

**CONSORTIUM AGREEMENT FOR**  
**[NAME OF IMI2 PROJECT]**

### Non negotiable Sections:

- ALL IP definitions
- Definitions Affiliated Entity, Associated Partner, Beneficiary, Beneficiary not receiving IMI2 JU funding, IMI2, IMI2JU
- Section 5.1.1 first four sentences
- Section 6.1.1. except options (choice to be done)
- 6.1.5. except for obligations regarding to additional information
- 6.1.6.
- 6.2.1. (note however that it is not in the legal instruments)
- 6.2.2.
- 6.2.3 (except delay in brackets)
- 7.1.1. (except options)
- 7.2.1.
- 7.2.2.
- 7.2.3. principle cannot be negotiated but different terms can
- 7.3.1
- 7.3.2.
- 7.3.3.
- 7.3.4. except delay in brackets
- 7.3.5.
- 7.4.1.
- 7.4.3
- 7.5.1.1.
- 7.5.2. principle of review is non-negotiable-process can be negotiated
- 7.5.3
- 7.5.4. except options
- 7.5.5.
- 7.6.
- 8.1.1.
- 8.1.5. Non-exclusive only
- 8.1.7. except delays in brackets
- 8.1.9
- 8.2.1.1.
- 8.2.1.2.
- 8.2.2.1.
- 8.2.2.2. except conditions in brackets
- 8.2.4.
- 8.3.1.1
- 8.3.1.2.
- 8.3.2.1. except conditions in brackets
- 8.3.2.2.
- 8.3.4.
- 8.4.

- 11.2.2.2: amendments are possible to the extent the end responsibility of the mandatory responsibilities listed in Article 41.2(b) of the Grant Agreement remains with the coordinator

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**THIS AGREEMENT DATED [\_\_\_] IS MADE BETWEEN:**

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

**WHEREAS:**

The Beneficiaries, having considerable experience in the field concerned, have submitted a proposal for the Action *[Insert name of project]* to IMI2 JU as part of the Innovative Medicines Initiative 2 Joint Undertaking programme, a public-private partnership between the European Union and the European pharmaceutical industry.

The IMI2 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, IMI2 JU operates under the general rules of participation of the H2020 programme, to which, however, a number of derogations apply due to the special character of the programme being a public-private partnership. In such respect, the terms “Research Use” and “Direct Exploitation” jointly constitute exploitation.<sup>1</sup>

Whereas, the IMI2 Model Grant Agreement (the “IMI2 Model Grant Agreement” or “IMI2 MGA”) (including its annexes and any amendments hereto and including the IMI2 Annotated Model Grant Agreement with guidance, explanations and and introduction) stipulates the undertaking of the IMI2 Action, this Consortium Agreement governs the Beneficiaries’ collaboration in relation to the Action.

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<sup>1</sup> Regulation (EU) No 1290/2013 laying down the rules for Participation and dissemination in “Horizon 2020”; and Commission Delegated Regulation (EU) No 622/2014 establishing a derogation from Regulation EU No 1290/2013 with regards to the Innovative Medicines Initiative 2 Joint Undertaking.



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

## **1. DEFINITIONS**

Any word(s) or expression(s) appearing in this Consortium Agreement shall have the meaning ascribed to them herein, unless such word(s) or expression(s) are defined in the Grant Agreement, in which case they shall be interpreted in accordance with the definition of such word(s) or expression(s) included within the Grant Agreement and any definition repeated in this Clause 1 has been so repeated for ease of reference only.

“**Access Rights**” means rights to use Results or Background under the terms and conditions laid down in 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 which are defined in Annex 1 of the Grant Agreement.

“**Action Share**” means the value of each Beneficiary’s total contribution (whether considered as eligible for IMI2 JU funding or not) to the Action as outlined in Annex 1 of the Grant Agreement;

“**Advisory Agreement**” shall have the meaning ascribed to it in Clause 11.5.1.4 of the Consortium Agreement.

“**Affiliated Entity**” means any legal entity that is under the direct or indirect control of a Beneficiary, or under the same direct or indirect control as the Beneficiary, or that is directly or indirectly controlling a Beneficiary. Control may, in particular, take either 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.

The following relationships between legal entities shall not in themselves be deemed to constitute controlling relationships:

- (i) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 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.

“**Agreement on Background**” means either any Annex of the Grant Agreement or Appendix 4 of the Consortium Agreement identifying Background.

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

“**Associated Partner**” means a legal entity supporting the IMI2 objectives in its specific areas of research as referred to in the Council Regulation (EU) No 557/2014 establishing the

IMI2 JU, and which has been accepted as such by the IMI2 Governing Board in accordance with articles 2 and 3 of the Statutes of the IMI2 JU.

**“Background”** means any data, know-how or information, whatever its form or nature, tangible or intangible, including any rights such as intellectual property rights that:

- a) are held by the Beneficiaries prior to their accession to the Grant Agreement,
- b) which are needed to implement the Action or to exploit the Results of the Action, and
- c) which are identified by the Beneficiaries in accordance with Clause 6.1.1 or 6.1.2 of the Consortium Agreement.

**“Beneficiary”** or **“Participant”** means a legal entity who has signed the Grant Agreement with the IMI2 JU or the Form of Accession. There can be two types of Beneficiaries in an IMI2 Action, i.e.:

- Beneficiaries receiving IMI2 JU funding; and
- Beneficiaries not receiving IMI2 JU funding, such as in particular those EFPIA Beneficiaries not eligible to IMI2 JU funding or not requesting it.

**“Beneficiary not receiving IMI2 JU funding”** shall include the following different types of entities:

- Legal entities not requesting funding or not eligible for funding (e.g. established in a third country not associated to Horizon 2020);
- Members of IMI2 JU other than the European Union (e.g. EFPIA) or their constituent entities or Affiliated Entities that participate in the said Member’s contribution to IMI2 through the costs they incur in implementing Actions;
- Associated Partners or their constituent entities or Affiliated Entities that participate in the said Associated Partner’s contribution to IMI2 through the costs they incur in implementing Actions.

**“CDA”** shall have the meaning ascribed to it in Clause 11.5.1.2 of the Consortium Agreement.

**“Chairperson of the General Assembly”** shall have the meaning ascribed to it in Clause 11.3.3.1 of the Consortium Agreement.

**“Chairperson of the Managing Board”** shall have the meaning ascribed to it in Clause 11.4.3.1 of the Consortium Agreement.

**“Chairperson of the Coordinating Team”** shall have the meaning ascribed to it in Clause 11.6.3.1 of the Consortium Agreement.

**“Communication”** means communications, other than Dissemination, concerning the Project.

**“Communication Guidelines”** mean the guidelines to be adhered to when making a Communication, as more particularly set out in Appendix 12.

**“Confidential Information”** means any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed.

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

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

“**Coordinator**” means the Beneficiary in charge of the grant administration, to whom are assigned the specific tasks identified in the introduction (IV.D) and Article 41.2(b) of the Grant Agreement, and as further defined in Clause 11.2 of the Consortium Agreement. For the avoidance of doubt, these responsibilities should not include the responsibilities of the Project Leader as further defined in this Consortium Agreement. The Coordinator is further defined in Clause 11.2 of the Consortium Agreement.

*[“**Coordinating Team**” shall be further defined in Clause 11.6 of the Consortium Agreement.]*

“**Co-Owners**” shall have the meaning ascribed to it in Clause 7.2.1 of the Consortium Agreement.

“**Days**” shall mean 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.

“**Deliverables**” means a distinct output of the Action meaningful in terms of the Action’s overall objectives and constituted by a report, a document, a technical diagram, a software etc.

“**Direct Exploitation**” means to develop Results for commercialization, including through clinical trials, or to commercialize Results themselves.

Examples of Direct Exploitation include:

- clinical trials performed on a compound or biomarker itself (to the extent such compound or biomarker can be qualified a Result) with a view to market that compound or biomarker;
- commercialization of a biomarker (to the extent such biomarker can be qualified a Result) as a diagnostic kit.

“**Disclosing Beneficiary**” shall have the meaning ascribed to it in Clause 10.1 of the Consortium Agreement.

“**Dissemination**” means any public disclosure by a Beneficiary of its Results by any appropriate means (other than public disclosure from seeking protection for and/or exploiting such Results), including but not limited to by means of scientific publication (in any medium), press release, on a website, or by presentation at a scientific conference.

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

“**EFPIA Beneficiary**” means a member of EFPIA itself, as defined by its statutes and internal rules, or an Affiliated Entity or constituent of EFPIA, and participating in the Action and regarded as Beneficiary in the Grant Agreement.

“**Eligible Costs**” means those costs incurred by each Beneficiary receiving IMI2 JU funding in carrying out its Work Package under the Action; the nature of such costs is more particularly detailed in Article 6 of the Grant Agreement.

“**Ethics Advisory Board**” shall be further defined in Clause 11.8 of the Consortium Agreement.

“**Excluded Beneficiary**” shall have the meaning set forth in Clause 13.2.3.

“**Fair and Reasonable Conditions**” means the appropriate conditions, including possible (a) Financial Terms, or (b) Royalty-Free Conditions, and 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 Research Use 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 Third Parties involved in the Action), and (d) proves to be inevitable in spite of exercising all due diligence. Notwithstanding the foregoing, Article 51 of the Grant Agreement and its annotations shall apply in any interpretation of whether specific circumstances shall constitute an event of Force Majeure. The following cannot be invoked as Force Majeure: (aa) any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of Force Majeure, (bb) labour disputes or strikes, or (cc) financial difficulties.

“**Form of Accession**” means the form of deed which all additional Beneficiaries to this Consortium Agreement must sign before becoming 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 11.3 of the Consortium Agreement.

“**Grant**” shall mean the IMI2 JU’s part of the financial contribution to the Action as determined by the Grant Agreement.

“**Grant Agreement**” means Grant Agreement No. [\_\_\_\_] (including its annexes and any amendments thereto) entered into between the Beneficiaries and the IMI2 JU for the undertaking by the Beneficiaries of the Action.

“**IMI2**” means the Innovative Medicines Initiative 2.

“**IMI2 JU**” means the IMI2 Joint Undertaking, a European Union body established by Council Regulation No. 557/2014 of 6 May 2014.

