month]** through written notice (fourteen (14) Days in advance) including an agenda. The meetings can be either face-to face meetings or telephone or video conference allowing votes to be submitted verbally and agreed by all Representatives of the Steering Committee. Additional ad hoc meetings may be held at any time as agreed among the Representatives of the Steering Committee; for circulation procedures Clause 10.5.5 of this Consortium Agreement shall apply *mutatis mutandis*, except for the voting rules, for which Clause 10.4.4 shall apply *mutatis mutandis*. Minutes of the meetings of the Steering Committee will be prepared by the Chairperson of the Steering Committee (or his replacement) and made available to each of the Representatives of the Steering Committee within fourteen (14) Days after each meeting.

10.4.3.4 Minutes of the meetings of the Steering Committee shall be considered as accepted by the Representatives of the Steering Committee if, within two (2) weeks from receipt, no Representative of the Steering Committee who was present at the relevant meeting has objected in a traceable form to the Chairperson of the Steering Committee. Requests for amendments will be considered by the Chairperson of the Steering Committee and if approved will be sent to all Representatives of the Steering Committee.

10.4.3.5 Any experts or qualified persons may be invited by any member of the Steering Committee to attend meetings of the Steering Committee with a role of non-voting advisor. Prior to their first participation in a meeting of the Steering Committee or their first receipt of Confidential Information, any Third Party expert or qualified person shall first enter into an Advisory Agreement in accordance with Clause 11.1.4 of this Consortium Agreement. This requirement to enter into an Advisory Agreement shall not apply to the extent such expert or qualified person is (i) an employee, agent, consultant, or Sub-Contractor of a Beneficiary which is under confidentiality obligations at least equivalent to the confidentiality

obligations provided herein and which is required to assign any Intellectual Property to such Beneficiary in order for the latter to comply with its obligations under this Consortium Agreement; or (ii) a representative of a governmental or administrative agency under confidentiality obligations imposed by law or regulations.

#### 10.4.4 Decisions

10.4.4.1 In order for a Steering Committee meeting to be quorate seventy-five (75) percent of its members need to attend as well as the Representatives of the Project Leader and the Coordinator.

10.4.4.2 Where a Steering Committee meeting shall be inquorate, the Chairperson of the Steering Committee shall reconvene its members at a date no later than three (3) weeks from the date of the original meeting, and shall advise the members accordingly by notice in writing. Clause 10.4.3.3 of this Consortium Agreement shall apply *mutatis mutandis*.

10.4.4.3 Decisions will be taken by **[simple majority]**. The Project Leader shall have a casting vote.

10.4.4.4 Decisions of which the subject matter has not been duly announced in the agenda of a meeting may only be taken if no member of the Steering Committee objects; absent members of the Steering Committee shall have the opportunity to object subsequently to these decisions within a reasonable period of time to be specified by the Chairperson of the Steering Committee.

### 10.5 GENERAL ASSEMBLY

#### 10.5.1 Members

The Consortium shall have a General Assembly. The General Assembly will be made up of one Representative nominated by each of the Beneficiaries. If necessary, each Beneficiary shall also be entitled to nominate a replacement Representative in the event that the original Representative is unable to attend any scheduled meetings of the General Assembly.

#### 10.5.2 Responsibilities

10.5.2.1 The General Assembly shall be responsible for the determination of policies and decision making in relation to the overall management of the Action.

10.5.2.2 The General Assembly shall undertake, and decide on, the following matters, provided such matters and their implementation are in compliance with the terms of the Grant Agreement and this Consortium Agreement:

- a) supporting the Project Leader and Coordinator in fulfilling their obligations towards the IHI JU;
- b) reviewing the progress of the Action;
- c) deciding on strategic direction, changes to the scope and project direction, proposal to expand or extent the Action, major re-allocation of IHI funding and contribution;

- d) deciding on principles for effective communication;
- e) agreeing (without prejudice to the Clause 6.6 of this Consortium Agreement) on procedures and policies in accordance with the Grant Agreement for dissemination of Results;
- f) agreeing on adequate management procedures, quality standards and quality for the Action;
- g) agreeing on entries of new Beneficiaries and departures of existing Beneficiaries;
- h) deciding in relation to the service of notice on a terminating Beneficiary pursuant to Clauses 13.2 and 13.4 of this Consortium Agreement and the reassignment of that Beneficiary 's Allocated Work;
- i) agreeing on proposals to the IHI JU to change direction of the Consortium, including Project Leader and/or Coordinator replacement;
- j) agreeing on Project termination;
- k) without limitation to any of the foregoing responsibilities, oversee proper management and administration of the Action and implementation of the provisions contained in the Grant Agreement and in this Consortium Agreement.

### 10.5.3 Meetings

10.5.3.1A Representative of the Project Leader shall chair (the “**Chairperson of the General Assembly**”), and a Representative of the Coordinator shall co-chair the General Assembly. Such co-chair shall be deemed Chairperson of the General Assembly in case the Representative of the Project Leader does not attend. The Chairperson of the General Assembly shall:

- a) With assistance of the PMO, be responsible for the convening of meetings, preparation and distribution of the agenda and minutes for meetings of the General Assembly; and
- b) chair meetings of the General Assembly.

10.5.3.2Where the Chairperson of the General Assembly or the co-chair cannot attend a General Assembly meeting, the General Assembly shall nominate a replacement to chair the meeting for the purposes of such meeting of the General Assembly only, provided that the replacement must be a Representative. Such replacement shall be deemed Chairperson of the General Assembly.

10.5.3.3The Beneficiaries will ensure that the General Assembly meets at least every **[twelve (12)]** months at venues to be agreed, if possible, or through online meetings otherwise, or at any other time at the request of any of the Beneficiaries. Meetings may be held via face-to-face or telephone or video conference allowing votes to be submitted verbally; for circulation procedures Clause 10.5.5 of this Consortium Agreement shall apply.

10.5.3.4Meetings of the General Assembly will be convened with at least twenty-one (21) Days written notice in advance by the Chairperson of the General Assembly. Invitation to the meetings may be in writing, by e-mail or by other electronic communication means. Such notice must include an

agenda. Minutes of the meetings of the General Assembly will be sent to each of the Beneficiaries within fourteen (14) Days after each meeting. Minutes of the meetings of the General Assembly shall be considered as accepted by the Representatives of the General Assembly if, within two (2) weeks from receipt, no Representative of the General Assembly who was present at the relevant meeting has objected in a traceable form to the Chairperson of the General Assembly. Requests for amendments will be considered by the Chairperson of the General Assembly and if approved will be sent to all Representatives of the General Assembly.

10.5.3.5 Any Representative of the General Assembly may participate in meetings of the General Assembly by tele-conference, video-conference or any other technology that enables interactive and simultaneous communication.

10.5.3.6 Any experts or qualified persons may be invited by any Representative of the General Assembly to attend meetings of the General Assembly with a role of non-voting advisor. Prior to their first participation in a meeting of the General Assembly or their first receipt of Confidential Information, any Third Party expert or qualified person shall first enter into an Advisory Agreement in accordance with Clause 11.1.4 of this Consortium Agreement. This requirement to enter into an Advisory Agreement shall not apply to the extent such expert or qualified person is (i) an employee, agent, consultant, or Sub-Contractor of a Beneficiary which is under confidentiality obligations at least equivalent to the confidentiality obligations provided herein and which is required to assign any Intellectual Property to such Beneficiary in order for the latter to comply with its obligations under this Consortium Agreement; or (ii) a representative of a governmental or administrative agency under confidentiality obligations imposed by law or regulations.

#### 10.5.4 Decisions; Voting Rules

10.5.4.1 In order for a General Assembly meeting to be quorate there shall be present no fewer than seventy-five (75) percent of the General Assembly Representatives.

10.5.4.2 Where a General Assembly meeting shall be inquorate, the Chairperson of the General Assembly shall reconvene the Representatives at a date no later than three (3) weeks from the date of the original meeting, and shall advise the Representatives accordingly by notice in writing. Clause 10.5.3.4 of this Consortium Agreement shall apply *mutatis mutandis*.

10.5.4.3 Each Beneficiary will, through its Representative, have one vote in the General Assembly. Decisions will be taken by a majority of [sixty (60)] percent in each of (i) the group of Beneficiaries Not Receiving IHI JU Funding; and (ii) the group of Beneficiaries Receiving IHI JU Funding, except where a decision necessitates a major change to the Allocated Work or a change to the allocation of any funding. In either of those cases, any decision must also be approved by any Beneficiary directly affected by

such change. The Coordinator will inform the IHI JU of any such decision. The Chairperson of the General Assembly will have a casting vote.

10.5.4.4 The Beneficiaries agree to abide by all decisions of the General Assembly, provided always that a Beneficiary whose scope of work, time for performance, in-kind contributions costs or liabilities are changed from those defined in the Allocated Work and/or this Consortium Agreement, or whose Confidential Information, including without limitation any Background or Results, is to be published, disclosed or disseminated or whose name is to be included in a press release, may veto such decisions at the relevant meeting of the General Assembly.

10.5.4.5 Decisions of which the subject matter has not been duly announced in the agenda of a meeting may only be taken if no Beneficiary objects; absent Beneficiaries shall have the opportunity to object subsequently to these decisions within a reasonable period of time to be specified by the Chairperson of the General Assembly.

#### 10.5.5 Circulation Procedure

10.5.5.1 Decisions may be taken by way of circulation procedure. Respective requests may be circulated by the Chairperson of the General Assembly in hard copy or by email.

10.5.5.2 The Chairperson of the General Assembly shall notify the Representatives of the General Assembly via email on the request for a decision, and a term of at least seven (7) Days to agree to the decision by approving it (email suffice).

10.5.5.3 A valid decision requires the participation of at least seventy-five (75) percent of the Representatives of the General Assembly in the circulation procedure within the given term.

10.5.5.4 Decisions will be taken in accordance with the voting rules of Clause 10.5.4 of this Consortium Agreement.

10.5.5.5 The decision must be notified to all Beneficiaries in order to become effective. The Chairperson of the General Assembly shall keep and sign minutes of all decisions taken.

### 10.6 PROJECT MANAGEMENT OFFICE (PMO)

#### 10.6.1 Members

10.6.1.1 The PMO is made up of Representatives of **[insert correct body or Beneficiary]** and will be dealing with the day-to-day project management of the Action and support of the Project Leader and the Coordinator

#### 10.6.2 Responsibilities

The Project Management Office will be responsible for:

- a) providing day-to-day project management of the Action;



- b) keeping the Consortium management structure up to date and stable by preparing internal documentation that allow for the successful monitoring of the project progress, by tracking of submitted Deliverables;
- c) informing the relevant bodies on delays, issues and problems, to enable effective communication across the Beneficiaries;
- d) advising partners on administrative requirements;
- e) organizing project meetings and to maintaining project documentation;

## 10.7 [OPTIONAL: LEGAL AND INTELLECTUAL PROPERTY ADVISORY COMMITTEE (LIPAC)]

### 10.7.1 Members

10.7.1.1 The LIPAC shall be composed of [*insert detail on members*] who are experts in legal and/or intellectual property matters. The members of the LIPAC will be approved by the Steering Committee.

10.7.1.2 On an as-need basis, the LIPAC shall be entitled to invite additional experts or advisors to the meetings, who will have no voting powers.

### 10.7.2 Responsibilities

10.7.2.3 The LIPAC shall, on a no-reliance basis (i) assist the Steering Committee [*OPTIONAL: and the Executive Committee*] in advising on the correct application of Clauses 5 to 9 of this Consortium Agreement, (ii) coordinate any amendments to this Consortium Agreement; and (iii) advise on potential other areas where legal or intellectual property advice is useful.

10.7.2.4 The LIPAC shall not be an arbitration body to deal with intellectual property or other legal conflicts among the Beneficiaries.

10.7.2.5 None of the interpretations or statements made by individual members of the LIPAC shall have a binding value, unless they have resulted in a signed amendment of this Consortium Agreement.

### 10.7.3 Meetings

10.7.3.1 The LIPAC shall meet regularly by telephone conference, and at least once a year face-to-face at venues to be agreed, or at any other time at the request of the Steering Committee [*OPTIONAL: or the Executive Committee*]. Such meetings may be held by face-to-face presence, telephone-conference, video-conference or any other technology that enables everyone participating in the meeting to communicate interactively and simultaneously with each other.

10.7.3.2 Any experts or qualified persons may be invited by any member of the LIPAC to attend meetings of the LIPAC with a role of non-voting advisor. Prior to their first participation in a meeting of the LIPAC or their first receipt of Confidential Information, any Third Party expert or qualified person shall first enter into an Advisory Agreement in accordance with Clause 11.1.4 of this Consortium Agreement. This requirement to enter into an Advisory Agreement does not apply to the extent such expert or qualified person is (i) an employee, agent, consultant, or Sub-Contractor of

a Beneficiary which is under confidentiality obligations at least equivalent to the confidentiality obligations provided herein and which is required to assign any intellectual property to such Beneficiary in order for the latter to comply with its obligations under this Consortium Agreement; or (ii) a representative of a governmental or administrative agency under confidentiality obligations imposed by law or regulations. ]

## 10.8 [OPTIONAL: THE SCIENTIFIC ADVISORY BOARD (SAB)]

### 10.8.1 Members

10.8.1.1 The Scientific Advisory Board (SAB) shall consist of at least [ ] and not more than [ ] members. Nominations for membership of the Scientific Advisory Board may be submitted to the Steering Committee [**OPTIONAL: can be replaced with the Executive Committee, if established**] by any Beneficiary. The Steering Committee shall ensure that the composition of the SAB is appropriate to provide the guidance required to achieve Action goals and shall invite nominees to the SAB accordingly. Members of the SAB shall be approved by the General Assembly.

10.8.1.2 Prior to their first participation in a meeting of the SAB or their first receipt of Confidential Information, any Third Party expert or qualified person shall first enter into a suitable Advisory Agreement pursuant to Clause 11.1.4 of this Consortium Agreement.

### 10.8.2 Responsibilities

10.8.2.1 The SAB is an advisory board to the Action in general and the General Assembly and Steering Committee in particular. The Scientific Advisory Board will advise the General Assembly and the Steering Committee upon the request of the Project Leader together with the Coordinator and provide non-binding advice to the General Assembly and the Steering Committee as decision making support.

### 10.8.3 Meetings

10.8.3.1 The SAB will meet upon request of the Project Leader [**OPTIONAL: can be replaced with the Executive Committee, if established**] but at least once every twelve (12) months during the Action.

10.8.3.2 Upon request of the Project Leader, the Scientific Advisory Board will be able to call to meetings additional experts covering particular fields of expertise on a case by case basis. ]

## 10.9 [OPTIONAL: ETHICS ADVISORY BOARD (EAB)]

### 10.9.1 Members

10.9.1.1 The Ethics Advisory Board (EAB) is composed of [ ] experts with detailed knowledge of ethical policies. Experts who make up the EAB shall represent the various interests involved in the Action. Nominations for membership of the Ethics Advisory Board may be submitted to the Steering Committee [**OPTIONAL: can be replaced with the Executive**

*Committee, if established*] by any Beneficiary. The Steering Committee shall ensure that the composition of the EAB is appropriate to provide the guidance required.

10.9.1.2 Prior to their first participation in a meeting of the EAB or their first receipt of Confidential Information, any Third Party expert or qualified person shall first enter into a suitable Advisory Agreement pursuant to Clause 11.1.4 of this Consortium Agreement.

#### 10.9.2 Responsibilities

10.9.2.1 The Ethics Advisory Board is an advisory board to the Action in general and the General Assembly and Steering Committee in particular. The Ethics Advisory Board will advise the General Assembly and the Steering Committee upon request of the Project Leader together with the Coordinator and provide non-binding advice to the General Assembly and the Steering Committee as decision making support.

10.9.2.2 The Ethics Advisory Board will be responsible for *[to be adapted on a case-by-case basis]*:

- a) reviewing the proper application of the ethical rules by the Beneficiaries;
- b) providing advice to the Beneficiaries, the General Assembly and the Steering Committee on ethical issues; and
- c) providing advice on the compliance with European ethical laws and regulations and with different guidelines, laws and regulations of countries where studies are being performed.