“**Indemnites**” shall have the meaning ascribed to it in Clause 12.1.2 of the Consortium Agreement.

“**Indemnitor**” shall have the meaning ascribed to it in Clause 12.1.2 of the Consortium Agreement.

“**Linked Third Parties**” shall mean any legal entity which has a legal link to a Beneficiary implying collaboration that is not limited to the Action as listed in Article 14.1 of Grant Agreement.

“**Loss**” or collectively “**Losses**” shall have the meaning ascribed to it in Clause 12.1.2 of the Consortium Agreement.

“**Managing Board**” shall be further defined in Clause 11.4 of the Consortium Agreement.

“**Mandate**” shall have the meaning ascribed to it in Clause 11.5 of the Consortium Agreement.

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

“**Mitigation Plan**” shall have the meaning set forth in Clause 13.2.2.

“**Project Leader**” means the Beneficiary, who is i.a. in charge of the overall scientific and Project leadership as further defined in Clause 11.1 of the Consortium Agreement.

“**Project Management Office**” or “**PMO**” shall support the Project Leader and the Coordinator in the day-to-day management of the Action.

*[“**Project Milestones**” means a scheduled event that marks a key event or series of events within an Action; it is often reached at the end of a stage to mark the completion of a major Deliverable, which marks the transition of the Action from one phase to another.]*

“**Providing Beneficiary**” shall have the meaning ascribed to it in Clause 9.1 of the Consortium Agreement.

“**Receiving Beneficiary**” shall have the meaning ascribed to it in Clause 10.1 of the Consortium Agreement.

“**Recipient Beneficiary**” shall have the meaning ascribed to it in Clause 9.1 of the Consortium Agreement.

“**Representative**” means the person chosen by a Beneficiary to represent it on one of the governing bodies of the Consortium as described in Clause 11 of the Consortium Agreement.

“**Research Use**” means the use of Results (or Background necessary to use Results), for all purposes other than for completing the Action or for Direct Exploitation, and which includes but is not limited to the application of Results as a tool for research, including clinical research and trials, and which directly or indirectly contributes to the objectives set out in the societal challenges health, demographic change and well-being referred to in Regulation (EU) No 1291/2013 (establishing Horizon 2020).

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

- 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)].*

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.

“**Results**” means any tangible or intangible output of the Action such as data, knowledge, know-how or information that is generated in the Action, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights<sup>2</sup> (such as copyright, design rights, patent rights, or similar forms of protection). Results shall not include any Sideground.

“**Retiring Beneficiary**” shall have the meaning set forth in Clause 13.2.2.

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

“**Scientific Advisory Board**” or “**SAB**” shall be further defined in Clause 11.7 of the Consortium Agreement.

“**Sideground**” means tangible or intangible output generated by a Beneficiary under the Action, such as data, knowledge and information, whatever its form or nature, whether or not it can be protected, but which is outside of the Action Objectives<sup>3</sup> as defined in the Grant Agreement and which therefore is not needed for implementing the Action or for Research Use of Results.

“**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.

“**Terminated Beneficiaries**” means the Beneficiary whose participation to the Action is terminated pursuant to Article 50.3.1 of the Grant Agreement.

“**Third Party**” shall mean a legal entity which is not a party to the Grant Agreement, including a legal entity only providing resources to a Beneficiary. Such Third Parties may benefit from rights entrusted to them by the Grant Agreement subject to the conditions laid down therein.

“**Third Party Claims**” shall have the meaning ascribed to it in Clause 12.1.2 of the Consortium Agreement.

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

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<sup>2</sup> “Intellectual property” being understood as set forth in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967;  
[http://www.wipo.int/wipolex/en/treaties/text.jsp?file\\_id=283833](http://www.wipo.int/wipolex/en/treaties/text.jsp?file_id=283833).

<sup>3</sup> Please ensure to review Action Objectives.

“**Work Package Leader(s)**” means the leader(s) of a Work Package.

## **2. PURPOSE**

- 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*, project management and governance structure, financial provisions, intellectual property rights, and access to Results and Background by the Beneficiaries and Third Parties and the liability and indemnification of the Beneficiaries amongst each other.
- 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.

## **3. FINANCIAL PROVISIONS**

- 3.1 The Action is funded by the Grant and the contribution (in kind and/or in cash) from the EFPIA companies not receiving IMI2 JU funding in the Action. The indicative budget of the Action is specified in [*Annexes 1 and 2 to the Grant Agreement*].
- 3.2 Each Beneficiary eligible to receive IMI2 JU funding shall maintain financial records in relation to its activities within the Action, including its Affiliated Entities, Linked Third Parties and Sub-contractors, according to the Grant Agreement.
- 3.3 The Coordinator shall give each Beneficiary eligible to receive IMI2 JU funding a minimum of forty-five (45) Days prior notice of the deadline to produce financial statements 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 in order to enable him to meet the sixty (60) Days timeline for submission to IMI2 JU.
- 3.4 Beneficiaries not receiving IMI2 JU funding should report their actual annual spending to IMI2 JU separately and in accordance with the IMI2 JU Council Regulation and the agreed “Guidelines for reporting in kind and financial contributions by EFPIA and members other than the Union and Associated Partners” approved by the IMI2 JU Governance Board. Certification of the contribution from Beneficiaries not receiving IMI2 JU funding is prescribed in this guideline.
- 3.5 The Beneficiaries eligible to receive IMI2 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 IMI2 JU funding, 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.
- 3.6 The Coordinator will receive directly the Grant from the IMI2 JU and undertakes to transfer,

in accordance with the Grant Agreement and the go/no go decisions outlined in Annex 1, the appropriate sums to the respective Beneficiaries eligible to receive IMI2 JU funding with minimum delay, but not later than thirty (30) Days from its receipt thereof from the IMI2 JU. The Coordinator will notify each of the Beneficiaries eligible to receive IMI2 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 IMI2 JU funding until such time such funds are transferred to the Beneficiaries eligible to receive IMI2 JU funding.

- 3.7 Bank account details of each Beneficiary eligible to receive IMI2 JU funding shall be provided to the Coordinator within thirty (30) Days of each such Beneficiary's signature of this Consortium Agreement.
- 3.8 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.
- 3.9 Without prejudice to the provisions of Clauses 4 and 12.1 and subject to the provisions of Clause 17 and the Grant Agreement, the Coordinator can withhold any payment if a Beneficiary eligible to receive IMI2 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 Managing Board and General Assembly will be informed of the decision.

#### **4. RIGHTS AND OBLIGATIONS OF THE PARTIES WITH RESPECT TO THE UNDERTAKING OF THE PROJECT**

- 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. For the avoidance of doubt, 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 or its Sub-Contractors, without such Affiliated Entities and/or Sub-Contractors becoming Beneficiaries. 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.
- 4.2 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.
- 4.3 Each Beneficiary will use reasonable endeavours to carry out its Allocated Work, however, 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.

- 4.4 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. The Beneficiaries shall require their Affiliated Entities, Sub-Contractors and Linked Third Parties to 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.
- 4.5 The Beneficiaries must process personal data under the Agreement in compliance with applicable EU and national laws on data protection (including, without being limited to, authorisation or notification requirements). Each Beneficiary represents and warrants that any personal data required for use in the Project that are obtained, handled or used by it 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 personal data and that any ethics committee approvals and Donor (as defined in Appendix 2) informed consents required for performing the Action will be obtained prior to the commencement of the respective part of the Allocated Work as described in detail in Appendix 2. The Beneficiaries may grant their personnel access only to such personal data if this is strictly necessary for implementing, performing, managing and monitoring the Grant Agreement and/or the Consortium Agreement.
- 4.6 Each Beneficiary represents and warrants that any human tissue or human biological material required for use in the Project that are obtained, handled or used by it 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 tissue or biological samples and that any ethics committee approvals and Donor (as defined in Appendix 2) informed consents required for performing the Action will be obtained prior to the commencement of the respective part of the Allocated Work, as described in detail in Appendix 2. The Beneficiaries may grant their personnel access only to such human tissue and human biological material if this is strictly necessary for implementing, performing, managing and monitoring the Consortium Agreement.
- 4.7 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;
- h) they pay each employee at least the minimum wage or a fair representation of the prevailing industry wage 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.

- 4.8 All work involving the use of animals in research will be performed in accordance with all applicable laws, regulations and ethical guidelines, as outlined in Appendix 3 and following consultation with the Ethics Advisory Board, if applicable.
- 4.9 In Actions involving clinical trials, the agreements governing such trials will form the subject of a separate agreement between the relevant Beneficiaries.

## **5. SUBCONTRACTING; LINKED THIRD PARTIES**

### **5.1 RULES FOR SUB-CONTRACTING OF PART OF THE ACTION**

- 5.1.1 If necessary to implement the Action, the Beneficiaries may award Sub-Contractors covering the implementation of certain Action tasks described in Annex 1 of the Grant Agreement. Sub-contracting may cover only a limited part of the Action. The Beneficiaries eligible to receive IMI2 JU funding must award the Sub-Contractors ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests. Further and to the extent applicable, they must ensure compliance with applicable Data Protection Legislation as defined in Appendix 2 and specified in its Clause 3.3. 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. For avoidance of doubt and in the case of Beneficiaries not receiving JU funding, the selection of Sub-Contractors and the reporting of the related costs borne by that Beneficiary is handled outside the IMI2 Model Grant Agreement.
- 5.1.2 The Beneficiary shall be liable for the acts and omissions of its Sub-Contractors as if those acts and omissions had been performed by such Beneficiary and, as such, shall remain responsible for the implementation of this Consortium Agreement and the Grant Agreement. Prior to the engagement of any Sub-Contractor, the sub-contracting Beneficiary shall ensure that each such Sub-Contractor shall be bound by the confidentiality obligations equivalent to those terms described under Clause 10.

## 5.2 **RULES FOR CALLING UPON LINKED THIRD PARTIES TO IMPLEMENT PART OF THE ACTION**

- 5.2.1 Linked Third Parties may implement the Action tasks attributed to them in Annex 1 of the Grant Agreement.
- 5.2.2 The Beneficiary shall be liable for the acts and omissions of its Linked Third Parties as if those acts and omissions have been performed by such Beneficiary and, as such, shall remain responsible for the implementation of this Consortium Agreement and the Grant Agreement. Prior to the engagement of any Linked Third Party, the Beneficiary which is linked with such Linked Third Party shall ensure that each such Linked Third Party shall be bound by the confidentiality obligations equivalent to those terms described under Clause 10.