#### 10.9.3 Meetings

The EAB will meet upon request of the General Assembly or Steering Committee *[OPTIONAL: can be replaced with the Executive Committee, if established]* but at least once every twelve (12) months during the Action. ]

## 11. MANDATE

11.1 To facilitate the work of the Project Leader, the Coordinator, the Steering Committee and the General Assembly and to allow for an easier engagement in discussions with Third Parties in fulfilment of their obligations under this Consortium Agreement, the Beneficiaries hereby give the following Mandate to the Project Leader and the Coordinator to jointly act for and on behalf of the Beneficiaries and to take the following legal acts and measures as it deems necessary, provided that it acts in compliance with the applicable laws and regulations:

11.1.1 **Initial non-binding discussions** with a Third Party that has expressed an interest in (i) providing independent advice to the Project, (ii) acceding to the Action in compliance with the Grant Agreement and this Consortium Agreement, or (iii) a collaboration between the Action, the specific Third Party, other IHI projects or other Third Party collaborations, provided, however, that no Confidential Information is exchanged;

11.1.2 **Negotiation and conclusion of a one-sided confidential disclosure agreement ("CDA")** materially in the form attached hereto in Appendix 10 with a Third Party

regarding disclosure of this Consortium Agreement (excluding Appendix 5) and disclosure of Confidential Information of the Beneficiaries, in order to engage in discussions with such specific Third Party that has expressed an interest in (i) providing independent advice to any of the various committees in the Project or to the Action as such, (ii) acceding to the Action in compliance with the Grant Agreement and this Consortium Agreement, or (iii) a collaboration between the Action and such specific Third Party, other IHI projects or other Third Party collaborations; provided, however, that the Beneficiaries have been informed at least one week in advance about the engagement in discussions with such Third Party by prior written notice (enclosing the CDA proposed for signature, detailing the types of Confidential Information to be disclosed and the purpose of disclosure) from either the Project Leader or the Coordinator (e-mail suffice) and have not objected to such the conclusion of such CDA in writing to the Project Leader and/or the Coordinator within one (1) week after receipt of such notification (e-mail for notification suffice).

11.1.3 **Negotiation and conclusion of a two-sided CDA** materially in the form attached hereto in Appendix 11 with a Third Party regarding disclosure of this Consortium Agreement (excluding Appendix 5), disclosure of Confidential Information of the Beneficiaries or its Beneficiaries and receipt of Confidential Information from such Third Party, in order to engage in discussions with such specific Third Party that has expressed an interest in a collaboration between the Action and such specific Third Party, other IHI projects or other Third Party collaborations; provided, however, that the Beneficiaries have been informed at least one week in advance about the engagement in discussions with such Third Party by prior written notice (enclosing the CDA proposed for signature, detailing the types of Confidential Information to be disclosed and received and the purpose of disclosure) from the Project Leader and/or the Coordinator (e-mail suffice) and has not objected to the conclusion of such CDA in writing to the Project Leader and/or the Coordinator within one (1) week after receipt such notification (e-mail suffice).

11.1.4 **Negotiation and conclusion of an advisory agreement** materially in the form attached hereto in Appendix 12 (“**Advisory Agreement**”) with the experts and qualified persons for which an advisory agreement needs to be executed in accordance with Clauses 10.3.3.7, 10.4.3.5, 10.5.3.6, 10.7.3.2, 10.8.1.2 and 10.9.1.2 of this Consortium Agreement.

11.2 If any material changes to the agreements as attached in Appendix 10 to Appendix 12 are proposed in the negotiations with a Third Party, the Project Leader and the Coordinator shall be entitled to accept such changes to the extent that the rights and obligations of the Beneficiaries under the Grant Agreement and this Consortium Agreement are not altered.

11.3 The Beneficiaries will receive a copy of each executed agreement for their files.

11.4 The Mandate shall remain in force until (i) this Consortium Agreement expires or is terminated, (ii) with respect to such leaving Beneficiary until this Beneficiary leaves the Action pursuant to this Consortium Agreement, or (iii) with respect to such revoking Beneficiary, until the Mandate is revoked by a Beneficiary by written notice to the Project Leader and the Coordinator. For the avoidance of doubt, in case one or more Beneficiaries leave the Action or revoke the Mandate, the Mandate will remain in force for each other Beneficiary, and any agreements entered into prior to such Beneficiary

leaving the Action or revoking its Mandate shall remain in full force and effect even for the leaving and/or revoking Beneficiary.

## **12. LIABILITY BETWEEN THE BENEFICIARIES, INDEMNIFICATION**

### **12.1 LIABILITY BETWEEN THE BENEFICIARIES OTHER THAN FOR THIRD PARTY CLAIMS**

- 12.1.1 No Beneficiary shall be liable to any other Beneficiary for the acts or omissions committed by such other Beneficiary in its performance of its obligations under the Grant Agreement or this Consortium Agreement.
- 12.1.2 In respect of any information or materials (including Results, Background, and Confidential Information) supplied by one Beneficiary to another hereunder or pursuant to the Grant Agreement, the supplying Beneficiary shall be under no obligation or liability other than as expressly stated herein and no warranty condition or representation of any kind is made, given or to be implied as to the sufficiency, accuracy or fitness for purpose of such information or materials, or the absence of any infringement of any (intellectual) proprietary rights of Third Parties or the other Beneficiaries. A recipient Beneficiary, by the use of such information and materials, shall be entirely responsible for any loss, damage or injury resulting from its use of such information and materials.
- 12.1.3 Without prejudice to any of the foregoing provisions of this Clause 12, each Beneficiary acknowledges that it shall be solely responsible for ensuring that its activities under this Consortium Agreement (as well as those of its Affiliated Entities, Sub-Contractors, and Associated Partners), in particular implementing the Action and making any Research Use of Results or undertaking the Direct Exploitation of Results whether such Results are owned by it or to which it has been granted Access Rights do not infringe or misappropriate Third Party Intellectual Property.
- 12.1.4 Subject always to such other undertakings and warranties as are provided for in this Consortium Agreement and the Grant Agreement, each Beneficiary shall be solely liable for any loss, damage or injury to its Sub-Contractors, Associated Partners or its Affiliated Entities resulting from carrying out its Allocated Work and from its use of Results and/or Background, or from entering into or defaulting under any contractual or other relationship with any such Sub-Contractor(s) or Affiliated Entities.
- 12.1.5 Except in the case of wilful misconduct **[OPTIONAL: gross negligence and breach of confidentiality obligations]**, no Beneficiary shall be liable to another Beneficiary for claims for indirect, special or consequential loss or damage, including but not limited to loss of profit, revenue or contracts.
- 12.1.6 **[OPTIONAL: Without prejudice to any indemnification obligations, which are solely governed by Clause 12.2 of this Consortium Agreement, the aggregate liability of any Beneficiary to another Beneficiary in respect of any one claim or series of connected claims under this Consortium Agreement shall not exceed the higher of (i) [1,000,000] euros; and (ii) twice the financial value (of the Grant**

or of the in-kind contribution, as the case may be), corresponding to that (liable) Beneficiary's Action Share.]

- 12.1.7 Nothing in this Consortium Agreement may be construed to limit (i) the right of any party to bring an action for damages against any Third Party, including claims for indirect, special or consequential damages, based on any acts or omissions of such Third Party (ii) the liability of a Beneficiary for personal injury or death resulting from the negligence of such party or its employees, officers, directors, agents, or representatives (as applicable); and (iii) the liability of a Beneficiary for any matters for which liability cannot be excluded under applicable laws and regulations.

## 12.2 INDEMNIFICATION FOR THIRD PARTY CLAIMS

- 12.2.1 Each Beneficiary ("Indemnitor") shall indemnify each other Beneficiary ("Indemnitee") from and against loss, damage, liability, cost, expense, or injury (including reasonable attorneys' fees and expenses) (individually a "Loss" and collectively, "Losses") incurred by such Indemnitee, its employees, or Affiliate Entities, resulting from any claim, complaint, proceeding or cause of action brought by a Third Party, including IHI JU ("Third Party Claims") arising from (i) the material breach of any representation, warranty or covenant made by the Indemnitor hereunder, (ii) gross negligence or wilful misconduct on the part of the Indemnitor in performing its obligations under this Consortium Agreement, or, subject to Clause 12.1 of this Consortium Agreement, (iii) infringement of Third Party Intellectual Property rights by such Indemnitor, its employees, Sub-Contractors, Associated Partners, Affiliated Entities or its agents; provided in each case that:

- except in the case of wilful misconduct [OPTIONAL: gross negligence and breach of confidentiality obligations], the foregoing obligation to indemnify shall not extend to claims for indirect, special or consequential loss or damage, including but not limited to loss of profit, revenue or contracts; and
- [OPTIONAL: the total limit of liability of any Indemnitor to any Indemnitee in respect of any one claim or series of connected claims, shall not exceed the higher of (i) [1,000,000] euros; and (ii) twice the financial value (of the Grant or of the in-kind contribution, as the case may be,) corresponding to that Indemnitor's Action Share; and]
- an Indemnitor shall not be obligated to indemnify an Indemnitee for any Losses to the extent such Losses arise as a result of (i) the material breach of any representation, warranty or covenant made by the Indemnitee under this Consortium Agreement or (ii) any gross negligence or wilful misconduct on the part of any Indemnitee.

- 12.2.2 The Indemnitee shall immediately advise the Indemnitor of any such Loss or Third Party Claim in writing. The Indemnitor shall have the right to select defence counsel and to direct the defence or settlement of any claim which is the subject of this indemnity. The Indemnitee shall reasonably co-operate with the Indemnitor and its legal representatives in the investigation and defence of any such claim. The Indemnitee may obtain representation by separate legal counsel, at its own expense. The Indemnitee shall refrain from making any

admission of liability or any attempt to settle the claim without the Indemnitor's prior written consent.

### **13. TERM; TERMINATION AND CONSEQUENCES**

#### **13.1 TERM**

This Consortium Agreement shall be deemed to have been validly entered into between the Beneficiaries, and to be legally binding, when signed on behalf of each Beneficiary by the appropriate authorized signatories, with effect as of the date that the Grant Agreement enters into force, irrespective of the date of signature of this Consortium Agreement. This Consortium Agreement shall be fully effective and valid between the Beneficiaries that have signed it (to the extent this includes the Coordinator and the Project Leader), even in case certain other Beneficiaries have not yet signed this Consortium Agreement.

This Consortium Agreement shall remain in force until the earlier of (i) the end of the Action pursuant to Article 4 of the Grant Agreement (including as the case may be any prolongation or suspension periods); and (ii) any earlier termination of the Grant Agreement.

The following Clauses of this Consortium Agreement shall survive termination or expiration of this Consortium Agreement, whether with respect to one Beneficiary or all Beneficiaries: Clauses 1, 2.2 to 2.4, 5 to 9, 12, 13.1 last paragraph, 13.5, 17 and 18 and Appendix 1 and Appendix 13, and any other Clause by its nature intended to survive termination or expiration of this Consortium Agreement.

#### **13.2 TERMINATION OF THE GRANT AGREEMENT AND THIS CONSORTIUM AGREEMENT**

13.2.1 The IHI JU may terminate the Grant Agreement in accordance with Article 32.3 of the Grant Agreement by notifying the Coordinator of its intent to terminate the Grant Agreement. The Coordinator shall, on receipt of such notice of termination from the IHI JU, forthwith provide the Project Leader and each Beneficiary with written notice to such effect. Further, the Coordinator shall take such actions as directed under Articles 32.3.2 and 32.3.3(a) of the Grant Agreement and shall ensure that the Project Leader and all Beneficiaries are informed about the progress of the intent to terminate. The Coordinator shall ensure to respond to IHI JU's notice with observations agreed with the [Project Leader/Beneficiaries] within thirty (30) days as required by the Grant Agreement, and inform the Project Leader and the other Beneficiaries of IHI JU's final decision on the termination.

13.2.2 The Beneficiaries may together, pursuant to unanimous agreement reached in a General Assembly meeting, in accordance with Article 32.1 of the Grant Agreement decide to give notice in writing to the IHI JU requiring that the Grant Agreement be terminated. The Coordinator shall provide such notice to the IHI JU which shall include the justification for termination, the date the Consortium ends work on the Action, and the effective date of the termination in accordance with Article 32.1.1 of the Grant Agreement. The Coordinator shall provide the reports and deliverables referred to in Article 32.1.2 of the Grant Agreement. The Coordinator shall promptly notify the Beneficiaries of the IHI JU's response to the notification of termination of the Grant Agreement.

#### **13.3 TERMINATION OR RETIREMENT OF A BENEFICIARY FROM THIS CONSORTIUM AGREEMENT**

- 13.3.1 The IHI JU may terminate the participation of one or more Beneficiaries ("**Terminated Beneficiaries**") in accordance with Article 32.3 of the Grant Agreement by notifying the respective Beneficiary of its intent to terminate. Such Beneficiary shall promptly inform the other Beneficiaries of such notification, and comply with the actions as directed under Article 32.3.2 of the Grant Agreement, including by providing its observations to the IHI JU following consultation with the Coordinator and the Project Leader. At the end of the procedure, the IHI JU will inform the Coordinator so that it can comply with the actions as directed under Article 32.3.3(b) of the Grant Agreement.
- 13.3.2 Any Beneficiary may request that its participation in the Action be terminated ("**Retiring Beneficiary**"). The Retiring Beneficiary shall first submit to and agree with the Steering Committee and with the Beneficiaries affected by its contemplated termination, on a plan to mitigate and minimize the disruption of the Action due to the Retiring Beneficiary's termination of its participation in the Action (the "**Mitigation Plan**"). The Retiring Beneficiary shall provide the Coordinator with such documentation as specified in Articles 32.2.1 and 32.2.2 of the Grant Agreement for transmission to the IHI JU.
- 13.3.3 The Beneficiaries may in accordance with Article 32.2.1 of the Grant Agreement, amongst themselves agree, by unanimous agreement of all of the Beneficiaries except that Beneficiary which is the subject of the proposed exclusion (the "**Excluded Beneficiary**"), that the IHI JU should terminate the participation of the Excluded Beneficiary. At the same time as such agreement shall be reached, such Beneficiaries shall agree how they propose to reallocate the outstanding Allocated Work of the Excluded Beneficiary. Where those Beneficiaries shall have so determined, the Coordinator shall promptly forward such request, including the documents specified in Articles 32.2.1 and 32.2.2 of the Grant Agreement to the IHI JU.

#### 13.4 TERMINATION FOR BREACH

- 13.4.1 Where the IHI JU terminates the participation of a Defaulting Beneficiary due to his breach of any obligation under the Grant Agreement in accordance with the provisions of the Grant Agreement, subject to the continuation in force of Clauses 13.4.2 and 13.5 of this Consortium Agreement, that Defaulting Beneficiary's participation under, and as a Beneficiary to, this Consortium Agreement shall be deemed to have been terminated.
- 13.4.2 Where the IHI JU shall have requested that the Beneficiaries should provide appropriate solutions to any breach of obligation under the Grant Agreement, notwithstanding that costs incurred by the Beneficiaries eligible to receive IHI JU funding shall only be recoverable as Eligible Costs within the limits of the maximum IHI JU financial contribution set forth in the Grant Agreement, in the event that a solution acceptable to the IHI JU shall be found, the Beneficiaries, (including the Defaulting Beneficiary, unless the IHI JU shall have terminated the participation of the Defaulting Beneficiary with immediate effect), shall continue to undertake their respective Allocated Work in accordance with the Grant Agreement and this Consortium Agreement.

#### 13.5 CONSEQUENCES OF TERMINATION

- 13.5.1 In the event of termination of a Beneficiary receiving IHI JU funding, such Beneficiary shall be entitled to receive IHI JU funding only in relation to Eligible



Costs incurred before termination. For the avoidance of doubt, where the IHI JU shall refuse to accept any cost claimed by a departing Beneficiary receiving IHI JU funding, that departing Beneficiary shall have no right to recover the same from any (other) Beneficiary or from any IHI JU funding held or which may be received.

- 13.5.2 A departing Beneficiary shall, notwithstanding termination as aforesaid, remain bound to provide to the Project Leader and the Coordinator, for onward transmission to the IHI JU, within forty-five (45) Days of such termination, those reports and Deliverables contemplated up to the date of termination which, under the Grant Agreement, such departing Beneficiary would have been obliged to deliver had such termination coincided with the end of a reporting period.
- 13.5.3 Where, as a result of any delay on the part of a departing Beneficiary in implementing the obligation included in Clause 13.5.2 of this Consortium Agreement (or any Beneficiary in the event that the Grant Agreement shall be terminated in its entirety), the IHI JU shall decide to withhold IHI JU financial contribution, or to demand repayment of any IHI JU financial contribution which has been paid, such departing Beneficiary eligible to receive IHI JU funding shall indemnify the other Beneficiaries in respect of any such amount, and shall, within thirty (30) Days of a written request therefore from the Coordinator, settle any such indebtedness. For the avoidance of doubt, such indemnification obligation shall survive such termination, but shall never exceed the departing Beneficiary's Action Share.
- 13.5.4 Where the departing Beneficiary is the Coordinator, the termination of this Consortium Agreement with respect to such departing Beneficiary shall not take effect until the replacement Coordinator has been approved by the IHI JU.

#### **14. FORCE MAJEURE**

- 14.1 Where a Beneficiary shall be unable to perform, or shall be delayed in the performance of, any obligation under this Consortium Agreement, as a result of a situation of Force Majeure, such non-performance or delay on the part of such Beneficiary shall be deemed not to be a breach of such obligation on the part of such Beneficiary.
- 14.2 Where a Beneficiary shall be prevented or delayed in the manner referred to in Clause 14.1 of this Consortium Agreement, such Beneficiary shall without undue delay notify the Coordinator and the Project Leader of such circumstance, stating the nature, likely duration and foreseeable effects as well as any further information which the Coordinator and the Project Leader may then, or during any such period of delay, reasonably require. The Coordinator shall promptly forward all such information to the other Beneficiaries and to the IHI JU, while copying the Project Leader.
- 14.3 The Beneficiary faced with a Force Majeure situation must immediately take all the necessary steps to limit any damage due to Force Majeure and do its best to resume implementation of the Action as soon as possible.
- 14.4 If the consequences of Force Majeure for the Action are not overcome within six (6) weeks after such notification, the Beneficiaries shall consider whether an amendment to Annex 1 of the Grant Agreement is required.

## **15. AMENDMENTS AND RECORD KEEPING**

- 15.1 Any amendment to the Grant Agreement shall become automatically an integral part of this Consortium Agreement with effect as of the effective date of the amendment to the Grant Agreement, without the need to formalise an amendment to this Consortium Agreement.
- 15.2 Amendments to this Consortium Agreement, other than for the purpose of implementing an amendment to the Grant Agreement, may be made only by written instrument signed by an authorised signatory of each of the Beneficiaries, other than where any such amendment shall relate solely to the contact details of a Beneficiary, or shall otherwise be permitted under any provision hereof such as Clauses 5.1.2 and 5.1.4 of this Consortium Agreement, in which event that Beneficiary's written notice in accordance with the provisions of this Consortium Agreement shall suffice.
- 15.3 The Project Leader shall keep records of this Consortium Agreement (including its Appendices) together with any amendments to this Consortium Agreement. For the avoidance of doubt, the Coordinator shall keep records of the Grant Agreement (including its appendices) together with any amendments to the Grant Agreement.

## **16. ACCESSION TO THE ACTION – NEW BENEFICIARIES**

- 16.1 Where, during the implementation of the Action, and with the prior approval of the IHI JU in accordance with the procedures specified in the Grant Agreement, the Beneficiaries agree to admit new Beneficiaries to the Action, each such new Beneficiary shall, as a condition of admission be required to accede to the Grant Agreement by completion of an Annex 3 of the Grant Agreement.
- 16.2 Each such new Beneficiary shall, at the same time as its execution of Annex 3 of the Grant Agreement, enter the consortium upon signature of the Form of Accession shown in Appendix 13 of this Consortium Agreement by the new Beneficiary and the Coordinator. Such accession shall have effect from the date identified in the Form of Accession.
- 16.3 New Beneficiaries must assume the rights and obligations under this Consortium Agreement with effect from the date identified in the Form of Accession.

## **17. APPLICABLE LAW AND DISPUTE RESOLUTION**

- 17.1 This Consortium Agreement shall be construed in accordance with and governed by the laws of Belgium, excluding its conflict of law provisions.
- 17.2 In case of disputes or differences arising in connection with this Consortium Agreement, the Beneficiaries shall endeavour to settle their disputes arising in connection with this Consortium Agreement by amicable settlement. All disputes or differences arising in connection with this Consortium Agreement which cannot be settled amicably shall be finally settled by ***[Please indicate the option chosen and, if applicable, work out an appropriate arrangement for Option 1 or 2]***

***[OPTION 1: arbitration in Brussels under the rules of arbitration of the International Chamber of Commerce (ICC) by [one (1) arbitrator] [three (3) arbitrators] to be appointed under the terms of those rules. The chairman shall be of juridical education and the arbitration proceedings shall be conducted in English. The award of the arbitration shall be final and binding upon the Beneficiaries concerned]***

[**OPTION 2:** arbitration in Brussels under the rules of arbitration of the World Intellectual Property Organisation (WIPO Arbitration Rules) by **[one (1) arbitrator] [three (3) arbitrators]** to be appointed under the terms of those rules. The chairman shall be of juridical education and the arbitration proceedings shall be conducted in English. The award of the arbitration shall be final and binding upon the Beneficiaries concerned]

[**OPTION 3:** the competent courts of Brussels, Belgium, except if mandatory applicable laws or regulations foresee another place of jurisdiction.]

- 17.3 The Beneficiaries concerned may, rather than arbitrate under Clause 17.2 of this Consortium Agreement, instead elect to resolve by mediation a dispute or difference arising in connection with this Consortium Agreement which cannot be settled amicably. Such election shall be by unanimous written consent of the Beneficiaries involved in the dispute. Such dispute or difference will then be submitted to mediation in accordance with the ICC or WIPO mediation rules or any other mediation instance agreed upon by the Beneficiaries concerned. The place of mediation shall be Brussels unless otherwise agreed upon. The language to be used in the mediation shall be English unless otherwise agreed upon.
- 17.4 Nothing in this Consortium Agreement shall limit the Beneficiaries' right to seek injunctive relief in any applicable competent court.

## **18. MISCELLANEOUS**

### **18.1 NOTICES**

Any contractual, financial, or administrative notice to be given under this Consortium Agreement shall be in writing and delivered to the relevant Beneficiary at the address and marked for the attention of a named recipient, all as more specifically detailed in Appendix Appendix 1 of this Consortium Agreement, or as a Beneficiary shall under separate cover advise. A Beneficiary may, by notice in writing to the Coordinator, amend its notice details as included in Appendix 1 of this Consortium Agreement, or as otherwise advised. Any such notice shall be deemed to have been served when personally delivered or delivered by internationally recognized courier service or, if transmitted by fax, electronic or digital transmission, at the time of such transmission, provided that such transmission is confirmed by receipt of a successful transmission report and thereafter confirmed by surface/air mail or delivered by internationally recognized courier service within five (5) Days.

### **18.2 ASSIGNMENT**

- 18.2.1 With the exception of transfers of Results and Background permitted under this Consortium Agreement, no Beneficiary shall assign any interest in this Consortium Agreement to any Third Party (for the avoidance of doubt, including an Affiliated Entity) without the prior written consent of each other Beneficiary and of the IHI JU and any such assignment shall be subject to such Third Party assignee agreeing in writing to (i) continue the performance of the Action undertaken by the assignor; and (ii) comply with the provisions of the Grant Agreement and this Consortium Agreement.
- 18.2.2 Where a Beneficiary shall wish to assign its interest in this Consortium Agreement pursuant to Clause 18.2.1 of this Consortium Agreement (for the avoidance of doubt, excluding any transfers of Results and Background permitted under this Consortium Agreement), such Beneficiary shall, within the limits of confidentiality, provide the remaining Beneficiaries and the IHI JU as the case may be, with such information as may be reasonably requested in

connection with such proposed assignment and that Beneficiary's Allocated Work, including, without limitation, the extent to which such Allocated Work has been completed and Eligible Costs incurred to date. That Beneficiary shall, notwithstanding such assignment, remain liable under the Grant Agreement to the IHI JU for any additional information which the IHI JU may, either through the Coordinator or directly of such Beneficiary, reasonably request regarding that Beneficiary's Allocated Work and/or Eligible Costs.

18.2.3 Where a Beneficiary shall have its request to assign any interest approved if needed, such Beneficiary shall remain liable to all other Beneficiaries for all additional costs incurred by such other Third Party assignee in the performance of such assignor Beneficiary's Allocated Work to the extent that such additional costs shall not be fully recoverable as Eligible Costs. This obligation shall survive the cessation of such Beneficiary's participation in the Action.

18.2.4 Where a Beneficiary shall properly assign any or all of its interest in this Consortium Agreement in accordance with this Consortium Agreement that Beneficiary's participation in the Action and under this Consortium Agreement shall, to the extent of such assignment, be deemed to have terminated, and the provisions of Clause 13 of this Consortium Agreement shall apply.

### **18.3 SEVERABILITY**

If any provision of this Consortium Agreement shall for any reason and to any extent be determined to be invalid or unenforceable under applicable law, then such invalidity or unenforceability shall not affect the remainder of this Consortium Agreement, unless the invalid or unenforceable provision is of such importance that it can be reasonably assumed that the Beneficiaries would not have entered into this Consortium Agreement without the invalid or unenforceable provision. The Beneficiaries agree to replace any such invalid or unenforceable provision with a valid and enforceable provision designed to achieve, to the extent possible, the purposes and intent of such invalid and unenforceable provision.

### **18.4 ENTIRE AGREEMENT**

18.4.1 This Consortium Agreement, its appendices and the Grant Agreement and its annexes constitute the entire agreement between the Beneficiaries in respect of the Action, and supersede all previous negotiations, commitments and writings.

18.4.2 Although the provisions of this Consortium Agreement have been drafted to reflect the provisions of the Grant Agreement as far as possible, in the event of any conflict between this Consortium Agreement and the Grant Agreement, the Grant Agreement shall prevail.

### **18.5 WAIVER**

Any term or condition of this Consortium Agreement may be waived only by a written instrument executed by the Beneficiary waiving the benefit of a right hereunder. The waiver by a Beneficiary of any right hereunder shall not be deemed a continuing waiver of such right or of another right hereunder, whether of a similar nature or otherwise.

### **18.6 PRIORITIES**

In the event of any ambiguity, doubt or conflict emerging herein, the terms and conditions of this Consortium Agreement shall take precedence over the terms and conditions of any Appendix, unless the latter makes an explicit reference to the provision of this Consortium Agreement that shall be amended.

## **19. ANTI-BRIBERY AND ANTI-CORRUPTION**

- 19.1 Each Beneficiary shall have in place an appropriate anti-bribery and anti-corruption policy and provide associated training and/or appropriate notification of responsibilities to its employees to enable such Beneficiary to comply with its obligations under Clause 19.2 of this Consortium Agreement, with which it shall comply at all times.
- 19.2 Each Beneficiary shall comply fully at all times with all applicable anti-bribery and anti-corruption laws, including but not limited to, all applicable anti-bribery and anti-corruption laws of the territory in which that Beneficiary conducts business with any other Beneficiary.
- 19.3 The General Assembly shall be entitled to decide on the termination of the participation under the Grant Agreement of a Beneficiary on written notice under Article 32.2 of the Grant Agreement, if a Beneficiary fails to perform its obligations under this Consortium Agreement in accordance with this Clause 19. A Beneficiary shall have no claim against the General Assembly or the other Beneficiaries for compensation for any loss of whatever nature by virtue of the termination of their participation under the Grant Agreement in accordance with this Clause 19. To the extent (and only to the extent) that the applicable laws provide for any such compensation to be paid to a Beneficiary upon the termination of their participation under the Grant Agreement, each Beneficiary hereby expressly agrees to waive (to the extent possible under such applicable laws) or to repay any such compensation or indemnity. The provisions of Clause 13.3.3 of this Consortium Agreement shall apply in such circumstances.

## **20. DEBARMENT**

- 20.1 Each Beneficiary represents that in performing the Action it has not and it will not use in any capacity the services of anyone debarred, disqualified, blacklisted or banned or under investigations or threat of investigations by any regulatory authority for debarment, disqualification, blacklisting or any similar regulatory action in any jurisdiction anywhere in the world. Furthermore, each Beneficiary represents and warrants that neither it, nor its employees, agents or Representatives, Affiliated Entities, Associated Partners or Sub-Contractors have been debarred, disqualified, blacklisted or banned by any regulatory authority, nor that they are currently to the best of each Beneficiary's knowledge, the subject of such a debarment, disqualification, blacklisting or banning proceeding. During the term of this Consortium Agreement, each Beneficiary shall promptly notify the other Beneficiaries should the Beneficiary, any of its employees, agents, or Representatives, Affiliated Entities, Associated Partners or Sub-Contractors become subject of such debarment, disqualification, blacklisting or banning proceeding and shall suspend all involvement in activities under this Consortium Agreement of any such entity or person subject to any such proceeding unless agreed otherwise by all Beneficiaries.

## **21. GLOBAL TRADE LAWS**

- 21.1 Actions covered by this Consortium Agreement may be subject to applicable Global Trade Control Laws and the Beneficiaries will implement the Action in full compliance with all applicable Global Trade Control Laws. For purpose of this Consortium Agreement, the term **"Global Trade Control Laws"** means all applicable import and export control laws, regulations, and orders, as well as all relevant economic sanctions laws, regulations and orders

## 22. TRANSPARENCY

22.1 Each Beneficiary acknowledges and agrees that in the interest of transparency, Beneficiaries and their Affiliated Entities may be required to collect, publicly disclose, and communicate to relevant authorities/institutions payments and/or other transfers of value associated with the Action and this Consortium Agreement, made to healthcare professionals (HCPs) and healthcare organisations (HCOs), if provided by applicable laws or regulations or any applicable industry codes, such as the EFPIA Disclosure Code adopted by the EFPIA Statutory General Assembly of 27 June 2019 and the national EFPIA member organizations implementation of the EFPIA Disclosure Code, respectively, and the Physician Payments Sunshine Act (US Sunshine Act), and the COCIR Code of Conduct (version November 2020 or any updates thereof), or any other applicable regulations.

## 23. ELECTRONIC SIGNATURES

The Beneficiaries explicitly agree to execute this Consortium Agreement by way of an electronic signature **[by using DocuSign/Adobe Sign]** and agree this shall constitute a valid and enforceable agreement between the Beneficiaries. The present Consortium Agreement is made in an electronic version which shall be electronically signed by each Beneficiary. Each Beneficiary hereby acknowledges receipt of the e-signed Consortium Agreement, electronically signed for approval by the Beneficiaries.

## 24. APPENDICES

The following appendices shall form an integral part of this Consortium Agreement:

Appendix 1	Notice Details
<b>[OPTIONAL:</b>	<b>Laboratory Animal Welfare]</b>
<b>Appendix 2</b>	
Appendix 3	Actions involving Personal Data
Appendix 4	Template Data Transfer Record Forms
Appendix 5	Background & Additional Data, Know-How, or Information and Materials
Appendix 6	Data Contributed as In-Kind
Appendix 7	Communication Guidelines
<b>[OPTIONAL:</b>	<b>Access Rights Table</b>
<b>Appendix 8</b>	
Appendix 9	Template Material Transfer Record Forms
Appendix 10	Contracts under Mandate: One-sided CDA
Appendix 11	Contracts under Mandate: Two-sided CDA
Appendix 12	Contracts under Mandate: Advisory Agreement
Appendix 13	Form of Accession
Appendix 14	Data Management Plan

**SIGNATURES**

The Beneficiaries have caused this Consortium Agreement, including its Appendices to be executed by their duly authorized representatives, on the date set forth below, each Beneficiary acknowledging receipt of one copy.

The Beneficiaries agree to execute this Consortium Agreement by way of an electronic signature, and agree this shall constitute a valid and enforceable agreement between the Beneficiaries. The present Consortium Agreement is made in an electronic version which is signed electronically by each Beneficiary.

Authorised to sign on behalf of:

**THE COORDINATOR** (give name)

Signature .....  
Name .....  
Title .....  
Date .....  
Stamp (if applicable)

Authorised to sign on behalf of:

**THE PROJECT LEADER** (give name)

Signature .....  
Name .....  
Title .....  
Date .....  
  