## 6. **INTELLECTUAL PROPERTY – GENERAL PROVISIONS ON BACKGROUND**

### 6.1 **IDENTIFICATION OF THE BACKGROUND**

- 6.1.1 Beneficiaries shall identify and agree the Background in writing in :

*[OPTION 1:]* Annex 1 of the Grant Agreement, or

*[OPTION 2:]* Appendix 4 of the Consortium Agreement.

Such annex or appendix shall be deemed the “**Agreement on Background**” pursuant to Article 24 of the Grant Agreement.

- 6.1.2 After the signature of the Grant Agreement and during the Action, each Beneficiary may identify additional Background. The Beneficiary shall identify such additional Background in writing by filling in the form set out in Appendix 5 and sending it to the other Beneficiaries and *[Insert appropriate governance body]*. Filling in such appendix shall constitute an amendment to the Consortium Agreement.
- 6.1.3 The Background identified in accordance with Clauses 6.1.1 and 6.1.2 of this Consortium Agreement shall be subject to the Access Rights pursuant to Clauses 8.2.1 (Background for implementation) and 8.2.2. (Background for Research Use) of the Consortium Agreement. For the avoidance of a doubt, anything which is not identified pursuant to Clauses 6.1.1 and 6.1.2 shall not constitute Background and shall not be subject to said Access Rights.
- 6.1.4 A Beneficiary may contribute additional data, know-how or information that it lawfully acquires control of following the date it acceded to the Grant Agreement and which could be useful for another Beneficiary to carry out the Action. Such additional data, information, or know-how shall be identified by filling-in the form set out in Appendix 6 of this Consortium Agreement and returning such form to the other Beneficiaries and *[Insert appropriate governance body]*. Such data, information and know-how, if contributed and identified, shall be subject to the same Access Rights as those granted between the Beneficiaries (and their Affiliated Entities) for Background required for implementation and Research Use of the Results.
- 6.1.5 When identifying Background pursuant to Clauses 6.1.1 and 6.1.2 or additional data, information or know-how pursuant to Clause 6.1.4, the Beneficiary shall at the same time

identify any obligation to others pertaining to such Background or such additional data, information or know-how that he is aware of and that could prevent or restrict the enjoyment of Access Rights granted under the Consortium Agreement.

- 6.1.6 When identifying Background pursuant to Clauses 6.1.1 and 6.1.2<sup>4</sup>, each Beneficiary may identify specific elements of such Background and provide a reasoned request to IMI2 JU that such elements must be wholly or partially, excluded from the Access Rights to Third Parties pursuant to Clause 8.4. IMI2 JU shall only grant such request in exceptional circumstances in accordance with Article 25.4. of the Grant Agreement. The Beneficiary requesting such exclusion shall inform the other Beneficiaries of any exclusion granted by IMI2 JU.

## 6.2 OWNERSHIP AND TRANSFER OF BACKGROUND

- 6.2.1 Each Beneficiary shall remain the exclusive owner of its Background. Participation in the Action shall not affect such ownership rights in its Background, without prejudice to any rights and obligations under this Consortium Agreement and the Grant Agreement.
- 6.2.2 Each Beneficiary remains free to license, transfer or otherwise dispose of its ownership rights in Background, subject to any rights and obligations under the Grant Agreement and this Consortium Agreement. Where a Beneficiary transfers its ownership rights in Background, it must pass on its obligations specified under the Grant Agreement and the Consortium Agreement regarding the Background to the transferee, including the obligation to pass those obligations on to any subsequent transferee. If a Beneficiary grants licences on the Background it owns or lawfully holds, it must ensure that access rights granted to others as defined in the Grant Agreement and the Consortium Agreement can be preserved and that obligations to grant access rights to others can be fulfilled.
- 6.2.3 A Beneficiary may transfer its ownership rights in Background without the consent of the other Beneficiaries but provided that the other Beneficiaries are informed [*within sixty (60) Days*] from the date of transfer and that the transferee agrees in writing to be bound by the Grant Agreement and this Consortium Agreement.

## 7. INTELLECTUAL PROPERTY – GENERAL PROVISIONS ON RESULTS

### 7.1 OWNERSHIP OF RESULTS

- 7.1.1 Results are owned by the Beneficiary who generates them.

***[Option 1: Beneficiaries may agree here that ownership of certain Results, once said Results have been generated, shall be transferred from the initial owner to another Beneficiary. If so wished, the following wording is suggested:] Notwithstanding the above,***

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<sup>4</sup> Please note that exclusions in this section only apply to Background as defined in Clause 1 above and not to additional information etc. pursuant to Clause 6.1.4.

any **[Describe specific result type]** Results are solely owned by the Beneficiary who generated such Results solely under the Action. However, immediately following generation of the **[Describe specific result 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 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 Beneficiary as a result of a cash contribution from another Beneficiary, these Results would be transferred to that second Beneficiary:]****[Describe specific result type]** Results generated by Beneficiary X who has received a cash contribution from Beneficiary Y shall be (jointly or solely, as the case may be) owned by the Beneficiary X. However, immediately following generation of the **[Describe specific result type]** Results, Beneficiary X automatically and in full transfers to Beneficiary Y any of its ownership rights, title and interest in the respective **[Describe specific result type]** Results. The cash contribution provided by Beneficiary Y to Beneficiary X shall be the unique and full compensation for the transfer of such Results **[Describe specific result type]**.

## 7.2 JOINT OWNERSHIP

7.2.1 Two or more Beneficiaries shall own Results jointly (“**Co-Owners**”) if:

- a) they have jointly generated the Results, and
- b) it is not possible to:
  - (i) establish the respective contribution of each Beneficiary, or
  - (ii) separate their contribution for the purpose of applying for, obtaining or maintaining their protection in accordance with Article 27 of the Grant Agreement.

7.2.2 Co-Owners shall conclude in writing a joint ownership agreement defining their respective rights and obligations with respect to the Results.

7.2.3 Unless otherwise agreed in the joint ownership agreement pursuant to Clause 7.2.2, in the case of joint ownership of Results, each Co-Owner is granted a non-exclusive, world-wide, fully paid up, royalty-free, perpetual, irrevocable licence to use the jointly owned Results for Research Use, including the right to grant non-exclusive sub-licences to its Affiliated Entities and to Third Parties without the need to inform the other Co-Owners. Each Co-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 licences subject to the following conditions **[Different terms can be determined here]:**

- [(a) prior notice of at least forty-five (45) Days must be given to any other Co-Owner(s); and,*
- (b) fair and reasonable compensation must be provided to the other Co-Owners, to be decided on a case-by-case basis.]*

7.2.4 **[Option 1:] [For certain Results which have been jointly generated, co-owning Beneficiaries may agree here that ownership of their share in the Results, once said Results have been generated, shall be transferred in full to a specific Beneficiary. If so**

**wished, the following wording is suggested:]**

*[Immediately following generation of the jointly-owned **[Describe specific result type]** Results, each such co-owning Beneficiary automatically and in full transfers to the **[Short name of specific beneficiary]** any of its ownership rights, title and interest in the respective **[Describe specific result type]** Results. In consideration of this assignment of ownership upon creation, the following conditions as outlined below apply: **[to be specified]**.*

*In the event that clause 7.2.4 is invalid or cannot be enforced fully or in part due to any applicable mandatory rules, or in the event it would be considered that clause 7.2.4 does not cover all situations in relation with the generation of **[Describe specific result type]** Results (for instance in the case it would be considered that clause 7.2.4 would not sufficiently cover a situation of jointly-owned Results or other) each such co-owning Beneficiary shall immediately following generation of the **[Describe specific result type]** Results grant to the **[Short name of specific Beneficiary]** a worldwide, exclusive, fully paid-up, royalty-free, perpetual, irrevocable licence to use the **[Describe specific result type]** Results for Direct Exploitation, including the right to grant sub-licenses to its Affiliated Entities and to Third Parties without the need to inform said co-owning Beneficiary or the other Beneficiaries. Grant of such licence shall become effective upon the signature of the present Agreement.*

***[Option 2: applies only in case agreement is not reached on option 1 or pre-agreement of transfer of such Results is not possible] : Consider grant of an exclusive license for Direct Exploitation to a specific Beneficiary.]***

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

- 7.3.1 Each Beneficiary remains free to transfer its ownership rights in Results.
- 7.3.2 Where a Beneficiary transfers ownership of Results, it must pass on its obligations specified under the Grant Agreement and the Consortium Agreement to the transferee.
- 7.3.3 Unless agreed otherwise (in writing) for specifically-identified Third Parties or unless impossible under applicable EU and national laws on mergers and acquisitions, 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.

Unless agreed otherwise (in writing), 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.

- 7.3.4 Notwithstanding the above, a Beneficiary may, without the consent of the other Beneficiaries but provided that the other Beneficiaries are informed *[within sixty (60) Days]* from the date of transfer and that the transferee agrees in writing to be bound by the Grant Agreement and the Consortium Agreement, transfer its Results to any of the following:
- a) its Affiliated Entity,
  - 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.

7.3.5 Provided that any Access Right to the Results can be exercised (requested and granted) and that any additional obligations under the Grant Agreement or the Consortium Agreement are complied with by the Beneficiary who owns Results, each Beneficiary may license its own Results to any legal entity as it deems fit.

## 7.4 **PROTECTION OF RESULTS**

### 7.4.1 **General Commitment to protect Results**

In accordance with Article 27 of the Grant Agreement, each Beneficiary agrees to examine the possibility of protecting its Results, and, where appropriate, adequately protect them by any means for an appropriate period and within appropriate territorial coverage if:

- a) the Results can reasonably be expected to be commercially or industrially exploited, and,
- b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection of such Results, the Beneficiary must consider its own legitimate interests, in particular the commercial interests, and the legitimate interests, in particular the commercial interests, of the other Beneficiaries. Means of protection may therefore include, but are not limited to, patenting or maintaining the Results as confidential know-how.