Stamp (if applicable)

[add a page for each additional Beneficiary]

Authorised to sign on behalf of:

THE BENEFICIARIES (give name)

Signature .....

Name .....

Title .....

Date .....

Stamp (if applicable)



## Appendix 1: Notice Details

### 1. [Beneficiary 1]

Name contact person: XX

Department: XX

Address: XX

Email: XX

### 2. [Beneficiary 2]

Name contact person: XX

Department: XX

Address: XX

Email: XX

### 3. [Beneficiary 3]

Name contact person: XX

Department: XX

Address: XX

Email: XX

[...]

## **[Optional:] Appendix 2: Laboratory Animal Welfare**

Beneficiaries agree to comply and further agree to oblige their Affiliated Entities, Associated Partners and Sub-Contractors to comply, with all relevant statutes, legislation, regulations and guidelines for the care, welfare and ethical treatment of animals used in research in the country where the research is being performed as well as applicable international regulations including US Guide of the Care and EU Directive 210/63/EU. Any laboratory animal research should be done in an AAALAC<sup>6</sup> accredited institution or approved by Pharma Animal Care and Use Council (PACC). In conducting any research involving the use of animals, the Beneficiaries further agree to comply and oblige their Affiliated Entities, Associated Partners and Sub-Contractors to comply with the “3R” Principles- replacing animals with non-animal methods whenever possible, reducing the number of animals used, and refining the research techniques used. All work must be conducted in adherence to the core principles for animals on research studies identified below. Local customs, norms, practices or laws may be additive to the core principles, but the Beneficiaries agree to comply and oblige their Affiliated Entities, Associated Partners and Sub-Contractors to comply, as a minimum, with these core principles:

- Access to species appropriate food and water;
- Access to species specific housing, including species appropriate temperature and humidity levels;
- Access to humane care and a programme of veterinary care;
- Ability to demonstrate species-specific behavior;
- Adherence to principles of replacement, reduction and refinement in the design of in vivo studies;
- Study design reviewed by institutional ethical review panel;
- Commitment to minimizing pain and distress during in vivo studies; and
- Work performed by appropriately trained staff.

Beneficiaries, Affiliated Entities, Associated Partners and Sub-Contractors may be required to provide evidence to other Beneficiaries within the Project that they can confirm adherence to the above principles and guidelines. Beneficiaries reserve the right to conduct due diligence, that could require site visits, to be assured of such compliance. If any material deficiencies are subsequently identified the Beneficiary concerned shall endeavour in good faith to take (or have their Affiliated Entity, Associated Partner and/or Sub-Contractor concerned take) reasonable and practical corrective measures to remedy any such material deficiencies.]

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<sup>6</sup> Association for Assessment and Accreditation of Animal Care and Use programs, [www.aaalac.org](http://www.aaalac.org)

## Appendix 3: Actions Involving Personal Data

### 1. APPLICATION

The Action consists of different Work Packages. Each Work Package may in turn consist of different tasks under which a Beneficiary may potentially Process Personal Data as either a Controller, Joint Controller or Processor and potentially engage a Third Party in such Processing, which may also be acting as a Controller or Processor.

Beneficiaries will have to comply (and procure that the Third Parties assigned by them will comply) with the following principles and applicable laws and regulations when collecting, processing, storing, using or transferring any Personal Data for activities conducted, sponsored, supported or funded pursuant to the Action.

To the extent that, according to the Data Protection Legislation, the information on the Processing of the Personal Data shall be provided to and/or any consent (if and where required) shall be granted by the legal guardian of the Data Subject, the provisions in that regard of this Appendix 3 regarding the Data Subject shall apply, where and to the extent relevant, to the Data Subject's legal guardian instead.

### 2. DEFINITIONS

**"Controller"** shall mean in respect of any particular transfer of Personal Data the Beneficiary which, alone or jointly with another Beneficiary or a Third Party, determines the purposes and means of Processing.

**"Joint Controllers"** shall mean where two or more Controllers jointly determine the purpose and means of the Processing of the Personal Data.

**"Processor"** shall mean any Beneficiary or Third Party that Processes Personal Data on behalf and according to the instructions of a Controller.

### 3. ACTIONS REGARDING PERSONAL DATA

#### 3.1. General obligations of the Beneficiaries when Processing Personal Data (when Beneficiaries are acting as a Controller).

When Personal Data are introduced to the Action by or on behalf of a Beneficiary, such Beneficiary must ensure that:

- (1) the Personal Data are Processed in accordance with all laws, rules, regulations and guidelines applicable to their collection, use, handling, disposal and further Processing of Personal Data, including – without limitation – data protection legislations (to the extent applicable on a Beneficiary Processing Personal Data), such as the General Data Protection Regulation 2016/679 (EU), "GDPR" (or succeeding regulations) and implementing national data protection laws as applicable, the UK Data Protection Act 2018 ("UK GDPR") and the Standards for Individually Identifiable Health Information (45 CFR Parts 160 and 164, the "Privacy Rule") promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (USA), and the Personal Health Information Protection Act of 2004 (Canada), all as updated from time to time and as applicable ("**Data Protection Legislation**")
- (2) if applicable, and in so far and to the extent required under the Data Protection Legislation, the Personal Data are Processed with voluntarily given informed consent covering the use of the Personal Data (including Research Use) in the field of the Project and/or a field compatible with the Project and permitting cross-border transfers within the EEA (or such cross-border EEA transfers are otherwise permitted pursuant to applicable Data Protection

Legislation) and/or outside the EEA, in which case additional safeguards and/or agreements and may need to be implemented between the data provider(s) and data receiver(s) in compliance with and pursuant to applicable Data Protection Legislation. Such informed consent may be revocable any time with effect for the future (taking into account that the consequences of such withdrawal may be restricted under the Data Protection Legislation),<sup>7</sup>

- (3) to the extent required under Data Protection Legislation, the responsible ethics committee/Institutional Review Board (IRB) has given its approval to the collection, processing, storage, use and transfer of the Personal Data under the Action, and
  - (4) if applicable, the Data Subjects have not withdrawn their informed consents (taking into account that the consequences of such withdrawal may be restricted under the Data Protection Legislation) before transferring the Personal Data to a data receiver (or otherwise Processing the Personal data), to the extent the informed consent is used as a legal basis to transfer such Personal Data or to otherwise Process such Personal Data. The Beneficiary introducing the Personal Data to the Action shall as soon as reasonably possible and without undue delay inform the other Beneficiaries in writing in case that the Data Subjects withdraws consent (taking into account that the consequences of such withdrawal may be restricted under the Data Protection Legislation).
  - (5) The Beneficiary shall procure that the Personal Data are (i) Processed lawfully, fairly and in a transparent manner, (ii) collected for specified, explicit and legitimate purposes, (iii) adequate, relevant and limited to what is necessary in relation to the purposes for which they are Processed (or further compatible processing if permitted under the Data Protection Legislation) (iv) accurate and (where necessary) kept up to date (v) not kept for a period longer than necessary (except if permitted by the Data Protection Legislation if appropriate technical and organisational measures are implemented) and (vi) Processed in a manner that ensures appropriate security of the Personal Data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures.
- 3.2 Beneficiaries shall ensure that the Processing of Personal Data is subject to appropriate security measures that: (a) are able to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services (b) where appropriate result in Pseudonymisation and/or Anonymization of Personal Data; (c) are able to restore the availability and access to the Personal Data in a timely manner in the event of a physical or technical incident; and (d) include a process for regularly testing, assessing and evaluating the effectiveness of technical and organizational measures for ensuring the security of the Processing.
- 3.3 Beneficiaries shall ensure that personnel dealing with the Processing of Personal Data are obliged to data secrecy under an enforceable confidentiality duty and that they are informed about the obligations under the Data Protection Legislation and contractual provisions

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<sup>7</sup> The Beneficiaries should consider to agree on a data protection concept including the minimum requirements for informed consents, if required under Data Protection Legislation, such as that (i) the purpose of use in informed consent must cover activities under the Action (and further processing in so far allowed under Data Protection Legislation), (ii) informed consent must allow for transfer of data and samples to academic and commercial entities inside and outside EU, and (iii) the informed consent must be voluntary with a right to withdraw at any time (taking into account that the consequences of such withdrawal may be restricted under the Data Protection Legislation).

regarding data protection and that they will act in accordance with those obligations and provisions.

- 3.4 To the extent a Sub-Contractor Processes Personal Data, the appointing Beneficiary will select such Sub-Contractor considering the adequacy of the technical and organizational measures for the protection of Personal data implemented by the Sub-Contractor and will oblige such Sub-Contractor in accordance with this Consortium Agreement. Where Personal Data are transferred to a Sub-Contractor outside the EEA, the appointing Beneficiary will procure that such transfer to the Sub-Contractor provides an adequate level of protection, according to applicable Data protection Legislation (as set out in Section 4.2 of this Appendix 3).
- 3.5 Beneficiaries will not introduce to the Action or Process Personal Data for reasons unrelated to the Action (which may include Access Rights to such Personal Data for Research Use pursuant to the provisions of the Consortium Agreement), unless (i) all legal requirements under applicable Data Protection Legislation for the collection, processing, storage, use and transfer of the Personal Data under the Action or under subsequent compatible processing (such as that the informed consent – to the extent it is relied upon – allows for such use or subsequent processing is allowed under the Data Protection Legislation) are fulfilled, and (ii) prior written approval of the competent ethics committee/IRB is obtained, to the extent required under applicable legislation. Further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall not be considered to be incompatible with the initial purpose subject to the conditions set out in the Data Protection Legislation. When a Beneficiary obtains Personal Data from a source where the collection was made for reasons unrelated to the Action the Beneficiaries shall need to become informed about the origin of the Personal Data.
- 3.6 Each Beneficiary is solely responsible for complying with applicable Data Protection Legislation, including evaluating its role as Controller, Joint Controller or Processor in relation to a Work Package and/or a Work Package task under the Project such Beneficiary participates in.
- 3.7 **Controller to Controller Actions.** To the extent a Beneficiary introduces to the Action Personal Data and thereby enables other Beneficiaries or Third Parties to access and Process such Personal Data within the Project independent from specific instructions regarding the handling of Personal Data (“**Controller to Controller**”), the introducing Beneficiary and the accessing Beneficiary/Third Party are additionally obliged as follows:
- (1) To the extent applicable and where required under Data Protection Legislation, the introducing Beneficiary shall inform the Data Subjects about Personal Data transfers and Processing by the accessing Beneficiary and/or Third Parties. The introducing Beneficiary may request the accessing Beneficiary and/or Third Parties to share all information required in order for the introducing Beneficiary to duly inform Data Subjects according to applicable transparency obligations.
  - (2) The introducing and accessing Beneficiary/Third Party respectively are the responsible contact for any requests of the Data Subjects, e.g. for information, correction or deletion of the Personal Data or for an objection to the Processing, the case being.
  - (3) The introducing and accessing Beneficiary/Third Party shall take all reasonable technical and organizational measures necessary to protect the introduced Personal Data against unauthorized or unlawful Processing and against accidental loss, destruction of or damage to such Personal Data, in accordance with Article (5).
  - (4) The accessing Beneficiary and introducing Beneficiary will assist each other upon first request in being able to ensure and show compliance (when Processing Personal Data with the provisions of the Consortium Agreement and/or applicable Data Protection Legislation,

taking into account the information available to the introducing and accessing Beneficiary (e.g. in ensuring the introducing and/or the accessing Beneficiary is able to comply with its obligations vis-à-vis the Data Subject and/or prove such compliance).

- (5) (If an accessing Beneficiary/Third Party is required by law or receives any order, demand, warrant or any other document from a court of competent jurisdiction or other governing body requesting or purporting to compel the production of Personal Data, accessing Beneficiary/Third Party shall, except to the extent prohibited by law, immediately notify the introducing Beneficiary and shall not produce the Personal Data for at least forty-eight (48) hours following such notice to the introducing Beneficiary so that the introducing Beneficiary may, at its own expense, exercise such rights as it may have under law to prevent or limit such disclosure. In addition to the foregoing, accessing Beneficiary/Third Party shall exercise reasonable efforts to prevent and limit any such disclosure, and/or to otherwise preserve the confidentiality of the Personal Data, and shall cooperate with the Introducing Beneficiary with respect to any action taken with respect to such legal process, including to obtain an appropriate protective order or other reliable assurance that confidential treatment will be accorded to the Personal Data, in compliance with applicable law.
- 3.8 The transfer of Personal Data on a Controller-to-Controller basis does not modify the acknowledgment and/or allocation of Intellectual Property rights of Clauses 6, 7 and 8 of this Consortium Agreement. This transfer shall only be the consequence of honoring the rights (e.g., ownership, licenses or Access Rights) that both the introducing Beneficiary and the accessing Beneficiary/Third Party shall have on the relevant Background and Results according to Clauses 6, 7 and 8 of this Consortium Agreement.
- 3.9 **Controller to Processor Actions.** To the extent the Beneficiary introduces to the Action Personal Data that are accessed and Processed by other Beneficiaries or Third Parties only on behalf and instructions of the introducing Beneficiary ("**Controller to Processor**"), the introducing Beneficiary (Controller) and the accessing Beneficiary/Third Party (Processor) are additionally obliged as follows:<sup>8</sup>
- (1) The introducing Beneficiary shall only use those Beneficiaries or Third Parties as Processors that provide sufficient guarantees to implement appropriate technical and organizational measures in such a manner that Processing will meet the requirements of the Data Protection Legislation and ensure the protection of the rights of the Data Subject.
  - (2) The accessing Beneficiary/Third Party as Processor shall not engage another Processor without prior specific or general written authorisation of the Controller. In the case of general written authorisation, the Processor shall inform the Controller of any intended changes concerning the addition or replacement of other Processors, thereby giving the Controller the opportunity to object to such changes. Where the accessing Beneficiary/Third Party as Processor does engages another Processor for carrying out specific processing activities on behalf of the Controller, the same data protection obligations as set out in the contract or other legal act between the Controller and the Processor as referred to in Article 3.9 (2) shall be imposed on that other processor by way of a contract or other legal act, in particular providing sufficient guarantees to implement appropriate technical and

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<sup>8</sup> Clause 3.8 may also become relevant in case that the consortium establishes databases and/or human sample repositories. In this case the Beneficiary responsible for database/repository may be considered a Processor so that Clause 3.8 would apply. Please also note that the prerequisites established in this Clause 3.5 may have to be supplemented with additional wording according to the national legal requirements for commissioned data processing.

organisational measures in such a manner that the processing will meet the requirements of the Data Protection Legislation. Where that other Processor fails to fulfil its data protection obligations, the accessing Beneficiary/Third Party as initial Processor shall remain fully liable to the Controller for the performance of that other Processor's obligations.

- (3) The Processing of the Personal Data by the accessing Beneficiary/Third Party as Processor shall be governed by a contract or other legal act under applicable data Protection Legislation, that is binding on the accessing Beneficiary/Third Party as Processor with regard to the Controller and that sets out amongst other the subject-matter and duration of the processing, the nature and purpose of the Processing, the type of Personal Data and categories of Data Subjects and the obligations and rights of the Controller.
- (4) The accessing Beneficiary/Third Party shall Process Personal Data exclusively in the name of and in accordance with the documented instructions of the introducing Beneficiary, including with regard to the transfer of Personal Data to a Third Country unless required to do so by Union or Member State law to which the accessing Beneficiary/Third Party as Processor is subject; in such a case, the accessing Beneficiary/Third Party as Processor shall inform the Controller of that legal requirement before processing, unless that law prohibits such information on important grounds of public interest (Commissioned Data processing). The introducing Beneficiary remains the Controller and responsible for the legality of Processing Personal Data.
- (5) The Processing of the Personal Data by the accessing Beneficiary shall exclusively and entirely occur in the type and extent and for the purposes (or further processing if and to the extent allowed under Data Protection Legislation).
- (6) The accessing Beneficiary /Third Party as Processor shall be regarded as Processor and shall not acquire any rights with respect to the Personal Data.
- (7) The accessing Beneficiary/Third Party as Processor will ensure that persons it authorises to Process the Personal Data comply with the duties set forth in Article 3.2.
- (8) The accessing Beneficiary/Third Party as Processor will implement appropriate, technical and organizational measures to ensure a level of security appropriate to protect the Personal Data against unauthorized or unlawful Processing and against accidental loss, destruction of or damage to such Personal Data in accordance with Article (5).
- (9) The accessing Beneficiary/Third Party as Processor will, by appropriate technical and organisational measures, assist the Controller insofar as this is possible, for the fulfilment of the Controller's obligation to respond to requests for exercising the Data Subject's rights, taking into account the nature of the processing.
- (10) The accessing Beneficiary/Third Party as Processor will assist the Controller, upon its request, in ensuring compliance with the obligations relating to the security of processing, data breach notifications, data protection impact assessment and prior consultation to the Data Protection Authority, taking into account the nature of the Processing and the information available to the Processor. In any case, the Processor will report to the Controller any data/privacy breach without undue delay and at the latest within 24 hours after having become aware of it and provide the Controller with all relevant information in that regard.
- (11) If an accessing Beneficiary/Third Party is required by law or receives any order, demand, warrant or any other document from a court of competent jurisdiction or other governing body requesting or purporting to compel the production of Personal Data, accessing Beneficiary/Third Party shall, except to the extent prohibited by law, immediately notify the introducing Beneficiary and shall not produce the Personal Data for at least forty-eight (48) hours following such notice to the introducing Beneficiary so that the introducing Beneficiary may, at its own expense, exercise such rights as it may have under law to prevent or limit

such disclosure. In addition to the foregoing, accessing Beneficiary/Third Party shall exercise reasonable efforts to prevent and limit any such disclosure, to otherwise preserve the confidentiality of the Personal Data and shall cooperate with the introducing Beneficiary with respect to any action taken with respect to such legal process, including to obtain an appropriate protective order or other reliable assurance that confidential treatment will be accorded to the Personal Data, in compliance with applicable law.