### 7.4.2 **Patents - Inventorship, assignment and inventor remuneration**

7.4.2.1 Each Beneficiary shall enter or have entered into appropriate (employment) agreements with its employees, agents and personnel, and have directed its Affiliated Entities, Linked Third Parties 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, unless this is already provided for automatically under applicable law.

7.4.2.2 If a Third Party generates Results, the Beneficiary concerned must obtain all necessary rights (transfer, licenses and other) from the Third Party, in order to be able to respect its obligations as if those Results were generated by the Beneficiary itself. If obtaining the rights is impossible, the Beneficiary must refrain from using the Third Party to generate the Results.

7.4.2.3 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 the patent laws and practices of the (i) United States of America and (ii), where applicable, according to the requirements of local laws.

7.4.2.4 In the event that the Beneficiary pursuant to Clause 7.4.2.1 is not the Beneficiary who will be preparing, applying for and prosecuting patent applications (the “**Filing Beneficiary**”) covering the invention pursuant to Clause 7.4.2.2 and that one of its employees, agents, subcontractors is designated as an inventor pursuant to Clause 7.4.2.2, such Beneficiary shall, subject to any local applicable laws and at the Filing Beneficiary's request:

- a) cause its own and its subcontractors' employees and agents to execute and deliver to the Filing Beneficiary all such documents and do all such things as may be reasonably required by the Filing Beneficiary to confirm the vesting of any and all the rights into the invention to the Filing Beneficiary;
- b) cause its own and its subcontractors' employees and agents to assist the Filing 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 Filing Beneficiary's costs.

7.4.2.5 Each Beneficiary shall claim any patentable Result from their own inventors according to the legal requirements of inventorship and inventor remuneration. Each Beneficiary shall be solely responsible for any potential compensation due to any of its own employees, agents, Linked Third Parties or Sub-Contractors in relation to the Action, including without limitation any potential remuneration due by operation of law to any employee, Affiliated Entity and Affiliated Entity's employees, its Sub-Contractors, or Sub-Contractor employees and Linked Third Parties and Linked Third Parties' employees, on account of commercialization or any other activity by the employing Beneficiary of any invention made or intellectual property rights created by such first Beneficiary's employee, in relation to the activities carried out or inventions made under this Consortium Agreement.

#### 7.4.3 **Mandatory Messaging in connection with Results**

Unless the IMI2 JU requests or agrees otherwise or unless it is impossible, applications for protection of Results filed on or behalf of a Beneficiary must include the following:

*"The project leading to this application has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under Grant Agreement n° [number]. This Joint Undertaking receives the support from the European Union's Horizon 2020 research and innovation programme and EFPIA."*

### 7.5 **DISSEMINATION OF RESULTS**

#### 7.5.1 **General commitment on Dissemination**

7.5.1.1 Each Beneficiary shall Disseminate its Results as soon as possible, unless such Dissemination goes against its 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).

7.5.1.2 A Beneficiary may not Disseminate Results generated by another Beneficiary or any Background or Confidential Information of such other Beneficiary, even if such Results, Background or Confidential Information are amalgamated with such Beneficiary's Results, without the other Beneficiary's prior written approval.

#### 7.5.2 **Review and Approval Process**

*[Consider whether the review and approval process is appropriate for Dissemination of all types of Results such as, for instance, clinical study reports.]*



- 7.5.2.1 A Beneficiary may only Disseminate any 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.
- 7.5.2.2 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 the Results would be significantly harmed, such as for the reasons as detailed here below:
- a) where protection of the objecting Beneficiaries' own Results or Background 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 are 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 of at least 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 or Background; and/or otherwise modify the publication as requested for scientific or patent 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.

[Please consider using the Programme Management Office for the Dissemination process.]

- 7.5.2.3 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 above, 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 or any Confidential Information of any other Beneficiary.
- 7.5.2.4 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.
- 7.5.2.5 Details of any publication and an electronic copy of the published version must be provided to the IMI2 JU within two (2) months following publication.
- 7.5.2.6 [Consider whether a clause acknowledging the right to submit a thesis incorporating project results, subject to review by the consortium and appropriate treatment of confidential Information and IP should be included:]

[Notwithstanding the provisions of this Clause, nothing in this Agreement shall prevent a

student from submitting for a degree of the university a thesis based on the Results obtained during the course of work undertaken as part of the Project, the examination of such a thesis by examiners appointed by the university, or the deposit of such a thesis in a library of the university in accordance with the relevant procedures of the university. The **[Insert responsible body]** will be informed on an on-going basis regarding the proposed contents of any thesis to be submitted to the university and the final draft shall be submitted to the **[Insert responsible body]** for review prior to submission to the university. Beneficiaries may comment on the contents of the thesis within sixty (60) Days of receipt of the thesis in accordance with Clause 7.5.2. All appropriate measures 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 Beneficiaries, which shall, where appropriate, require examiners external to the university to sign an agreement of non-disclosure prior to receipt of the thesis.]

### 7.5.3 **Open access to scientific publications**

Where Dissemination concerns a peer-reviewed scientific publication, each publishing Beneficiary shall comply with Article 29.2 of the Grant Agreement.

### 7.5.4 **[Open access to research data for projects from the Research Data Pilot]**

*[This section should be removed if Article 29.3 Grant Agreement is selected inapplicable.]*

Parties confirm this Action is part of the Research Data Pilot, as provided for in Article 29.3 of the Grant Agreement.

*[Optional clauses:]*

*[Option 1:] [Open access to research data is agreed to be granted according to the provisions of Article 29.3 of the Grant Agreement.]*

*[Option 2:] [As an exception to Article 29.3 of the Grant Agreement, as provided for in its last paragraph, certain parties have indicated that their main objective in the Action would be jeopardized by making all or specific parts of the research data of the Action openly accessible. Parties have therefore agreed to a data management plan, which describes how data will be handled instead of open access, and which plan details the reasons for not giving open access. Such data management plan is added as Appendix X to this Consortium Agreement.]*

### 7.5.5 **Mandatory Messaging in connection with Dissemination**

Unless the IMI2 JU requests or agrees otherwise or unless it is impossible, any type of Dissemination that shall arise from the Action shall include the logos, emblems, and text provided for in Article 29.4 of the Grant Agreement.

## 7.6 **COMMUNICATIONS**

- 7.6.1 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 12.

## **8. INTELLECTUAL PROPERTY –ACCESS RIGHTS**

### **8.1 GENERAL PROVISIONS ON ACCESS RIGHTS**

8.1.1 Unless otherwise specified in this Consortium Agreement, in order for a Beneficiary to exercise its Access Rights, these must first be requested in writing.

8.1.2 Access Rights under Clauses 8.2.1 (Background for implementation) and 8.3.1. (Results for implementation) are hereby requested in writing by the Beneficiaries by means of signature of the Consortium Agreement. Such Access Rights are hereby granted by the respective Beneficiary by means of signature of the Consortium Agreement.

8.1.3 During the Action and after completion of the Action, Access Rights for Research Use pursuant to Clauses 8.2.2 (Background for Research Use) and 8.3.2. (Results for Research Use) and which are provided under (i) Royalty Free Conditions, or (ii) pre-agreed Fair and Reasonable Conditions (Clauses 8.2.2.2 and 8.3.2.2), are hereby requested in writing by the Beneficiaries by way of signature of the Consortium Agreement. Such Access Rights (which are provided under Royalty Free Conditions), are hereby granted by the respective Beneficiary, by means of signature of the Consortium Agreement.

8.1.4 Unless Fair and Reasonable Conditions, other than Royalty Free Conditions, have been pre-agreed as set forth in accordance with Clauses 8.2.2.2 and 8.3.2.2 of this Consortium Agreement, during the Action and after completion of the Action, each Beneficiary shall request in writing Access Rights for Research Use which are provided under Fair and Reasonable Conditions other than Royalty Free Conditions. Such Access Rights shall become effective upon written agreement defining the Fair and Reasonable Conditions applicable.

8.1.5 All Access Rights pursuant to the Consortium Agreement shall be granted on a non-exclusive basis and are worldwide, perpetual and irrevocable.

8.1.6 Unless otherwise specified herein, Access Rights granted pursuant to the Consortium Agreement shall not include the right to sub-license such Access Rights. However, a Beneficiary who enjoys Access Rights pursuant to Clauses 8.2.1. (Background for implementation), 8.2.2. (Background for Research Use), 8.3.1. (Results for implementation) and 8.3.2. (Results for Research Use) may authorize another legal entity, for instance an Affiliated Entity, to exercise those 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.

In case of the granting of Access Rights for Project implementation Clause 5.1 shall apply.

8.1.7 Request for Access Rights in accordance with Clause 8.1.4 and request for Access Rights made by Third Parties after the Action pursuant to Clause 8.4 can be made until *[5][10][15][20]* years after completion of the Action. ***[If different time limits apply for different categories of Access Rights, please specify it here]***

- 8.1.8 During the Action, request for Access Rights made in accordance with Clause 8.1.4. shall be sent to ***[Choose appropriate governance body]***.
- 8.1.9 Unless otherwise specified herein, each Beneficiary remains the exclusive owner of its Sideground. Beneficiaries are not required to grant any Access Rights to Sideground.
- 8.1.10 ***[Option:]****[The Research Use Access Right includes that any Beneficiary, or its Affiliated Entities, 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 Affiliated Entities, 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 notice 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 for [a reasonable period of time] necessary to obtain such a protection.]*

## 8.2 ACCESS RIGHTS TO BACKGROUND

### 8.2.1 Background - Access Rights to Beneficiaries for implementation

- 8.2.1.1 During the Action, the Beneficiaries enjoy, unless prevented or restricted from doing so by obligations to others identified pursuant to Clauses 6.1.1 and 6.1.2, Access Rights to the Background of the other Beneficiaries, solely for the purpose and to the extent necessary for undertaking and completing the Action.
- 8.2.1.2 Such Access Rights are granted under Royalty-Free Conditions.
- 8.2.1.3 In accordance with Clause 8.1.2 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 8.1.1 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.
- 8.2.1.4 Beneficiaries hereby authorize their Affiliated Entities to exercise on their behalf the Access Rights requested and granted in accordance with Clause 8.2.1.1, subject to the conditions set forth in Clause 8.1.6 of the Consortium Agreement.

### 8.2.2 Background - Access Rights for purpose of Research Use of Results

- 8.2.2.1 Subject to the provisions of this Consortium Agreement, in particular Clauses 6.1, 8.1 and 10, during and after completion of the Action, Beneficiaries and their Affiliated Entities enjoy Access Rights to the Background of the other Beneficiaries, only to the extent reasonably required for the purpose of the Research Use of Results.
- 8.2.2.2 Such Access Rights for the purposes of Research Use are granted under Clause 8.2.2.1 on the following Fair and Reasonable Conditions: ***[Please indicate the option chosen and, if***

*applicable, work out an appropriate arrangement for Option 2. Conditions for Option 2 can also be outlined in the appropriate Annex pursuant to Clause 6.1 of the Consortium Agreement, on a Beneficiary per Beneficiary basis.]*

**[Option 1:]** [on Royalty-Free Conditions]

**[Option 2:]** [on Fair and Reasonable Conditions other than Royalty Free Conditions] **[Detail applicable terms which may include Financial Terms.]**

8.2.2.3 In accordance with Clause 8.1.3 of the Consortium Agreement, the Beneficiaries agree that the signature of the Consortium Agreement shall constitute in itself a valid request of Access Rights pursuant to Clause 8.2.2.1 for those Beneficiaries to enjoy these Access Rights to Background for Research Use of 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 8.2.2.1, for which conditions pursuant to Clause 8.2.2.2 have been pre-agreed and are set out therein.

### 8.2.3 **Background - Access Rights to Affiliated Entities for Research Use**

8.2.3.1 Beneficiaries hereby authorize their Affiliated Entities to exercise on their behalf the Access Rights requested and granted under Royalty-Free Conditions pursuant to Clause 8.2.2.1 of the Consortium Agreement, subject to the conditions set forth in Clause 8.1.6.

8.2.3.2 [Choose preferred option only if no royalty-free conditions are granted:]

***[Option 1:]** [Beneficiaries hereby authorize their Affiliated Entities to exercise on their behalf the Access Rights requested and granted under Fair and Reasonable Conditions, other than Royalty-Free, pursuant to Clauses 8.2.2.1 of the Consortium Agreement.]*

***[Option 2:]** [During the Action and after completion of the Action, Affiliated Entities of a Beneficiary shall request in writing Access Rights for Research Use pursuant to Clause 8.2.2.1 and which are granted under Fair and Reasonable Conditions other than Royalty Free Conditions. Grant of such Access Rights shall become effective upon written agreement between the Affiliated Entities of a Beneficiary and the granting Beneficiary of the Fair and Reasonable Conditions applicable.]*

### 8.2.4 **Background - Access Rights for Direct Exploitation**

8.2.4.1 Beneficiaries are not required to grant Access Rights for Direct Exploitation to their Background and may use, exploit, sublicense or otherwise commercialize their Background as they see fit, subject to the Access Rights granted for implementation as set forth in Clause 8.2.1.1 and for Research Use as set forth in Clauses 8.2.2.1 and 8.4.2.

8.2.4.2 In the event that Direct Exploitation of Results by a Beneficiary requires Background of another Beneficiary necessary to use such Results the Access Rights to such Background may be negotiated between the Beneficiary owning such Background and the Beneficiaries involved.

## 8.3 **ACCESS RIGHTS TO RESULTS**

### 8.3.1 **Results - Access Rights to Beneficiaries for implementation**

- 8.3.1.1 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.
- 8.3.1.2 Such Access Rights are granted under Royalty-Free Conditions.
- 8.3.1.3 In accordance with Clause 8.1.2 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 8.3.1.1 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.
- 8.3.1.4 Beneficiaries hereby authorize their Affiliated Entities to exercise on their behalf the Access Rights requested and granted in accordance with Clause 8.3.1.1, subject to the conditions set forth in Clause 8.1.6 of the Consortium Agreement.

### 8.3.2 **Results - Access Rights for Research Use**

- 8.3.2.1 Subject to the provisions of this Consortium Agreement, in particular Clauses 7, 8.1 and 10, during and after completion of the Action, Beneficiaries and their Affiliated Entities enjoy Access Rights to the Results for Research Use.
- 8.3.2.2 Such Access Rights to Results for the purposes of Research Use are granted on the following Fair and Reasonable Conditions: *[Please indicate the option chosen and, if applicable, work out an appropriate arrangement for Option 2.] [\_\_\_]*

**[Option 1:]** [on Royalty-Free Conditions]

[Option 2:] [on Fair and Reasonable Conditions other than Royalty Free Conditions] [Detail applicable terms which may include Financial Terms. Conditions for Option 2]

- 8.3.2.3 In accordance with Clause 8.1.3. of this Consortium Agreement, the Beneficiaries agree that the signature of the Consortium Agreement by the Beneficiaries shall constitute in itself a valid written request of Access Rights pursuant to Clause 8.3.2.1 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 under Clause 8.3.2.1 for which conditions pursuant to Clause 8.3.2.2 have been pre-agreed and are set out therein.

### 8.3.3 **Results - Access Rights to Affiliated Entities for Research Use**

- 8.3.3.1 Beneficiaries hereby authorize their Affiliated Entities to exercise on their behalf the Access Rights to Results for Research Use requested and granted under Royalty-Free Conditions pursuant to Clause 8.3.2.1 of the Consortium Agreement, subject to the conditions set out in Clause 8.1.6.
- 8.3.3.2 [Choose preferred option:]

**[Option 1:]** *[Beneficiaries hereby authorize their Affiliated Entities to exercise on their behalf the Access Rights requested and granted under Fair and Reasonable Conditions, other than Royalty-Free, pursuant to Clause 8.3.2.1 of the Consortium Agreement.]*

**[Option 2:]** *[During the Action and after completion of the Action, Affiliated Entities of a Beneficiary shall request in writing Access Rights for Research Use pursuant to Clause 8.3.2.1 and which are granted under Fair and Reasonable Conditions other than Royalty Free Conditions. Grant of such Access Rights shall become effective upon written agreement between the Affiliated Entities of a Beneficiary and the granting Beneficiary of the Fair and Reasonable Conditions applicable.]*

#### 8.3.4 **Results - Access Rights for Direct Exploitation**

8.3.4.1 Beneficiaries are not required to grant Access Rights for Direct Exploitation to their Results.

8.3.4.2 Where Direct Exploitation of Results owned by a Beneficiary requires Results owned by another Beneficiary, the Access Rights to the Results owned by the other Beneficiary may be negotiated between the Beneficiary owning such Results and the Beneficiary wishing to perform Direct Exploitation.

#### 8.4 **ACCESS RIGHTS TO THIRD PARTIES FOR RESEARCH USE**

8.4.1 After completion of the Action, Third Parties have the right to request Access Rights to the Results for Research Use. Such conditions may not be more favourable than the conditions applied between Beneficiaries (and their Affiliated Entities) for Research Use, pursuant to Clause 8.3.2 of the Consortium Agreement.

8.4.2 After completion of the Action and unless prevented or restricted from doing so by obligations to others which have been identified under Clause 6.1.5 or excluded under Clause 6.1.6, Third Parties have the right to request Access Rights to the Background of the Beneficiaries only to the extent reasonably required for the purpose of the Research Use of Results.

8.4.3 Requests for Access Rights pursuant to Clauses 8.4.1 and 8.4.2 shall be submitted as a written request directly to the Beneficiary owning the Results or the Background concerned.

8.4.4 Such Access Rights will be granted subject to a separate written bilateral agreement between the Third Party and the Beneficiary owning the Results or Background, defining the appropriate conditions agreed between the Beneficiary and the Third Party, including but not limited to ensuring that Access Rights will be used only for the intended purpose and that appropriate confidentiality obligations are in place.

#### 8.5 **ACCESS RIGHTS FOR NEW AND DEPARTING BENEFICIARIES**

8.5.1 Beneficiaries joining during the Action in accordance with the provisions of Clause 16 will be granted the Access Rights as provided for in Clauses 8.1 to 8.3 hereof as from the date of their signature of the Form of Accession as described in Appendix 11 of this Consortium Agreement.

8.5.2 For Beneficiaries leaving the Action in accordance with the provisions of Clause 13.2 hereof

the following provisions will apply:

- 8.5.2.1 With the exception of the cases where the participation of a Beneficiary is terminated by reason of default, 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.
- 8.5.2.2 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 departing Beneficiary pursuant to this Consortium Agreement shall cease immediately upon termination of the participation of the defaulting Beneficiary as a Beneficiary to this Consortium Agreement, or the Grant Agreement, if earlier.

## **9. MATERIAL TRANSFER OBLIGATIONS**

### **9.1 MATERIAL TRANSFER FOR THE PERFORMANCE OF THE ACTION**

- 9.1.1 If any Materials are transferred for the performance of the Action from one Beneficiary (including through its Affiliated Entities, Linked Third Parties, Associated Partners and/or Sub-Contractors) (“**Providing Beneficiary**”) to another Beneficiary (“**Recipient Beneficiary**”), or to its Affiliated Entities, Linked Third Parties, Associated Partners and/or Sub-Contractors, each Recipient Beneficiary shall be bound by the following provisions and shall be responsible for ensuring that its Affiliated Entities, Linked Third Parties, Associated Partners and/or Sub-Contractors comply with such provisions:
  - 9.1.2 The Recipient Beneficiary needs to have all the required authorisations under all applicable laws and regulations to perform the Allocated Work using the Materials.
  - 9.1.3 The Materials shall be used in full compliance with all applicable laws and regulations.
  - 9.1.4 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.
  - 9.1.5 The Materials shall not be analysed or modified except as necessary for the purpose of the Action.
  - 9.1.6 The Materials shall not be transferred or made available to any individual other than those under the supervision and control of the Recipient Beneficiary, its Affiliated Entities, Linked Third Parties, Associated Partners and/or Sub-Contractors. Upon completion of the Action, or the expiry or termination of this Consortium Agreement, any unused Materials will be either returned to the Providing Beneficiary, which made them available, or disposed of/destroyed in accordance with all applicable laws and regulations and provide Providing Beneficiary with a written confirmation of such disposal or destruction.
  - 9.1.7 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.