- (12) The accessing Beneficiary/Third Party as Processor shall return all the Personal Data to the Controller after the end of the provision of services relating to processing and delete existing copies (unless applicable law requires storage of the Personal Data).
- (13) The accessing Beneficiary/Third Party as Processor shall make available to the Controller all information necessary to demonstrate compliance with the obligations laid down in this Section 3.8, and allow for and contribute to audits, including inspections, conducted by the Controller or another auditor mandated by the Controller.

**3.10 Joint Controller Actions.** To the extent joint controllership is established with regard to determining the purposes and the means of the Processing, the Joint Controllers shall in a transparent manner determine their respective responsibilities for compliance with the obligations under the Data Protection Legislation, in particular as regards the exercising of the rights of the Data Subject and their respective duties to provide the information to the Data Subjects as required under Data Protection Legislation by means of an arrangement between them unless, and in so far as, the respective responsibilities of the Joint Controllers are determined by applicable law to which the Joint Controllers are subject. The arrangement referred shall duly reflect the respective roles and relationships of the Joint Controllers vis-à-vis the Data Subjects.

**3.11** In general, cells lines (e.g. HeLa), derivatives (e.g. isolated proteins) and preparations of human biological materials (e.g. sub-cellular fractions) that are well established and made available for research use, do not require re-consent and/or ethics committee/IRB approval for the intended research use. Beneficiaries will need to make a case-by-case analysis, in order to determine whether consent is required or not.

#### **4. FURTHER PROVISIONS ON THE USE OF PERSONAL DATA IN THE ACTION**

- 4.1. Additional individual Data Subject consent and ethics committee/IRB approval may need to be obtained when the project activities intended (or the intended Research Use as provided for under the Consortium Agreement) are inconsistent with or beyond the scope of the original consent, and to the concerning Beneficiary(ies) assessment there is no other legal basis allowing the intended Processing.
- 4.2. If and to the extent required under the Data Protection Legislation, additional consent should also be obtained if the original consent (where needed under Data Protection Legislation) did not include analysis of DNA and other genetic tests (if relevant to the Project activities) or use of any associated medical information (if relevant to the Project activities).
- 4.3. If the Processing or intended Processing of Personal Data by a Beneficiary or Third Party, as data Controller or data Processor, takes place in a third country (i.e. a country outside the European Economic Area) which do not offer an adequate level of protection, this Processing shall be carried out in accordance with the (additional) requirements and appropriate safeguards under the Data Protection Legislation, such as:
  - a) Entering into the appropriate EU Standard Contractual Clauses;
  - b) Implementing Binding Corporate Rules that have received European approval and that cover all Personal Data concerned;



- c) the countries where the Processing of such Personal Data takes place have received a binding adequacy decision by the European Commission; or
- d) another validly executed transfer mechanism applies to the transfer of Personal Data to such countries that have not received a binding adequacy decision by the European Commission.

## Appendix 4: Template Data Transfer Record Forms

*[In order to select the correct template, please determine whether the data to be transferred are (i) either pre-existing or generated outside of the project (Background or Additional Data, Know-How or Information) in which case DTR Form A could be used, or (ii) otherwise generated during the Project as a Result of performance of the Project (Data which are Results) in which case DTR Form B could be used.]*

### 1. Template Data transfer record form for pre-existing data or data generated outside the project (DTR Form A)

- 1.1. The template DTR Form A, may be required to be used by the transferring Beneficiary when pre-existing data or data generated outside the project are transferred between Beneficiaries. It should only be used for any data that are (i) not and do not contain Personal Data, (ii) Anonymous and/or (iii) fully Anonymized data.
- 1.2. The DTR Form A is to be used when the data transfer takes place to grant Access Rights to such data as stated and in compliance with the provisions of the Consortium Agreement.
- 1.3. The DTR Form A should be executed prior to providing/receiving the data to/from the other Beneficiary.
- 1.4. Highlighted sections remain to be completed.

#### DATA TRANSFER RECORD FORM A

(for IHI **XX** Project)

(for Data which are pre-existing or generated outside the project)

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Capitalized terms used herein that are not defined herein shall have the meanings set forth in the IHI **XX** Consortium Agreement effective **XX** (the “Consortium Agreement”).

This Data Transfer Record covers the transfer of Data (as defined hereunder) under the terms and conditions as provided for in the Consortium Agreement.

From: **XXXXX**, whose administrative offices are at **XXXXX** (the “Providing Beneficiary”),

To: **XXXXX**, whose administrative offices are at **XXXXX** (the “Receiving Beneficiary”).

For **[SPECIFY PURPOSE(S) OF TRANSFER IN LINE WITH CONSORTIUM AGREEMENT]** and pursuant to the terms of the Consortium Agreement, the Providing Beneficiary agrees that Receiving Beneficiary, can use the Data under the Access Rights provided for in the Consortium Agreement.

**[OPTIONAL and to the extent foreseen in the Consortium Agreement]**. The Providing Beneficiary and the Receiving Beneficiary explicitly agree the transfer of the Data under following Fair and Reasonable Conditions;

**[SPECIFY FAIR AND REASONABLE CONDITIONS]**

The data to be provided are not considered Results, but are considered pre-existing or generated outside of the Action. The Access Rights as provided for Background in the Consortium Agreement for [SPECIFY USE(S)] apply.

- (Short) Description of data(sets): XX
- Envisaged Transfer Date: XX
- Method of transfer: XX
- Details of Third Party use Restrictions, if any: XX (ask provider IP Dept)

The Providing Beneficiary represents and warrants that the Data do not or no longer contain Personal Data (whether or not Pseudonomized).

The Providing Beneficiary and the Receiving Beneficiary explicitly agree to execute this Data Transfer Record by way of an electronic signature and agree this shall constitute a valid and enforceable agreement between the Providing Beneficiary and the Receiving Beneficiary. The present Data Transfer Record is made in an electronic pdf-version (using Adobe Sign or DocuSign) which shall be electronically signed by each of the Providing Beneficiary and the Receiving Beneficiary. Each of the Providing Beneficiary and the Receiving Beneficiary hereby acknowledges receipt of the e-signed Data Transfer Record, electronically signed for approval by the Providing Beneficiary and the Receiving Beneficiary.

## **2. Template Data transfer record form for data that are Results of the Project - (DTR Form B).**

- 2.1. The template DTR Form B, may be required to be used by the transferring Beneficiary when data which were generated during the Project as a result of performance of the Project (Result), are transferred between Beneficiaries. It should only be used for any data that are (i) not and do not contain Personal Data, (ii) Anonymous and/or (iii) fully Anonymized data.
- 2.2. The DTR Form B is to be used when the data transfer takes place for Access Rights to such data that are Results as stated and in compliance with the provisions of the Consortium Agreement.
- 2.3. The DTR Form B should be executed prior to providing/receiving the Data to/from the other Beneficiary.
- 2.4. Highlighted sections remain to be completed.

### **DATA TRANSFER RECORD FORM B**

**(for IHI XX Project)**

**(for Data which are Results of the Project)**

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Capitalized terms used herein that are not defined herein shall have the meanings set forth in the IHI XX Consortium Agreement effective XX (the "Consortium Agreement").

This Data Transfer Record covers the transfer of Data (as described hereunder) under the terms and conditions as provided for in the Consortium Agreement.

From: XXXXX, whose administrative offices are at XXXXX (the "Providing Beneficiary"),

To: **XXXXX**, whose administrative offices are at **XXXXX** (the “Receiving Beneficiary”).

For **SPECIFY PURPOSE(s) OF TRANSFER IN LINE WITH CONSORTIUM AGREEMENT** and pursuant to the terms of the Consortium Agreement, the Providing Beneficiary agrees that Receiving Beneficiary, can use the Data under the Access Rights provided for in the Consortium Agreement.

[OPTIONAL and to the extent foreseen in the Consortium Agreement]. The Providing Beneficiary and the Receiving Beneficiary explicitly agree the transfer of the Data under following Fair and Reasonable Conditions;

[SPECIFY FAIR AND REASONABLE CONDITIONS]

The Data described hereunder are considered “Results” of the Project, and the Access Rights as provided for Results for **[SPECIFY USE(S)]** in the Consortium Agreement apply.

- (Short) Description of data(sets): **XX**
- Envisaged Transfer Date: **XX**
- Method of transfer: **XX**
- Details of Third Party use Restrictions, if any: **XX** (ask provider IP Dept)

The Providing Beneficiary represents and warrants that the Data do not or no longer contain Personal Data (whether or not Pseudonomized).

The Providing Beneficiary and the Receiving Beneficiary explicitly agree to execute this Data Transfer Record by way of an electronic signature and agree this shall constitute a valid and enforceable agreement between the Providing Beneficiary and the Receiving Beneficiary. The present Data Transfer Record is made in an electronic pdf-version (using Adobe Sign or DocuSign) which shall be electronically signed by each of the Providing Beneficiary and the Receiving Beneficiary. Each of the Providing Beneficiary and the Receiving Beneficiary hereby acknowledges receipt of the e-signed Data Transfer Record, electronically signed for approval by the Providing Beneficiary and the Receiving Beneficiary.

## Appendix 5: Agreement on Background, Additional Data, Know-How or Information and Materials

The Beneficiaries to this Action hereby identify and agree on the Background for this Action pursuant to Clause 5.1.1 of this Consortium Agreement as listed in the chart below. The Beneficiaries acknowledge and agree that the Access Rights as identified in the Grant Agreement and Consortium Agreement apply to the below identified Background.

During the Action, Beneficiaries may add certain additional Background by updating the list below and circulating it in accordance with Clause 5.1.2 of this Consortium Agreement.

During the Action, a Beneficiary may contribute Additional Data, Know-How or Information pursuant to Clause 5.1.4 of this Consortium Agreement that it lawfully acquires control of following the date it accedes to the Grant Agreement. Such Additional Data, Know-How or Information shall be identified in the chart below in Section 1.2. and shall be circulated in accordance with Clause 5.1.4 of this Consortium Agreement.

Section 1.3. lists the Materials needed to carry out the Action. For the avoidance of doubt, as indicated in this Consortium Agreement, unless they are also listed as Background, no Access Rights are granted on such Materials other than those expressly provided.

### 1.1. Background TO BE SUBJECT OF ACCESS pursuant to Clause 5.1 of THIS Consortium Agreement

N° Beneficiary	Owner (Beneficiary acronym)	Background (with the exclusion of Materials)	Type of Background <sup>9</sup>	Beneficiary who needs access to the Background <sup>10</sup>	Related WP or task	Is there any pre-existing contractual or legal restriction to the use of your Background outside of your control? <sup>11</sup>

<sup>9</sup> Please indicate the nature of the Background (or similarly materials under section 2) you plan to bring by including one of the following categories:

- models (incl. *in vitro* models, *in vitro* models, *in silico* models...),
- cells & culture (liver cells, liver bioreactors, cell banking...),
- samples,
- data,
- animals (e.g. specific mice...),
- tests,
- methodologies (e.g.: biology of test system, computational modeling, high throughput analysis, database design...),
- tools (e.g.: *in vivo* tools, *in vitro* tools, drug transporters...),
- proprietary biomarkers,
- training material,
- if other, please specify according to generic categories.

<sup>10</sup> Please indicate which IHI project partner(s) would need to access this knowledge (for carrying out the project)?

<sup>11</sup> If there is any such restriction, please precise this restriction (e.g. informed consent restriction, third-party in-licensing restriction, obligations in relation to traceability of human samples).

[x]	[company]	[describe the needed background]	[add type]	[All ] [Benf. Of WPx]	[WP x]	[describe third party limitations on use or other restrictions imposed by appl. Law]
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1.2. ADDITIONAL DATA, KNOW-HOW or INFORMATION ENTERED INTO THE ACTION AFTER ITS START DATE.

N° Beneficiary	Owner (Beneficiary acronym)	Data, Know-How, information (with the exclusion of Materials)	Type of data, Know-How, information	Beneficiary who needs access to the data-Know-How, information	Related WP or task	Is there any legal restriction to the use of your data, Know-How, information?
[x]	[company]	[describe the Additional Data, Know-How or Information ]	[add type]	[All ] [Benf. of WPx]	[WP x]	[describe third party limitations on use or other restrictions imposed by appl. law]

1.3. PRESENTATION OF THE MATERIALS BROUGHT IN BY THE BENEFICIARIES AND NEEDED TO CARRY OUT THE ACTION.

*[Identify and list – on a per Beneficiary basis- the Materials needed]*

Owner(s) of materials	Material description / type	WP used?	Which BENEFICIARY is needing the Materials	Legal or Contractual Limitations on use of Materials?*
[party name]	[identify material / amount]	[WP x]	[All] / [WP x]	[Standard/Non-Standard terms]


\*Standard use: The standard MTA provisions of Clause 8 of this Consortium Agreement apply to this Material

\*Non-Standard use: A separate MTA will need to be agreed with the owner of the Material. Only in case no separate MTA would have been agreed, the standard provisions of Clause 8 of this Consortium Agreement shall apply.

## Appendix 6: Data Contributed as In-Kind



## Appendix 7: Communication Guidelines

### COMMUNICATION GUIDELINES

This Appendix governs Communication, by means other than Dissemination, by or on behalf of one or more Beneficiaries. It is intended to cover, for example, the use of social media where the Project is associated with such Communication, e.g., a tweet that includes a reference to the Project, the Project twitter handle, “[XX]”, or the like. The use of social media, e.g., Twitter, Facebook, Instagram, Linked-In, blogs, and the like, is generally encouraged to build awareness of and publicize the Project and its progress. It is within this spirit that the following binding guidelines are provided. These guidelines cover Communications related to the Project that do not contain Results or Background, including by means of newsletters, blogs, and websites of patient groups, caregiver organizations, and the like.

Any activity listed as “**Permitted Communications**” below can be undertaken. Activities that are listed as “Prohibited Activities” below may be permissible, but are subject to the terms of the Consortium Agreement, including those on Dissemination and Confidential Information. Activities that constitute Communication, by means other than Dissemination, by or on behalf of one or more Beneficiaries and that are not listed in either the “Permitted Communications” or “Prohibited Activities” sections below can be undertaken to the extent not contrary to the terms of this Consortium Agreement and to the extent they have been approved by the Steering Committee **[OPTIONAL: can be replaced with the Executive Committee, if established]**.