- 9.1.8 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.
- 9.1.9 In case that a Beneficiary requires more stringent clauses in order to protect his Materials to be transferred under the Action, the relevant parties may agree to enter into a separate material transfer agreement.

## 9.2 **MATERIAL TRANSFER FOR RESEARCH USE**

If any Materials are transferred for Research Use from the Providing Beneficiary to a Recipient Beneficiary, or to its Affiliated Entities, Linked Third Parties, Associated Partners and/or Sub-Contractors, on request of the Providing Beneficiary, a material transfer agreement may be established between the Providing 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.

## 10. **CONFIDENTIALITY**

- 10.1 During implementation of the Action and for [*seven (7) years*] after the completion of the Action, unless another term is agreed upon, 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 and 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 this is confirmed in writing within thirty (30) Days of the oral disclosure.
- 10.2 Unless otherwise agreed between the Parties, they may use Confidential Information only to implement this Consortium Agreement and the Action. 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.
- 10.3 The Beneficiaries may disclose Confidential Information to their personnel, other individuals under the supervision and control of the Receiving Beneficiary, Affiliated Entities, Linked Third Parties, Associated Partners and/or Sub-Contractors involved in the Action only if they: (i) need to know the Confidential Information to implement this Consortium Agreement or the Action, and (ii) are bound by obligations of confidentiality at least equivalent to those set forth herein. Any disclosure of Confidential Information by the Receiving Beneficiary to other Third Parties requires the prior written consent of the Disclosing Beneficiary. The Receiving Beneficiary must use all reasonable endeavours to

ensure that persons and/or entities receiving Confidential Information from it do not disclose such Confidential Information. The Receiving Beneficiary shall be responsible to the Disclosing Beneficiary for any disclosure by any such personnel, Affiliated Entities, Linked Third Parties, Associated Partners, Sub-Contractors and Third Parties, which violates the terms of this Consortium Agreement.

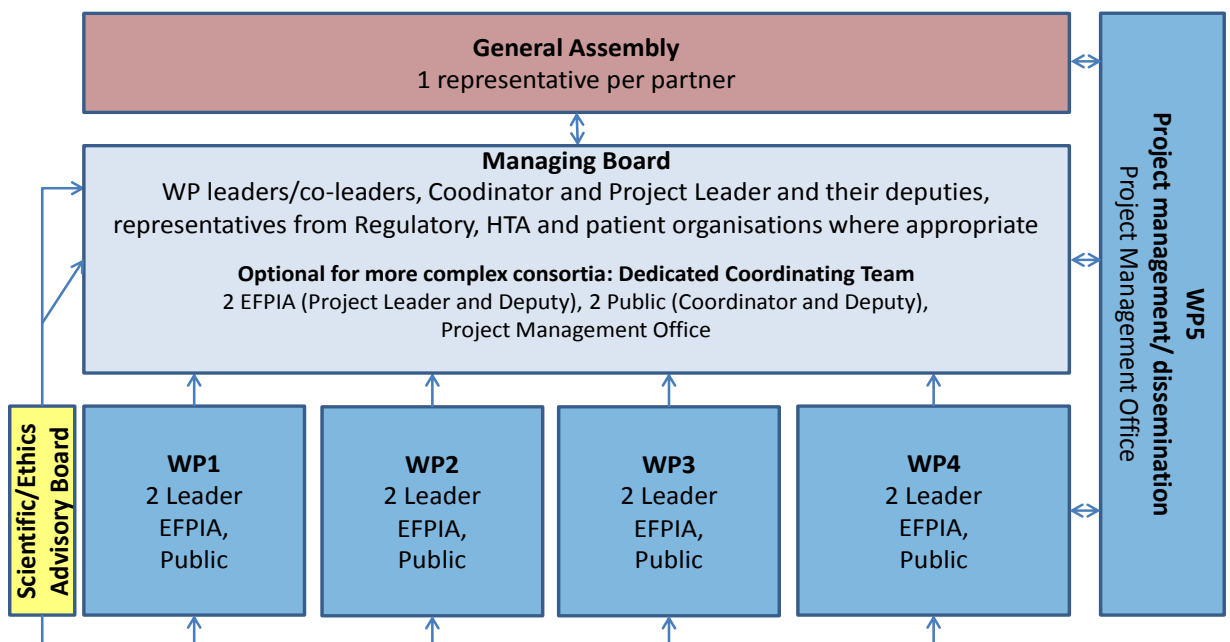
- 10.4 The confidentiality obligations under this Clause 10 do not apply if:
- 10.4.1 the Disclosing Beneficiary agrees in writing that it no longer considers the Confidential Information as protected by the terms of this Clause 10;
  - 10.4.2 the Confidential Information was already known by the Receiving Beneficiary or any of its Affiliated Entities, Linked Third Parties, 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;
  - 10.4.3 the Receiving Beneficiary proves that the information was developed independently by the Receiving Beneficiary or its Affiliated Entity, Linked Third Parties, Associated Partners and/or Sub-Contractors without the use of Confidential Information;
  - 10.4.4 at the time of disclosure, the Confidential Information is or after such disclosure becomes generally and publicly available, without breaching any confidentiality obligation by the Receiving Beneficiary.
- 10.5 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 supervisory 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 with a view to agreeing the timing and the content of such disclosure.
- 10.6 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, Affiliated Entities, Linked Third Parties, Associated Partners and/or Sub-Contractors involved in the Action who have received such Confidential Information from the Receiving Beneficiary pursuant to this Clause, 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 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.

**11. 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.]*

**Governance of the consortium (Example)**



**11.1 PROJECT LEADER**

### 11.1.1 **Appointment**

*[EFPIA Beneficiary X]* is appointed as Project Leader.<sup>5</sup> The Project Leader shall act through a designated Representative.

### 11.1.2 **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 Action Deliverables and reports before submission by the Coordinator to the IMI2 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 the Consortium Agreement;
- d) advising the Coordinator on the allocation and distribution of the IMI2 JU financial contribution among Beneficiaries eligible to receive IMI2 JU funding, in accordance with the IMI2 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 and its 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 11.5.

11.1.3 Except as stated in Clause 11.5 below, 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.

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

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<sup>5</sup> In line with the Annotated Model Grant Agreement, the Project Leadership role would typically be appointed to an EFPIA Beneficiary.

11.1.5 Other than where expressly provided in this Consortium Agreement, any information, 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 IMI2 JU, shall first be approved by the Project Leader who will send such approved information, report or other correspondence to the Coordinator.

## 11.2 COORDINATOR

### 11.2.1 Appointment

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

### 11.2.2 Responsibilities

*[Copy and paste what is in Grant Agreement]*

11.2.2.1 The Coordinator is and shall be a central point of contact between the Beneficiaries and the IMI2 JU in particular regarding the management of the Grant.

11.2.2.2 The Coordinator will perform certain duties as part of the general management of the Action, as provided for in the Grant Agreement. The Coordinator shall act in close collaboration with the Project Leader. In particular, the Coordinator shall be responsible for: *[To be readjusted]*

- a) coordinating and managing of the Grant;
- b) central point of contact for IMI2 JU for its administration, meaning that the Coordinator shall be responsible for
  - receiving all payments made by the IMI2 JU;
  - distributing the IMI2 JU funding to Beneficiaries eligible to receive IMI2 JU funding;
  - ensuring that all the appropriate payments are made to the Beneficiaries eligible to receive IMI2 JU funding without unjustified delay;
  - keeping accurate accounts of the amounts of, and distribution of, IMI2 JU funding to Beneficiaries eligible to receive IMI2 JU funding;
  - informing the IMI2 JU of the distribution of IMI2 JU funding, the amounts and the dates of such transfer to Beneficiaries eligible to receive IMI2 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 IMI2 JU, in particular, when relating to the administration and management of the Grant;
- e) request and review together with the Project Leader, any documents or information required by IMI2 JU and verifying their completeness and correctness before submission to IMI2 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;
- i) submitting reports on the Deliverables and other requested reports to the IMI2 JU following prior review by the Project Leader.

11.2.3 Except as stated in Clause 11.5 below, 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.

11.2.4 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 IMI2 JU without the contribution of the defaulting Beneficiaries and report the delay of these Beneficiaries to the IMI2 JU after approval by the Project Leader.

11.2.5 The Coordinator shall forward any information, report or other correspondence referred to in Clause 11.1.5 promptly to IMI2 JU.

### 11.3 **GENERAL ASSEMBLY**

#### 11.3.1 **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.

#### 11.3.2 **Responsibilities**

11.3.2.1 The General Assembly shall be responsible for the determination of policies and decision making in relation to the overall management of the Action and the finding amicable solutions for any unresolved disputes between the Beneficiaries relating to the execution of the Action.

11.3.2.2 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:

- a) supporting the Project Leader and Coordinator in fulfilling their obligations towards the IMI 2 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 IMI 2 funding and contribution;
- d) deciding on principles for effective communication;
- e) agreeing (without prejudice to the Clause 7.4) 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 and the reassignment of that Beneficiary 's Allocated Work;
- i) agreeing on proposals to the IMI2 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.

### 11.3.3 Meetings

11.3.3.1 A 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) 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.

11.3.3.2 Where 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.

11.3.3.3 The Beneficiaries will ensure that the General Assembly meets at least every *[twelve (12)]* months at venues to be agreed, or at any other time at the request of any of the Beneficiaries. Such other meetings may be held via face-to-face or telephone or video conference allowing votes to be submitted verbally; for circulation procedures Clause 11.3.5 shall apply.

11.3.3.4 Meetings 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 fax, 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.

11.3.3.5 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.

11.3.3.6 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 11.5.1.4. 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.

#### 11.3.4 **Decisions; Voting Rules**

11.3.4.1 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.

11.3.4.2 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 11.3.3.4 shall apply accordingly.

11.3.4.3 Each Beneficiary will, through its Representative, have one vote in the General Assembly. Decisions will be taken by *[a majority of sixty(60) percent]*, 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 be unanimous. The Coordinator will inform the IMI2 JU of any such decision. The Chairperson of the General Assembly will have a casting vote.