#### Permitted Communications \*

*\* To the extent not including any Results of any Beneficiary or any Background or Confidential Information of another Beneficiary and to the extent applicable confidentiality obligations are respected.*

- A. Announcements regarding upcoming Project presentations
- B. Links to web pages containing news coverage of Project, and any web-based content, e.g., journal articles and abstracts.\* But see “Links Guidelines” below
- C. Information raising awareness about the need to treat, prevent, or diagnose of [XX], but statements in a tweet that include health statistics and scientific content must include a link to a credible independent site that supports the information
- D. Information about the IHI JU’s values and the IHI JU’s commitment in society
- E. Information about partnership/collaboration with patients’ associations/charitable associations and foundations
- F. Information aimed at involving and engaging people in a future IHI JU or Project event directed to general public
- G. Information about the launch of the Project website or a Project app open to general public
- H. Information about new EU health policies/regulations
- I. Information that may refer to healthy living tips
- J. Information about the Project’s press releases that have been approved
- K. General chats about Project

- L. [Enrollment announcements]
- M. Links to caregiver support groups and other similar resources, unless permission to link is required
- N. Links to general news regarding [XX], treatments, screening, biomarkers, and diagnostics developed outside of the Project.

### **Prohibited Activities\***

*\* May be permissible by applying the relevant provisions concerning Confidential Information and Dissemination.*

1. Communications including Results of any Beneficiary or any Background or Confidential Information of another Beneficiary
2. Dosage amounts/timing
3. Photos and video of people (unless prior written permission has been obtained)
4. Any post/comment regarding a Beneficiary's products or compounds, including compound names, off-label or inappropriate use, making claims that are false or unsubstantiated, and making claims about another Beneficiary's products
5. Promotion of products (considered identifiable or viewable), promotional text regarding specific product or comparison of products
6. Attempts to diagnose a condition, recommend a treatment, or address other topics more appropriately reserved to healthcare professionals
7. Disclosure of Confidential Information or Background of another Beneficiary
8. Financial disclosures about a Beneficiary and predictions of its future performance
9. Commentary regarding ongoing litigation or other dispute resolution matters
10. Commentary regarding any crisis situation, adverse events, side effects resulting from the Project
11. Any harassing, threatening, derogatory, defamatory, discriminatory, abusive, hateful, violent, inciteful, or obscene language or material
12. Any reference to personal information of another, including name or information that may be used to identify or locate an individual (including last name, e-mail address, phone number, age or geographical location) or that could otherwise be deemed to constitute invasion of another's privacy
13. Libel, slander or defamation of the character of anyone
14. Any direct use (not linked) of third party copyrighted materials without prior permission
15. Any illegal statements, material, or content
16. Any political or religious content or propaganda
17. Any language that promotes drugs or alcohol, predation of minors, illegal or inappropriate activities or dangerous behavior that may result in harm to anyone reading the tweet or any linked content.

### **LINKS GUIDELINES**

- A. Links must be to non-product promotional websites/content only

- B. The content of the Communication with a link must be consistent with and supported by the content found in the link. Such a supporting link should be to a credible and appropriate independent source
- C. Linked content must not include statements that the Beneficiary making the Communication cannot communicate itself
- D. Ensure the linked content is credible and appropriate, and aligns with the IHI JU and the Project's values, tone & objectives
- E. Make it clear that the linked content belongs to a Third Party by including an appropriate citation or link back to the original source
- F. Ensure there is no implication that linked non-sponsored third party content is affiliated with or endorsed by the IHI JU, the Project or the Beneficiaries.
- G. Do not alter Third Party content
- H. Links to Third Party websites are permissible, provided the website content is approved taking into account these guidelines. Review of content linked to the Third Party website hosting the article linked to the Communication is not required unless there is some indication that the linked content may contain unsubstantiated statements or promotional claims.

### **THIRD PARTY PERMISSION GUIDELINES**

- A. Third Party content is generally copyright protected. Obtain or ensure that permission to use or a copyright license is in place prior to communicating content as use of copyright protected content without a copyright licence / written permission could lead to a claim for copyright infringement.
- B. Personally identifiable information of living individuals is protected by data protection legislation, and the individual's written consent to use this is generally required. However, other legal basis may apply according to applicable Data Protection Legislation.
- C. It is permissible to retweet a link that a Third Party content owner has already tweeted, provided the content is approved under these guidelines for this use.
- D. It is also permissible to retweet a retweet of content, provided that the original source can be verified and has social sharing for Twitter enabled, and the content has been approved for this use.

### **FOR THIRD PARTY CONTENT FROM ORGANISATIONS (E.G. MEDIA, PARTICIPANTS, ASSOCIATIONS, ETC.)**

- A. Photographs of trademarked content (e.g. magazine covers or articles) should not be posted without the express written permission from the publisher.
- B. No content from an image or stock photography warehouse should be used without first obtaining a proper licence. No content that says "courtesy of" a stock photography warehouse, even if it has social sharing functionality, should be used without obtaining a proper license.

### **FOR THIRD PARTY CONTENT FROM INDIVIDUALS**

- A. Photos and/or videos depicting individuals may not be taken (and posted) without the express written consent of each of the depicted individuals (right of self-image and personal data protection right if the images are identifiable information) and the photographer (Intellectual Property rights).

- B. Names and other personally identifiable information of individuals may not be publicly posted without the individual's express written consent. However, other legal basis may apply according to the applicable Data Protection Legislation.
- C. Quotations and sayings from living individuals or individuals that have been deceased less than 75 years (or any other applicable period during which authorship is protected under the relevant applicable law) should not be used without written permission from the individual or their estate. Whether copyright rules apply to the relevant individuals' saying must be first assessed.
- D. Content from minors should be accompanied or replaced, as the case may be, by the parents/guardian consent. In any event, information on minors should not be posted publicly or retweeted.
- E. Third Party tweets should not be used on other social media platforms or for offline uses (e.g., in printed materials) without first obtaining the individual's express written permission, unless permitted by applicable Data Protection Legislation.

[OPTIONAL: Appendix 8: Access Rights Table]

ACCESS RIGHTS TABLE (IMPLEMENTATION AND RESEARCH USE)

[Note: the below table is just an example. Adapt as needed to align with the Consortium Agreement]

In case of any inconsistency between this Appendix 8 and the main body of the Consortium Agreement, the main body of the Consortium Agreement shall prevail.

IMPLEMENTATION (7.2)

7.2 Access Rights For Implementation	Terms (7.2.1.1 / 7.2.2.2)	Formalities on granting (7.2.1.3/ 7.2.2.3)
7.2.1. Background (incl. all subcategories)	Royalty-Free Conditions	Automatic
7.2.2 Results (incl. all subcategories)	Royalty-Free Conditions	Automatic

EXPLOITATION – RESEARCH USE (7.3)

To Background – for Research Use of Own Results (7.3.1)

To:	Terms (provide details on Fair and Reasonable Conditions if any)	Formalities on Granting (if not Royalty-Free, provide details on granting procedure)	Time Limit for request in case not automatic (7.1.4)
Background	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]
(a) XX Background	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]
(b) Software Background	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]
(c) Background Databases	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]
(d) Other Background	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]

### To Background – for Research Use of Results of other Beneficiaries (7.3.2)

To:	Terms (provide details on Fair and Reasonable Conditions if any)	Formalities on Granting (if not Royalty-Free, provide details on granting procedure)	Time Limit for request in case not automatic (7.1.4)
Background	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]
(a) XX Background	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]
(b) Software Background	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]
(c) Background Databases	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]
(d) Other Background	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]

### EXPLOITATION – RESEARCH USE

#### To Results - for Research Use of Own Results (7.3.3)

To:	Terms (provide details on Fair and Reasonable Conditions if any)	Formalities on Granting (if not Royalty-Free, provide details on granting procedure)	Time Limit for request in case not automatic (7.1.4)
Action Objective Results	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]
(a) XX Results	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]

(b) Software Results	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]
(c) Database Results	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]
(d) Imaging Results	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]
(e) Other Results	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]
Sideground Results	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]

**To Results** - for Research Use of the Results of the Other Beneficiaries (7.3.4)

To:	Terms (provide details on Fair and Reasonable Conditions if any)	Formalities on Granting (if not Royalty-Free, provide details on granting procedure)	Time Limit for request in case not automatic (7.1.4)
Action Objective Results	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]
(a) XX Results	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]
(b) Software Results	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]
(c) Database Results	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]
(d) Imaging Results	[on Royalty-Free Conditions/ Fair	[Automatic / On written request]	[5][10][15][20]

	and Reasonable Conditions]		
(e ) Other Results	[on Royalty-Free Conditions/ Fair and Reasonable Conditions]	[Automatic / On written request]	[5][10][15][20]
Sideground Results	None granted	n.a.	n.a.



## Appendix 9: Template Material Transfer Record Forms

*[In order to select the correct template, please determine whether the to be transferred Materials were (i) either pre-existing or generated outside of the project in which case MTR Form A could be used, or (ii) otherwise were generated during the Project as a Result of performance of the Project (a Material which is a Result) in which case MTR Form B could be used.]*

### 1. Template Material transfer record form for Materials which are pre-existing or generated outside the project. - (MTR Form A)

- 1.1. The template MTR Form A, is to be used when Materials which were pre-existing or generated outside the Project (Background Materials) are transferred.
- 1.2. The MTR Form A is to be used when the Material transfer takes place for purposes of *Action Implementation only* more specifically the purposes described in Annex 1 of the Grant Agreement and the Work Packages identified therein.
- 1.3. The MTR Form A should be executed prior to providing/receiving the Materials to/from the other Beneficiary.
- 1.4. Highlighted sections remain to be completed.

#### MATERIAL TRANSFER RECORD FORM A

(for IHI XX Project)

(for Materials which are pre-existing or generated outside the project)

Capitalized terms used herein that are not defined herein shall have the meanings set forth in the IHI XX Consortium Agreement effective XX (the “Consortium Agreement”).

This Material Transfer Record covers the transfer of Materials (as defined hereunder) under the terms and conditions as provided for in the Consortium Agreement, including its Clause 8 – for Material Transfer under standard use terms as indicated in this Appendix.

From: XXXXX, whose administrative offices are at XXXXX (the “Providing Beneficiary”),

To: XXXXX, whose administrative offices are at XXXXX (the “Receiving Beneficiary”).

For the performance of the Project and pursuant to the terms of the Consortium Agreement, the Providing Beneficiary agrees that Receiving Beneficiary, can use the Materials under the standard use terms as provided for in Clause 8 of the Consortium Agreement – Materials Transfer.

The Materials to be provided are not considered Results, but are considered pre-existing or generated outside of the Project. The Access Rights as provided for Background in the Consortium Agreement apply, to the extent the Materials were listed as Background.

- (Short) Description of Materials: XX
- Envisaged Transfer Date: XX
- For use at: Receiving Beneficiary’s Premises / Receiving Beneficiary’s CRO

- **Delivery Address:** XX
- **Details of Third Party use Restrictions, if any:** XX (ask provider IP Dept)

These Materials are being transferred for use for Project Implementation only, more specifically the purposes described in Annex 1 of the Grant Agreement and the Work Packages identified therein. A separate agreement will be required to arrange for additional terms for Research Use, if relevant.

The Providing Beneficiary and the Receiving Beneficiary explicitly agree to execute this Material Transfer Record by way of an electronic signature and agree this shall constitute a valid and enforceable agreement between the Providing Beneficiary and the Receiving Beneficiary. The present Material Transfer Record is made in an electronic pdf-version (using Adobe Sign or DocuSign) which shall be electronically signed by each of the Providing Beneficiary and the Receiving Beneficiary. Each of the Providing Beneficiary and the Receiving Beneficiary hereby acknowledges receipt of the e-signed Material Transfer Record, electronically signed for approval by the Providing Beneficiary and the Receiving Beneficiary.

## 2. Template Material transfer record form for Materials which are Results of the Project - (MTR Form B).

- 2.1. The template MTR Form B, is to be used when Materials which were generated during the Project as a result of performance of the Project (a material which is a Result), are transferred.
- 2.2. The MTR Form B is to be used when the Material transfer takes place for purposes of *Action Implementation only* more specifically the purposes described in Annex 1 of the Grant Agreement and the Work Packages identified therein.
- 2.3. The MTR Form B should be executed prior to providing/receiving the Materials to/from the other Beneficiary.
- 2.4. Highlighted sections remain to be completed.

### MATERIAL TRANSFER RECORD FORM B

(for IHI XX Project)

(for Materials which are Results of the Project)

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Capitalized terms used herein that are not defined herein shall have the meanings set forth in the IHI XX Consortium Agreement effective XX (the “Consortium Agreement”).

This Material Transfer Record covers the transfer of Materials (as described hereunder) under the terms and conditions as provided for in the Consortium Agreement. including its Clause 8 – for Material Transfer under standard use terms as indicated in this Appendix.

From: XXXXX, whose administrative offices are at XXXXX (the “Providing Beneficiary”),

To: XXXXX, whose administrative offices are at XXXXX (the “Receiving Beneficiary”).

For the performance of the Project and pursuant to the terms of the Consortium Agreement, the Providing Beneficiary agrees that Receiving Beneficiary, can use the Materials under the standard use terms as provided for in Clause 8 – Materials Transfer.

The Materials described hereunder are considered “Results” of the Project, and the Access Rights as provided for Results in the Consortium Agreement apply.

- (Short) Description of Materials: XX
- Envisaged Transfer Date: XX
- For use at: Receiving Beneficiary’s Premises / Receiving Beneficiary’s CRO
- Delivery Address: XX
- Details of Third Party use Restrictions, if any: XX (ask provider IP Dept)

**These Materials are being transferred for use for Project Implementation only, more specifically the purposes described in Annex 1 of the Grant Agreement and the Work Packages identified therein. A separate agreement will be required to arrange for additional terms for Research Use, if relevant.**

The Providing Beneficiary and the Receiving Beneficiary explicitly agree to execute this Material Transfer Record by way of an electronic signature and agree this shall constitute a valid and enforceable agreement between the Providing Beneficiary and the Receiving Beneficiary. The present Material Transfer Record is made in an electronic pdf-version (using Adobe Sign or DocuSign) which shall be electronically signed by each of the Providing Beneficiary and the Receiving Beneficiary. Each of the Providing Beneficiary and the Receiving Beneficiary hereby acknowledges receipt of the e-signed Material Transfer Record, electronically signed for approval by the Providing Beneficiary and the Receiving Beneficiary.

## Appendix 10: Contracts under Mandate: One-sided CDA

[THIS IS A TEMPLATE CDA PROPOSED FOR THE [X] ACTION, WHOSE MEMBERS HAVE APPROVED THE SUBSTANTIVE PROVISIONS AND AUTHORISED ITS SIGNATURE ON THEIR BEHALF.]

ANY CHANGES TO THE SUBSTANCE SHOULD NOT BE MADE WITHOUT CONSORTIUM APPROVAL, WHICH MAY CAUSE A DELAY.]

### CONFIDENTIAL DISCLOSURE AGREEMENT (ONE WAY)

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

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

and

*[insert Recipient’s name and Recipient’s address; if Recipient is another (as the case may be: IHI) consortium insert: “[Y] Consortium Members, as defined below and listed in Exhibit 2”] (“Recipient”)*

WHEREAS,

- (A) The parties intend to disclose/receive confidential information for the purpose of facilitating discussions between the [X] Consortium Members and the Recipient;
- (B) The [X] Consortium Members have formed a consortium under the Innovative Health Initiative (“IHI”) for the purpose of establishing the project called “[title of IHI Consortium]” (IHI Grant Agreement No. [ ]) (the “[X] Action”) and are parties to the [X] Consortium Agreement, as defined below, supported by the IHI Joint Undertaking;
- (C) The [X] Consortium Members have authorized [name of authorized company or institution] (the “Mandate Holder”) to execute this Agreement on behalf of the [X] Consortium Members.

*[Delete Sections (D) and (E) if not applicable:]*

- (D) The [Y] Consortium Members have formed a consortium *[Delete if not applicable:]* under the Innovative Health Initiative (“IHI”) for the purpose of establishing the project called “[title of Consortium]” *[Delete if not applicable:]* (IHI Grant Agreement No. [ ]) (the “[Y] Action”) and are parties to the [Y] Consortium Agreement, as defined below, *[Delete if not applicable:]* supported by the IHI Joint Undertaking;
- (E) The [Y] Consortium Members have authorized [name of authorized company or institution] (the “[Y] Mandate Holder”), to execute this Agreement on behalf of the [Y] Consortium Members.

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

## 5. DEFINITIONS

- a) “**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.
- b) “**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 [X] Consortium Members (each referred to as a “**Disclosing Party**” and collectively as the “**Disclosing Parties**”) to any Recipient that relates to the [X] Action. *[the general description of Confidential Information can be replaced with a limitative list of Confidential Information if required by the Beneficiaries.]*
- c) “[X] **Consortium Members**” shall mean the parties to the Innovative Health Initiative Consortium Agreement for *[title of IHI Consortium]* effective as of [...] (“[X] Consortium Agreement”) as listed at EXHIBIT 1. For the avoidance of doubt, if new members join the [X] Action, they are considered to be a [X] Consortium Member under this Agreement and EXHIBIT 1 will be considered to have been updated accordingly, to include the new member(s).

*[Delete if not applicable:]*

- a) “[Y] **Consortium Members**” shall mean the parties to the Consortium Agreement for *[title of Consortium]* effective as of [...] (“[Y] Consortium Agreement”) as listed at Exhibit 2. For the avoidance of doubt, if new members join the [Y] Action, they are considered to be a [Y] Consortium Member under this Agreement and Exhibit 2 will be considered to have been updated accordingly, to include the new member(s).]

## 6. PURPOSE OF DISCLOSURE

The Confidential Information is being disclosed to the Recipient for the purpose of facilitating discussions between [X] Consortium Members and the Recipient **[CHECK THE APPROPRIATE BOX]:**

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

(the “**Purpose**”).

## 7. MAINTENANCE OF CONFIDENTIALITY; NON-USE OBLIGATIONS

- a) 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.

- b) 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.

## **8. EXCLUDED INFORMATION**

Subject to applicable data protection legislation providing otherwise, Confidential Information shall not include any information which:

- a) at the time of disclosure is in the public domain;
- b) after disclosure becomes part of the public domain, except through breach of this Agreement by Recipient;
- c) 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;
- d) 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
- e) 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.
- f) 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.

## **9. NOTIFICATION OF MANDATORY DISCLOSURE**

- a) 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.
- b) 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 any freedom of information law or regulation in any applicable jurisdiction, the Recipient shall in all instances seek to apply the exemptions under that law or regulation. The disclosure of personal data shall furthermore be subject to the provisions of applicable data protection legislation.

## 10. 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 ten (10) years *[To be checked if this is sufficient for the Consortium Members and in line with the Consortium Agreement]*.

## 11. 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.

## 12. 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.

## 13. 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 13 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.

## 14. NO PUBLICITY

Subject to Clauses 5 and 6, 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.

## 15. RIGHTS OF THIRD PARTIES

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

## 16. 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.

## 17. 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.

## 18. 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.

## 19. GOVERNING LAW; 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. The headings in this Agreement are for convenience of reference only and shall not affect its interpretation.

The parties hereto have caused this Agreement to be executed in their own name and in case of the Mandate Holder(s) in addition in the name and on behalf of their respective Consortium Members as their duly authorized representative. [OPTION 1 – *standard signature*: This Agreement is executed in [insert number of necessary originals], each party acknowledging receipt one original copy.][ OPTION 2 – *e-signature*: The parties explicitly agree to execute this Agreement by way of an electronic signature [by using DocuSign/Adobe Sign] and agree this shall constitute a valid and enforceable agreement between the parties. The present Agreement is made in an electronic version which shall be electronically signed by each party. Each party hereby acknowledges receipt of the e-signed Agreement, electronically signed for approval by the parties.]

[name of authorized company or institution]

(☒) Mandate Holder )

[Recipient, as the case may be:

„name of authorized company or institution;” ]



\_\_\_\_\_  
Name:

Function:

Place: \_\_\_\_\_

Date: \_\_\_\_\_

\_\_\_\_\_  
Name:

Function:

Place: \_\_\_\_\_

Date: \_\_\_\_\_

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

#### EXHIBIT 1

*[list names and addresses of [X] Consortium Members]*

*[Delete if not applicable:]*

#### EXHIBIT 2

*[list names and addresses of [Y] Consortium Members]*

## Appendix 11: Contracts under Mandate: Two-sided CDA

THIS IS A TEMPLATE CDA PROPOSED FOR THE [X] PROJECT, WHOSE MEMBERS HAVE APPROVED THE SUBSTANTIVE PROVISIONS AND AUTHORISED ITS SIGNATURE ON THEIR BEHALF.

THE DEFINITION OF CONFIDENTIAL INFORMATION OF THE CONTRACT PARTNER NEEDS THE APPROVAL OF ALL CONSORTIUM MEMBERS RECEIVING SUCH INFORMATION.

ANY CHANGES TO THE SUBSTANCE SHOULD ONLY BE MADE IN ACCORDANCE WITH CLAUSE 10.5.2. OF THE CONSORTIUM AGREEMENT; CHANGES MAY CAUSE A DELAY.

### CONFIDENTIAL DISCLOSURE AGREEMENT (TWO WAY)

THIS CONFIDENTIAL 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; if Recipient is another (as the case may be: IHI) consortium insert: “[Y] Consortium Members, as defined below and listed in Exhibit 2”]** (“Contract Partner”)

WHEREAS,

- (A) The parties intend to disclose/receive confidential information for the purpose of facilitating discussions between the **[X]** Consortium Members and the Contract Partner;
- (B) The **[X]** Consortium Members have formed a consortium under the Innovative Health Initiative (“IHI”) for the purpose of establishing the project called “**[title of IHI Consortium]**” (IHI Grant Agreement No. **[...]**) (the “**[X]** Action”) and are parties to the **[X]** Consortium Agreement, as defined below, supported by the IHI Joint Undertaking;
- (C) The **[X]** Consortium Members have authorized **[name of authorized company or institution]** (the “**[X]** Mandate Holder”), to execute this Agreement on behalf of the **[X]** Consortium Members.

**[Delete Sections (D) and (E) if not applicable:]**

- (D) The **[Y]** Consortium Members have formed a consortium **[Delete if not applicable: under the Innovative Health Initiative (“IHI”)]** for the purpose of establishing the project called “**[title of Consortium]**” **[Delete if not applicable: (IHI Grant Agreement No. [...])]** (the “**[Y]** Action”) and are parties to the **[Y]** Consortium Agreement, as defined below, **[Delete if not applicable: supported by the IHI Joint Undertaking];**
- (E) The **[Y]** Consortium Members have authorized **[name of authorized company or institution]** (the “**[Y]** Mandate Holder”), to execute this Agreement on behalf of the **[Y]** Consortium Members.

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

#### 1. DEFINITIONS

- a) “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.
- b) “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 [X] Consortium Members, on the one hand, or by the Contract Partner, on the other hand (each referred to as a “Disclosing Party” and collectively as the “Disclosing Parties”) under this Agreement for the Purpose to *[Add language highlighted in yellow if deemed appropriate to reduce contamination risk: the [X] Project Leader and] any of the [X] Consortium Members, [as applicable,] on the one hand, or to the Contract Partner, on the other hand (each referred to as a “Recipient” and collectively as the “Recipients”). [Confidential Information shall only be disclosed to the individual [X] Consortium Members upon their prior written approval (e-mail suffice) given to the [X] Project Leader]. In case of the [X] Consortium Members, Confidential Information shall be limited to comprise any of their information that relates to the [X] Action. In case of Contract Partner, Confidential Information shall be limited to comprise [to be inserted. Definition to be approved by each and any [X] Consortium Member prior to conclusion of this CDA].* Personal Data processed in view of the Purpose (as defined below) shall also be deemed Confidential Information. “[X] Consortium Members” shall mean the parties to the Innovative Health Initiative Consortium Agreement for *[title of IHI Consortium]* effective as of [...] (“[X] Consortium Agreement”) as listed at Exhibit 1. For the avoidance of doubt, if new members join the [X] Action, they are considered to be a [X] Consortium Member under this Agreement and Exhibit 1 will be considered to have been updated accordingly, to include the new member(s). *[the general description of Confidential Information can be replaced with a limitative list of Confidential Information if required by the Beneficiaries.]*

*[Delete if not applicable:]*

- c) “[Y] Consortium Members” shall mean the parties to the Consortium Agreement for *[title of Consortium]* effective as of [...] (“[Y] Consortium Agreement”) as listed at Exhibit 2. For the avoidance of doubt, if new members join the [Y] Action, they are considered to be a [b] Consortium Member under this Agreement and Exhibit 2 will be considered to have been updated accordingly, to include the new member(s).

## 2. PURPOSE OF DISCLOSURE

The Confidential Information is being disclosed for the purpose of facilitating discussions between [X] Consortium Members and Contract Partner *[CHECK THE APPROPRIATE BOX]:*

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

(the “Purpose”).

### **3. MAINTENANCE OF CONFIDENTIALITY; NON-USE OBLIGATIONS**

- a) Each Disclosing Party's Confidential Information shall be kept confidential by each 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. Each 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. Each Recipient may disclose the Confidential Information only to its officers, employees, consultants and/or Affiliates on a need-to-know basis, provided that it imposes on them restrictions on disclosure and use equivalent to those set forth herein. Each 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.
- b) 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**

Subject to applicable data protection legislation providing otherwise, Confidential Information shall not include any information which:

- a) at the time of disclosure is in the public domain;
- b) after disclosure becomes part of the public domain, except through breach of this Agreement by Recipient;
- c) 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;
- d) 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
- e) 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.

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**

- a) Each 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. Each 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.

- b) If, in the absence of such legal relief or other remedy, a Recipient is nonetheless required to disclose any part of the Confidential Information, Recipient may disclose such Confidential Information without liability hereunder, provided that, Recipient shall furnish only such portion of the Confidential Information which Recipient is legally required to disclose. For the avoidance of any doubt, if a Recipient is required to disclose Confidential Information pursuant to Recipient's obligations under the provisions of any freedom of information law or regulation in any applicable jurisdiction, Recipient shall in all instances seek to apply the exemptions under that Act. The disclosure of personal data shall be subject to the applicable data protection legislation.

## 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 ten (10) years after the end of the [X] Action. *[To be checked if this is sufficient for the Consortium Members and in line with the Consortium Agreement]*

*[Delete if not applicable:]*

*[For the avoidance of doubt, in the event a [X] Consortium Member is also a [Y] Consortium Member, such [X] Consortium Member, respectively [Y] Consortium Member shall only be obligated to hold Confidential Information disclosed under the present Agreement confidential for the confidentiality term to which it is bound under the [X] Consortium Agreement respectively the [Y] Consortium Agreement, whichever is longer, for the same Confidential Information]*

## 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 a Recipient, as well as any right which could result from such Confidential Information, remains the exclusive property of that Disclosing Party.

## 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, each 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 each 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 Recipient according to the provisions of mandatory applicable law. The provisions of this clause shall not apply to copies of electronically exchanged Confidential Information made as a matter of routine information technology backup and to Confidential Information or copies thereof which must be stored by the Receiving Beneficiary according to provisions of mandatory law.

#### 10. NO PUBLICITY

Subject to Clauses 5 and 6, 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. ~~if not applicable: Each ☐ Consortium Member shall have a right to enforce the terms of this Agreement.]~~

#### 12. ASSIGNMENT

This Agreement shall not be assigned by Contract Partner without the prior written consent of the ☒ Consortium Members, whose consent may be withheld at the ☒ Consortium Members' sole discretion, and any purported assignment without such consent shall be void; provided, however, that Contract Partner 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; 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. The headings in this Agreement are for convenience of reference only and shall not affect its interpretation.

The parties hereto have caused this Agreement to be executed in their own name and in case of the Mandate Holder(s) in addition in the name and on behalf of their respective Consortium Members as their duly authorized representative. [OPTION 1 – standard signature: This Agreement is executed in [insert number of necessary originals], each party acknowledging receipt one original copy.][ OPTION 2 – e-signature: The parties explicitly agree to execute this Agreement by way of an electronic signature [by using DocuSign/Adobe Sign] and agree this shall constitute a valid and enforceable agreement between the parties. The present Agreement is made in an electronic version which shall be electronically signed by each party. Each party hereby acknowledges receipt of the e-signed Agreement, electronically signed for approval by the parties.]

[name of authorized company or institution]

[Recipient, as the case may be:

[X] Mandate Holder(s)

“name of authorized company or institution”]

\_\_\_\_\_  
Name:

\_\_\_\_\_  
Name:

Function:

Function:

Place: \_\_\_\_\_

Place: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

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

#### EXHIBIT 1

*[list names and addresses of [X] Consortium Members]*

*[Delete if not applicable:]*

#### EXHIBIT 2

*[list names and addresses of [Y] Consortium Members]*

## Appendix 12: Contracts under Mandate: Advisory Agreement

### Advisory Agreement

between **[X]** Consortium Members as listed in Appendix **Appendix 1**

- hereinafter jointly referred to as “Consortium” -

and **[Name and private address of consultant]**

- hereinafter referred to as “Advisor” -

#### WHEREAS,

- (A) The Consortium has been formed under the Innovative Health Initiative (“IHI”) for the purpose of establishing the project called **“[title of IHI Consortium]”** (IHI Grant Agreement No. **[...]**) (the “Action”). It consists of the beneficiaries listed in Exhibit 1 hereto (collectively the “Beneficiaries”), including **[name of authorized company or institution]** acting as the “Project Leader”. The Beneficiaries are parties to an IHI Consortium Agreement for **[title of IHI Consortium]** effective as of **[...]** (the “Consortium Agreement”). For the avoidance of doubt, if new members join the Action, they are considered as a Beneficiary to the Consortium under this Agreement and Exhibit 1 will be considered to have been updated accordingly, to include the new member(s).
- (B) Subject to the Consortium Agreement, a **[insert name of committee]** is established to **[insert short description of the role of the committee]**.
- (C) Advisor, who is employed by **[name and address of employer]**, has extensive experience, scientific and/or industrial prominence and leadership in the field of **[field of expertise]** relating to the Action.
- (D) The Consortium is interested to have the Advisor to be part of the **[insert name of committee]**.
- (E) Each Beneficiary has authorized the Coordinator to execute this Advisory Agreement on its behalf.

#### **[Alternative in case of “on the spot/one time consultancy”:**

- (A) *Advisor, who is employed by **[name and address of employer]**, has extensive experience, scientific and/or industrial prominence and leadership in the field of **[field of expertise]** relating to the Action.*
- (B) *The Consortium is interested to have the advice of the Advisor be brought into the Action.*
- (C) *Each Beneficiary has authorized the Project Leader to execute this Advisory Agreement on its behalf.]*

Therefore, it is agreed as follows:



## 1. SUBJECT MATTER OF THE AGREEMENT

- 1.1. Advisor shall provide consultative and advisory services to the Consortium according to the terms and conditions of the Consortium Agreement and this Agreement as set forth below (hereinafter referred to as the “Services”):

*[In case Advisor is to be a member of a committee:*

*The Advisor agrees to be a member of the [insert name of committee] in accordance with the Consortium Agreement.]*

*The Advisor shall [insert precise description of services, e.g., providing expert interpretation, analysis and opinion on scientific data/information, project management, attending meetings etc., including preparation and timelines tasks, e.g.: “be available for [time needed] and shall, on request by [committee to be inserted], provide and/or approve reports or meeting minutes as agreed upon.]*

Further details of the Services will be agreed between the parties.

- 1.2 **[Insert for healthcare professionals, otherwise delete]** For the term of this Agreement Advisor agrees to declare in an appropriate way that he/she is an advisor to the Consortium whenever he/she writes or speaks in public about a topic that is the subject matter of this Agreement or any other issue relating to the Action.

## 2. COMPENSATION

- 2.1. The parties agree that the Advisor shall not be compensated for the performance of the Services.
- 2.2. **[Insert Beneficiary who reimburses below costs]** will, in compliance with the applicable laws, regulations and codices, offer to pay for reasonable travel expenses and hospitality, such as flights (business class airfare for intercontinental flights and economy class airfare for intracontinental flights), train travel, accommodation (up to 4-star rating), work related meals and transportation. In addition, Advisor shall be reimbursed by **[insert Beneficiary who reimburses costs]** for other reasonable travel expenses actually incurred by Advisor in connection with providing the Services, subject to the receipt of invoices or receipts. Costs for meals and drinks are not considered as travel expenses.
- 2.3. Any payments will be made by **[insert Beneficiary who reimburses costs]** within 90 days to an account nominated by the Advisor previously in writing upon receipt of a correct invoice (i) complying with applicable legal and tax requirements and (ii) containing the original receipts. Further details will be agreed between the parties. Advisor acknowledges and agrees that the amounts paid will be reported to the members of the Consortium as well as the country to which the amount is paid.
- 2.4. Advisor shall be responsible for all other taxes payable on account of payments made hereunder.
- 2.5. Advisor agrees that the Consortium (by stating Advisor’s private information) may store, process and publish any payments made by the Consortium under this Agreement, if such disclosure is required by statutory or internal regulation or any binding Code of Conduct.