11.3.4.4 The Beneficiaries agree to abide by all decisions of the General Assembly, provided always that a Beneficiary whose scope of work, time for performance, costs or liabilities are changed from those defined in the Allocated Work and/or the 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.

11.3.4.5 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.

#### 11.3.5 **Circulation Procedure**

11.3.5.1 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.

- 11.3.5.2 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 signing it. In case of agreement the Beneficiaries can either return the signed original to the Chairperson of the General Assembly, or they can scan the signed original and send an electronic copy by email to the Chairperson of the General Assembly.
- 11.3.5.3 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.
- 11.3.5.4 Decisions will be taken in accordance with the voting rules of Clause 11.3.4.
- 11.3.5.5 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.

## 11.4 **MANAGING BOARD**

### 11.4.1 **Members**

The Consortium shall have a Managing Board. The Managing Board shall be made up of the Project Leader, the Coordinator, the Work Package Leaders, and a representative of the Project Management Office (the latter if established shall have no voting rights).

### 11.4.2 **Responsibilities**

- 11.4.2.1 The Managing Board 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, Deliverables and Milestones. 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.
- 11.4.2.2 The Managing Board 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 IMI2 JU;
- h) mediate conflicts which cannot be handled within the Work Packages;
- 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.

11.4.2.3 The Managing Board will be supported by the Project Management Office.

#### 11.4.3 Meetings

11.4.3.1 A Representative of the Project Leader shall act as the chairperson of the Managing Board (the “**Chairperson of the Managing Board**”) 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 Managing Board; and
- b) chair meetings of the Managing Board.

11.4.3.2 Where the Chairperson of the Managing Board cannot attend a Managing Board meeting, the representative of the Project Management Office or the Coordinator shall chair the meeting for the purposes of such meeting.

11.4.3.3 The Chairperson of the Managing Board 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 Managing Board. Additional ad hoc meetings may be held at any time as agreed among the Representatives of the Managing Board; for circulation procedures Clause 11.3.5 shall apply accordingly. Minutes of the meetings of the Managing Board will be prepared by the Chairperson of the Managing Board (or his replacement) and made available to each of the Representatives of the Managing Board within fourteen (14) Days after each meeting.

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

11.4.3.5 Any experts or qualified persons may be invited by any member of the Managing Board to attend meetings of the Managing Board with a role of non-voting advisor. Prior to their first participation in a meeting of the Managing Board 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 11.5.1.4. 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.

#### 11.4.4 **Decisions**

11.4.4.1 In order for a Managing Board 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.

11.4.4.2 Where a Managing Board meeting shall be inquorate, the Chairperson of the Managing Board 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 11.4.3.3 shall apply accordingly.

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

11.4.4.4 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 Managing Board objects; absent members of the Managing Board shall have the opportunity to object subsequently to these decisions within a reasonable period of time to be specified by the Chairperson of the Managing Board.

#### 11.5 **MANDATE**

11.5.1 To facilitate the work of the Project Leader, the Coordinator, the Managing Board 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/Coordinating Team]* 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:

11.5.1.1 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 IMI projects or other Third Party collaborations, provided, however, that no Confidential Information is exchanged;

11.5.1.2 Negotiation and conclusion of a one-sided confidential disclosure agreement (“CDA”)

materially in the form attached hereto in Appendix 8 with a Third Party regarding disclosure of the Consortium Agreement (excluding Appendices 4 to 6) 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 IMI 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 from the Project Leader (e-mail suffice) [*Alt.: from either the Project Leader or the Coordinator/Coordinating Team*] and have not objected to such discussions in writing to the Project Leader [*Alt.: and/or the Coordinator/the Coordinating Team*] within one (1) week after receipt of such notification (e-mail for notification suffice). Under no circumstances will the conclusion of a CDA allow the Project Leader [*Alt.: and/or the Coordinator/the Coordinating Team*] or any Beneficiaries to disclose Confidential Information belonging to another Beneficiary without such other Beneficiary's written approval.

- 11.5.1.3 Negotiation and conclusion of a two-sided CDA materially in the form attached hereto in Appendix 9 with a Third Party regarding disclosure of the Consortium Agreement (excluding Appendices 4 to 6), 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 IMI 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 from the Project Leader [*Alt.: and/or the Coordinator/the Coordinating Team*] (e-mail suffice) and has not objected to such discussions in writing to the Project Leader [*Alt.: and/or the Coordinator/the Coordinating Team*] within one (1) week after receipt such notification (e-mail suffice). Under no circumstances will the conclusion of a CDA allow the Project Leader [*Alt.: and/or the Coordinator/the Coordinating Team*] or any Beneficiaries to disclose Confidential Information belonging to another Beneficiary without such other Beneficiary's written approval.
- 11.5.1.4 Negotiation and conclusion of an advisory agreement materially in the form attached hereto in Appendix 10 (“**Advisory Agreement**”) with the experts and qualified persons for which an advisory agreement needs to be executed in accordance with Clauses 11.3.4.4, 11.4.3.5[, or 11.6.3.8], 11.7.1.2 and 11.8.1.2.
- 11.5.2 If any material changes to the agreements as attached in Appendixes 8 to 10 are proposed in the negotiations with a Third Party, the Project Leader [*Alt.: and/or the Coordinator/the Coordinating Team*] shall be entitled to accept such changes to the extent that the rights and obligations of the Beneficiaries under the Grant Agreement and the Consortium Agreement are not altered.
- 11.5.3 Furthermore, in case any of the above agreements include an obligation for the Beneficiaries to keep Third Party information confidential, the Project Leader [*Alt.: and/or the Coordinator/the Coordinating Team*] is [*are*] entitled to execute such agreements only upon prior receipt of the Beneficiaries' (from the Representatives as listed in Appendix 1) written

consent (e.g., express prior e-mail consent) to the scope of the Third Party's Confidential Information to be set forth in such agreement. Alternatively, this Mandate entitles the Project Leader [*Alt.: and/or the Coordinator/the Coordinating Team*] to oblige only itself [*themselves*] to receive and review Confidential Information of Third Parties in order to evaluate the Action's interest in it. In this case, no further sharing of such Confidential Information within the Action shall take place. The Project Leader [*Alt.: and/or the Coordinator/Coordinating Team*] may, however, disclose Confidential Information of a Third Party to the Beneficiaries upon the Beneficiaries prior written consent (e-mail suffice), in which case the consenting Beneficiary will be bound to the terms of the respective confidential disclosure agreement concluded with the Third Party.

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

11.5.5 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 [*Alt.: and/or the Coordinator/the Coordinating Team*]. 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.

11.6 **[OPTIONAL: COORDINATING TEAM]:**

*[Complex and large projects may establish a Coordinating Team to facilitate the effective execution of the Action.]*

11.6.1 **Members**

The Coordinating Team 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).

11.6.2 **Responsibilities**

*[Decide which of the listed responsibilities of the Managing Board that should be given to the Coordinating Team. Most likely, the Coordinating Team 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 arbitration 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.]*

11.6.3 **Meetings**

11.6.3.1 The Project Leader shall act as the chairperson of the Coordinating Team (the "**Chairperson of the Coordinating Team**") and shall

- a) be responsible for the convening of meetings, preparation and distribution of the agenda and minutes for meetings of the Coordinating Team; and

b) chair meetings of the Coordinating Team.

11.6.3.2 Where the Chairperson of the Coordinating Team cannot attend a Coordinating Team meeting, the Representative of the Project Management Office or the Coordinator shall chair the meeting for the purposes of such meeting.

11.6.3.3 The Coordinating Team will have regular [ ] meetings which shall be held via telephone conference or face-to-face at venues to be agreed with at least [ ] Days written notice in advance. That notice must include an agenda. The Chairperson convenes the meetings of the Coordinating Team. Invitation to the meetings may be in writing, by fax, by e-mail or by other electronic communication means. Additional ad hoc meetings may be held at any time as agreed among the members of the Coordinating Team via face-to-face or telephone or video conference allowing votes to be submitted verbally;

11.6.3.4 For circulation procedures Clause 11.3.5 shall apply.

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

11.6.3.6 Minutes of the meetings of the Coordinating Team shall be considered as accepted by the members of the Coordinating Team if, within two (2) weeks from receipt, no member of the Coordinating Team who was present at the relevant meeting has objected in a traceable form to the Chairperson. Requests for amendments will be considered by the Chairperson and if approved will be sent to all members of the Coordinating Team. The minutes may be shared with the Managing Board after acceptance.

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

11.6.3.8 Any experts or qualified persons may be invited by any member of the Coordinating Team to attend meetings of the Coordinating Team with a role of non-voting advisor. Prior to their first participation in a meeting of the Coordinating Team 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 11.5.1.4. 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.

#### 11.6.4 **Decisions**

11.6.4.1 In order for a Coordinating Team 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]*

- 11.6.4.2 Where a Coordinating Team meeting shall be inquorate, the Chairperson of the Coordinating Team 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 11.6.3.3 shall apply accordingly.
- 11.6.4.3 Decisions will be taken by simple majority. The Project Leader shall have a casting vote.
- 11.6.4.4 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 Coordinating Team objects; absent members of the Coordinating Team shall have the opportunity to object subsequently to these decisions within a reasonable period of time to be specified by the Chairperson.

## 11.7 THE SCIENTIFIC ADVISORY BOARD (SAB) [OPTIONAL]

### 11.7.1 Members

- 11.7.1.1 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 Managing Board *[Option:] [Coordinating Team, if established]* by any Beneficiary. The Managing Board 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.
- 11.7.1.2 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 11.5.1.4.

### 11.7.2 Responsibilities

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

### 11.7.3 Meetings

- 11.7.3.1 The SAB will meet upon request of the Project Leader *[Option:] [Coordinating Team]* but at least once every twelve (12) months during the Action.
- 11.7.3.2 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.

## 11.8 ETHICS ADVISORY BOARD (EAB) [OPTIONAL]

### 11.8.1 Members

- 11.8.1.1 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 Managing Board **[Option:]** *[Coordinating Team]* by any Beneficiary. The Managing Board shall ensure that the composition of the EAB is appropriate to provide the guidance required.

11.8.1.2 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 11.5.1.4.