## 3. CONFIDENTIALITY, ARCHIVING, DATA PROTECTION

- 3.1. Advisor undertakes to hold in strict confidence any information, in particular without limitation scientific, technical or commercial information relating to the business, products or research of the Consortium, which becomes known to Advisor during the course of this collaboration, together with any information regarding the Action and all results of the cooperation with the Consortium, to use such information and results only for the purposes of this Agreement, and not to disclose such information or results to any third party without a prior written consent of the Consortium. The foregoing restrictions on use and disclosure will not apply to any of such information which: (a) at the time of receipt by Advisor is available to the public; or (b) becomes public knowledge other than by an act or omission on the part of Advisor; or (c) which Advisor can prove was known to Advisor before the date of its disclosure to Advisor by the Consortium; or (d) is legally acquired by Advisor from a third party not bound to Consortium or any of its Beneficiaries by any express or implied obligation of secrecy, or (e) Advisor can prove was developed independently by him/her without reference to or use of the information.
- 3.2. Furthermore, Advisor may disclose such information to the extent that such disclosure is required to comply with law or an enforceable judicial order, provided, however, that Advisor shall give reasonable advance notice to the Consortium and on request, shall cooperate with the Consortium to seek a protective order or other appropriate remedy. The Advisor will use his/her reasonable efforts to secure confidential treatment of any such information that will be disclosed.
- 3.3. Information shall not be deemed to be or have become public knowledge merely because any part of such Information is embodied in general disclosures or because individual features, components or combinations thereof are known or become known to the public.
- 3.4. Advisor agrees to duly preserve all information and documentation provided to Advisor and to ensure that no third parties gain access thereto. Any documentation provided must be returned to the Consortium at Consortium's request during the term of this Agreement, and shall be returned to the Consortium, without being asked, upon the termination of this Agreement.
- 3.5. This confidentiality and non-use obligation shall remain in effect for ten (10) years after the Action expires or is terminated. ***[To be checked if this is in line with the Consortium Agreement]***  
  
In the event the performance of Services or the preparation thereof requires Advisor to use or process any personal data, Advisor agrees to use such personal data only for the Services provided hereunder and in compliance with applicable data protection laws, and therefore the Advisor shall:
  - (1) process the personal data exclusively in the name of and in accordance with the documented instructions (in so far as needed under the applicable legislation) of the controller, including with regard to the transfer of personal data to a third country unless required to do so by applicable law to which the Advisor as processor is subject; in such a case, the Advisor shall inform the controller of that legal requirement before processing, unless that law prohibits such information on important grounds of public interest
  - (2) not acquire any rights with respect to the personal data;
  - (3) ensure that its employees dealing with the processing of personal data are obliged to data secrecy in writing and that they are informed about the applicable obligations under the Data Protection Legislation and applicable contractual provisions regarding data protection and that they will act in accordance with those obligations and provisions
  - (4) take all reasonable technical and organizational measures necessary to protect the personal data against unauthorized or unlawful processing and against accidental loss, destruction or damage to such personal data that: (a) are able to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services (b) where appropriate result in pseudonymisation and/or encryption of personal data; (c) are able to

restore the availability and access to the personal data in a timely manner in the event of a physical or technical incident; and (d) include a process for regularly testing, assessing and evaluating the effectiveness of technical and organizational measures for ensuring the security of the processing.

- (5) assist the controller insofar as this is possible, for the fulfilment of the controller's obligation to respond to requests for exercising the data subject's rights taking into account the nature of the processing;
- (6) assist the controller, upon its request, in ensuring compliance with the obligations relating to the security of the processing data breach notifications, data protection impact assessment and prior consultation to the data protection authority, taking into account the nature of the processing of the personal data and the information available to the Advisor;
- (7) obtain the controller's prior written specific authorization prior to engaging another processor on which it shall impose the same data protection obligations as set out herein by way of a contract or other legal act and, if this new processor fails to fulfil its data protection obligations, it shall remain fully liable to the controller for the performance of new processor's obligations;
- (8) return or delete at the choice of the controller (and subject to the provisions of the Consortium Agreement) all the personal data to the controller after the end of the provision of services relating to processing, and delete existing copies (unless applicable law requires storage of the personal data);
- (9) process the personal data exclusively in the EEA; otherwise, the controller's written consent will be required as well as appropriate safeguards (e.g., EU model clauses);
- (10) make available to the controller all information necessary to demonstrate compliance with the obligations laid down in this Section 3.4; and
- (11) allow for and contribute to audits, including inspections, conducted by the controller or another auditor mandated by the controller during the implementation of the Agreement and for seven (7) years after the completion of the Agreement.

3.6 [The personal data that will be processed in view of Section 3.4 of this Agreement are **[DESCRIPTION of the Type of Personal Data]**. The categories of the data subjects to which the personal data relate that are processed are **[DESCRIPTION]**. The nature and the purpose of the processing of the personal data are as follows: **[DESCRIPTION]**].

3.7 In Section 3.4, data protection terminology including "personal data", "processing", "data subject" and "data protection authority" shall have the meaning given to it in the General Data Protection Regulation (Regulation (EU) 2016/679) or any other applicable data protection legislation

#### 4. RIGHTS TO RESULTS

In case that results are generated by Advisor including intellectual property rights relating thereto (collectively "Results") Advisor shall promptly disclose any Results to the Project Leader in writing. All rights, title and interest in any Results will be owned exclusively by the Beneficiaries in equal shares, and Advisor shall assign (or cause to be assigned) and does hereby assign fully to each of the Beneficiaries in equal shares all rights, title and interest in and to any Results, without payment of any additional compensation to Advisor. At a Beneficiary's request and expense, Advisor shall also reasonably assist such Beneficiary in obtaining, perfecting, or defending such Beneficiary's rights, title, and interest in any Results, including, without limitation, the drafting, filing and prosecution of any patent applications. As between the

Beneficiaries, such results shall be deemed to be Results and rights thereto shall be exploited and shared pursuant to the terms of the Consortium Agreement. With regard to any copyrights, Advisor consents to the right to reproduce, modify and use all copyrightable works designed or made by the Advisor by each of the Beneficiaries.

## 5. COMPLIANCE

- 5.1. The parties declare that this Agreement is in no way associated with any business or sales activities between the parties hereto and in particular Advisor is by no means obligated to prescribe, recommend or purchase any goods from the Consortium.
- 5.2. Advisor agrees to comply with all applicable laws and regulations in the performance of the Services pursuant to this Agreement.
- 5.3. Advisor represents and warrants that: (a) Advisor has received all necessary approvals in connection with entering into this Agreement and performing the Services to be provided hereunder; (b) compliance with the terms of this Agreement and performance of the Services do not and will not breach or conflict with (i) any other agreement or arrangement, to which Advisor is a party, or (ii) any statutory or internal regulations Advisor is subject to; (c) compliance with the terms of this Agreement and performance of the Services do not and will not breach any agreement to keep in confidence information acquired in confidence or in trust; and (d) during performance of the Services, Advisor will not disclose to Consortium, or induce Consortium to use, any information belonging to a third party.
- 5.4. Advisor further represents and warrants that he/she has fully informed the management of his/her medical agency/institution or other employer, or any other organizations or authorities, if necessary, about the execution and content of this Agreement and that he/she has obtained the necessary written approvals of such employer that are required for the performance of this Agreement. *[The medical agency/institution or other employer may confirm that it has no objections to Advisor entering into this Agreement, through an authorized representative's signature at the place indicated below.]*
- 5.5. The Advisor represents that in performing the Services he has not and he will not use in any capacity the services of anyone debarred, disqualified, blacklisted or banned or under investigations or threat of investigations by any regulatory authority for debarment, disqualification, blacklisting or any similar regulatory action in any jurisdiction anywhere in the world. Furthermore, the Advisor represents and warrants that neither he, nor its employees, agents, representatives or permitted sub-contractors have been debarred, disqualified, blacklisted or banned by any regulatory authority, nor that they are currently to the best of his knowledge, the subject of such a debarment, disqualification, blacklisting or banning proceeding. During the term of this Advisory Agreement, the Advisor shall promptly notify the Project Leader should the Advisor, any of its employees, agents, representatives or permitted sub-contractors become subject of such debarment, disqualification, blacklisting or banning proceeding.

[FOR US:

Advisor hereby represents that Advisor is not an employee of the U.S. Department of Health and Human Services, National Institutes of Health ("NIH") and that Advisor shall immediately notify if he/she becomes an employee of NIH at any time during the term of this Agreement. In such case, the Consortium has the right to terminate this Agreement with immediate effect.

Advisor agrees to comply with all applicable federal, state and local laws and regulations in the performance of the Services pursuant to this Agreement, including, without limitation, laws related to fraud, abuse, privacy, discrimination, disabilities, samples, confidentiality, false claims

and prohibition of kickbacks. Without limiting the generality of the foregoing, each party to this Agreement certifies that such party shall not violate the U.S. Anti-Kickback Statute (42 U.S.C § 1320a-7b (b)) with respect to the performance of this Agreement.

Without prejudice to the generality of section above, Advisor further agrees to comply with all applicable U.S. federal, state and local laws and regulations relating to the privacy of patient health information, including, but not limited to, the Standards for Individually Identifiable Health Information, 45 C.F.R. §§ 160 and 164 (the "HIPAA Privacy Regulation") promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996. If Advisor deems it necessary in the performance of the Services under this Agreement to disclose to the Consortium the "Protected Health Information" (as such term is used in the HIPAA Privacy Regulation) of a patient, then, in advance of any such disclosure, Advisor shall obtain a written authorization executed by such patient for the use and disclosure of such Protected Health Information in accordance with the HIPAA Privacy Regulation.]

## 6. TERM

- 6.1. This Agreement comes into force upon signature by the parties and continues effective until all parties' obligations pursuant to Section 1 and 2 hereof have been fulfilled [or specific date].
- 6.2. Notwithstanding Section 6, this Agreement may be terminated in full by the Project Leader and the Coordinator acting jointly and on behalf of all the Beneficiaries, at any time and with immediate effect
- 6.3. The terms set forth in Sections 3, 4, 6.2 and 7 shall survive any termination or expiration of this Agreement.

## 7. MISCELLANEOUS

- 7.1. Advisor shall not use any name, logos or trade names or product trademarks owned by a member of the Consortium, IHI or the Consortium as such in any public announcement, press release or other public document without prior written consent of the Consortium and/or the member of the Consortium that owns the name, logos or trade names or product trademarks.
- 7.2. Advisor shall be deemed for all purposes to be an independent contractor. Advisor shall not have the authority to enter into agreements or make any representations on behalf of or otherwise bind the Consortium.
- 7.3. This Agreement contains the entire agreement between the Advisor and the Consortium. Any amendments to this Agreement shall be made in writing. If any provision of this Agreement is or becomes invalid or unenforceable, this shall not affect the remaining provisions hereof. The parties shall in this case replace the invalid or unenforceable provision with a provision that is as close as possible to the economic effect of the invalid or unenforceable provision.
- 7.4. Each Beneficiary is intended to be a third party beneficiary with the ability to enforce the terms of the Agreement in its own name and as if it was a party to this Agreement.
- 7.5. This Agreement shall be construed, controlled and interpreted by the laws of Belgium, regardless of its conflict of laws provisions. Exclusive place of jurisdiction shall be Brussels.

The parties hereto have caused this Agreement to be executed in their own name and in case of the Mandate Holder(s) in addition in the name and on behalf of their respective Consortium Members as their duly authorized representative. [OPTION 1 – standard signature: This Agreement is executed in [insert number of necessary originals], each party acknowledging receipt one original copy.] [OPTION 2

– **e-signature:** The parties explicitly agree to execute this Agreement by way of an electronic signature **[by using DocuSign/Adobe Sign]** and agree this shall constitute a valid and enforceable agreement between the parties. The present Agreement is made in an electronic version which shall be electronically signed by each party. Each party hereby acknowledges receipt of the e-signed Agreement, electronically signed for approval by the parties.] **[name of authorized company or institution]**

**[Advisor]**

**(Mandate Holder(s))**

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

**Acknowledged and agreed**

**[Beneficiary responsible for reimbursement of costs]**

\_\_\_\_\_

Name:

Function:

Place: \_\_\_\_\_

Date: \_\_\_\_\_

Approval of Employer: **[Insert name of employer]**

We have read the foregoing Advisory Agreement between the Consortium and **[Insert name of advisor]** and approve the content and the conclusion of such Agreement:

Name:

Place/Date: \_\_\_\_\_

Signature/Seal: \_\_\_\_\_

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

#### EXHIBIT 1

**[list names and addresses of Consortium Beneficiaries]**

## Appendix 13: Form of Accession

### FORM OF ACCESSION

ACCESSION of a new Beneficiary to the **[insert Project Title]** Consortium Agreement, effective as of **[...]**

**[OFFICIAL NAME OF THE NEW BENEFICIARY AS IDENTIFIED IN THE GRANT AGREEMENT]**

hereby consents to become a Beneficiary to the Consortium Agreement identified above and accepts all the rights and obligations of a Beneficiary starting **[date]** subject to acceptance of the **[insert Project Title]** consortium and further subject to approval of IHI JU of such accession by **[OFFICIAL NAME OF THE NEW PARTY AS IDENTIFIED IN THE GRANT AGREEMENT]**.

**[OFFICIAL NAME OF THE NEW BENEFICIARY AS IDENTIFIED IN THE GRANT AGREEMENT]** intends to provide contribution to the **[insert Project Title]** project in the amount of EUR **[...]** by way of **[in-kind / cash-contribution]**. The **[insert Project Title]** consortium members and **[OFFICIAL NAME OF THE NEW PARTY AS IDENTIFIED IN THE GRANT AGREEMENT]** will align on the specifics of **[OFFICIAL NAME OF THE NEW PARTY AS IDENTIFIED IN THE GRANT AGREEMENT]** contribution to the **[insert Project title]** project and the necessary amendments to Annex 1 of the Grant Agreement for the **[insert Project title]** project.

**[OFFICIAL NAME OF THE NEW BENEFICIARY AS IDENTIFIED IN THE GRANT AGREEMENT]**, hereby consents to be bound as of the date of its accession to the Consortium Agreement to any confidential disclosure agreement and advisory agreement that have already been concluded under mandate by the Project Leader and the Coordinator pursuant to Clauses 11.1.2, 11.1.3 and/or 11.1.4 and materially based on the templates provided in the Consortium Agreement in Appendices Appendix 10, Appendix 11 and Appendix 12. Copies of such agreement will be provided to **[OFFICIAL NAME OF THE NEW BENEFICIARY AS IDENTIFIED IN THE GRANT AGREEMENT]** upon request (e-mail suffice) to the **[Project Management Office/Coordinator]**.

The Coordinator of **[insert Project Title]**

hereby certifies that the **[insert Project title]** consortium has accepted in the meeting held on **[date]** the accession of the **[OFFICIAL NAME OF THE NEW PARTY AS IDENTIFIED IN THE GRANT AGREEMENT]** to the consortium starting **[date]**.

This Accession document has been executed in two (2) originals to be duly signed by the undersigned authorised representatives. **[OPTION 1 – standard signature:** The parties hereto have caused this Accession document to be executed in **[insert number of necessary originals]**, each party acknowledging receipt one original copy.][ **OPTION 2 – e-signature:** The parties hereto explicitly agree to execute this Accession document by way of an electronic signature **[by using DocuSign/Adobe Sign]** and agree this shall constitute a valid and enforceable agreement between the parties. The present Accession document is made in an electronic version which shall be electronically signed by each party. Each party hereby acknowledges receipt of the e-signed Accession document, electronically signed for approval by the parties.]

**[Date and Place]**

**[INSERT NAME OF THE NEW BENEFICIARY]**

Signature(s) Name(s) Title(s)

Coordinator

Signature(s) Name(s) Title(s)

#### **Appendix 14: Data Management Plan**

Once this Deliverable is approved in accordance with Annex 1 of the Grant Agreement, it will be added automatically to this Consortium Agreement upon approval by the Beneficiaries.