## 11.8.2 Responsibilities

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

11.8.2.2 The Ethics Advisory Board will be responsible for:

- a) reviewing the proper application of the ethical rules by the Beneficiaries *[to be adapted on a case-by-case basis]*;
- b) providing advice to the Beneficiaries, the General Assembly and the Managing Board 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.

## 11.8.3 Meetings

The EAB will meet upon request of the General Assembly or Managing Board **[Option:]** *[Coordinating Team]* but at least once every twelve (12) months during the Action.

## 12. LIABILITY

### 12.1 TO EACH OTHER

12.1.1 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.

12.1.2 Each Beneficiary (“**Indemnitor**”) shall indemnify each other Beneficiary and their employees, Affiliated Entities, Sub-Contractors, Linked Third Parties, and agents (“**Indemnitee**”) and defend and hold each of them harmless, 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 resulting from any claim, complaint, proceeding or cause of action brought by a Third Party, including IMI2 JU ("**Third Party Claims**") alleging or 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, (iii) infringement of Third Party intellectual property rights by such Indemnitor, its employees, Sub-Contractors, Linked Third Parties, Affiliated Entities or its agents; provided in each case that

- the foregoing obligation to indemnify shall not extend to claims for indirect or consequential loss or damage, including but not limited to loss of profit, revenue or contracts; and
- the total limit of liability of any Indemnitor to the Indemnitee collectively in respect of any one claim or series of connected claims, shall not exceed 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.

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 or (ii) the liability of a party for personal injury or death resulting from the negligence of such party or its employees, officers, directors, agents, or representatives (as applicable).

- 12.1.3 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.

## 12.2 **TOWARDS SUB-CONTRACTORS AND AFFILIATED ENTITIES INVOLVED IN THE COMPLETION OF THE ACTION**

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, Linked Third Parties 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.

## 12.3 **FREEDOM TO OPERATE**

Without prejudice to any of the foregoing provisions of this Clause 12, each Beneficiary acknowledges that it shall be solely responsible for ensuring that, to the best of its knowledge, its activities under the Consortium Agreement, 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.

### **13. TERMINATION AND CONSEQUENCES**

#### **13.1 TERMINATION OF THE GRANT AGREEMENT AND THE CONSORTIUM AGREEMENT**

13.1.1 The IMI2 JU may terminate the Grant Agreement in accordance with Article 50.3 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 IMI2 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 50.3.2 and 50.3.3 (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. This Consortium Agreement shall be deemed to have terminated on the same date as the effective date of termination of the Grant Agreement.

13.1.2 The Beneficiaries may together, pursuant to unanimous agreement reached in a General Assembly meeting, in accordance with Article 50.1 of the Grant Agreement give notice in writing to the Coordinator and the Project Leader requiring that the Grant Agreement be terminated. The Coordinator shall provide notice to the IMI2 JU which shall include the justification for termination and the effective date of the termination in accordance with Article 50.1.1 of the Grant Agreement and the Coordinator shall provide the reports and deliverables referred to in Article 50.1.2 of the Grant Agreement. Upon the IMI2 JU confirming to the Coordinator receipt of notice of termination, the Grant Agreement shall be terminated with effect from that date as stated in the notice of termination and this Consortium Agreement shall be deemed to have been terminated on the same date. The Coordinator shall promptly notify the Beneficiaries of the IMI2 JU's response to the notification of termination of the Grant Agreement.

#### **13.2 TERMINATION OR RETIREMENT OF A BENEFICIARY FROM THE CONSORTIUM AGREEMENT**

13.2.1 The IMI2 JU may terminate the participation of one or more Beneficiaries (“**Terminated Beneficiaries**“) in accordance with Article 50.3 of the Grant Agreement by notifying the Coordinator of its intent to terminate the participation of the Terminated Beneficiaries. The Coordinator shall, on receipt of such notice of termination from the IMI2 JU, forthwith provide each Terminated Beneficiaries with written notice to such effect. Further, the Coordinator shall take such actions as directed under Articles 50.3.2 and 50.3.3 (b) of the Grant Agreement and shall ensure that all Beneficiaries are informed about the progress of the intent to terminate. This Consortium Agreement shall be deemed to have terminated on part of the Terminated Beneficiaries on the same date as the effective date of termination of

Terminated Beneficiaries participation in the Grant Agreement.

13.2.2 Any Beneficiary may request that its participation in the Action be terminated (“**Retiring Beneficiary**”). The Retiring Beneficiary shall submit to and agree with the Managing Board 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 50.2 of the Grant Agreement for transmission to the IMI2 JU.

13.2.3 The Beneficiaries may in accordance with Article 50.2.1 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, hereinafter the “**Excluded Beneficiary**”), that the IMI2 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 obligations of the Excluded Beneficiary. Where those Beneficiaries shall have so determined, the Coordinator shall promptly forward such request, including the documents specified in Article 50.2.1 and 50.2.2 of the Grant Agreement to the IMI2 JU.

### 13.3 **RELATIONSHIP OF SUB-CONTRACTORS AND LINKED THIRD PARTIES AT TERMINATION OR RETIREMENT OF BENEFICIARY**

13.3.1 Where the participation of any Beneficiary under the Action and as a Beneficiary to the Grant Agreement may be terminated by the IMI2 JU, pursuant to the Grant Agreement, the participation of that Beneficiary’s Sub-contractor(s) and Linked Third Parties under this Consortium Agreement shall be deemed to have been terminated on the same date as such termination by the IMI2 JU.

### 13.4 **TERMINATION FOR BREACH**

13.4.1 Where the IMI2 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, 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 IMI2 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 IMI2 JU funding shall only be recoverable as Eligible Costs within the limits of the maximum IMI2 JU financial contribution set forth in the Grant Agreement, in the event that a solution acceptable to the IMI2 JU shall be found, the Beneficiaries, (including the Defaulting Beneficiary, unless the IMI2 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, under Clause 13.1, of this Consortium Agreement or of the

participation of one or more Beneficiaries under this Consortium Agreement, the departing Beneficiaries eligible to receive IMI2 JU funding shall be entitled to receive IMI2 JU funding only in relation to such Eligible Costs which are non-cancellable and were incurred before termination and which are permissible under the terms of the Grant Agreement. For the avoidance of doubt, where the IMI2 JU shall refuse to accept any cost claimed by a departing Beneficiary eligible to receive IMI2 JU funding, that departing Beneficiary shall have no right to recover the same from any (other) Beneficiary or from any IMI2 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 IMI2 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, (or any Beneficiary in the event that the Grant Agreement shall be terminated in its entirety), the IMI2 JU shall decide to withhold IMI2 JU financial contribution, or to demand repayment of any IMI2 JU financial contribution which has been paid, such departing Beneficiary eligible to receive IMI2 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 or Project Leader, the termination of this Consortium Agreement with respect to such departing Beneficiary shall not take effect until the replacement Coordinator or Project Leader has been approved by the IMI2 JU.

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

- 14.1 Where a Beneficiary shall be unable to perform, or shall be delayed in the performance of, any obligation hereunder, 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, 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 IMI2 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 procedure for amending the Description of the Action shall be complied with.

## **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 6.1.2 and 6.1.4, 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 the Consortium Agreement together with (i) all amendments to the Grant Agreement amending this Consortium Agreement, and (ii) any other amendments to this Consortium Agreement.

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

- 16.1 Where, during the implementation of the Action, and with the prior approval of the IMI2 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, enter the consortium upon signature of the Form of Accession shown in Appendix 11 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 by amicable settlement. All disputes or differences arising in connection with this Consortium Agreement which cannot be settled amicably shall be finally settled by arbitration in Brussels under the rules of arbitration of the International Chamber of Commerce (ICC) by 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.

- 17.3 The Beneficiaries concerned may, rather than arbitrate under Clause 17.2, 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. VALIDITY AND ENTRY INTO FORCE; MISCELLANEOUS**

### **18.1 VALIDITY**

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 authorised signatories, as of the date that the Grant Agreement enters into force.

This Consortium Agreement shall remain in force until the Action has been completed according to the Grant Agreement and the Beneficiaries have performed their obligations, unless earlier terminated in accordance with this Consortium Agreement and/or the Grant Agreement. The following clauses shall survive termination or expiration of this Consortium Agreement, whether with respect to one Beneficiary or all Beneficiaries: Clauses 1, 6 to 10, 12, 13.5, 17 and 18, and any other Clause by its nature intended to survive termination or expiration of this Consortium Agreement.

### **18.2 NOTICES**

Any contractual, financial/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 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 contact 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.

### **18.3 ASSIGNMENT**

- 18.3.1 With the exception of Article 30.1 of the Grant Agreement and as otherwise expressly set out

in this Consortium Agreement, no Beneficiary shall assign any interest in this Consortium Agreement to any Third Party without the prior written consent of every other Beneficiary and of the IMI2 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.

- 18.3.2 Where a Beneficiary shall wish to assign its interest in this Consortium Agreement following Clause 18.3.1, such Beneficiary shall, within the limits of confidentiality, provide the remaining Beneficiaries and the IMI2 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 IMI2 JU for any additional information which the IMI2 JU may, either through the Coordinator or directly of such Beneficiary, reasonably request regarding that Beneficiary's Allocated Work and/or Eligible Costs.
- 18.3.3 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.
- 18.3.4 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.

#### 18.4 **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 business purposes and intent of such invalid and unenforceable provision.

#### 18.5 **ENTIRE AGREEMENT**

- 18.5.1 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.
- 18.5.2 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.

#### 18.6 **INDEPENDENT CONTRACTOR**

Nothing in the Agreement shall create, or be deemed to create, a partnership, joint venture or the relationship of principal and agent or employer and employee between the Beneficiaries. Neither Beneficiary shall enter into or have authority to enter into any engagement or make any representation or warranty on behalf of the other Beneficiary or otherwise bind or oblige the other Beneficiary hereto. Each Beneficiary agrees to perform under the Agreement solely as independent contractor.

#### 18.7 **WAIVER**

Any term or condition of the 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.

#### 18.8 **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 antitrust policy to enable such Beneficiary to comply with its obligations under Clause 19, 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 [ ] 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 laws of the territory 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 the laws of the territory) or to repay any such compensation or indemnity. The provisions of Clause 13.2.3 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, Linked Third Parties 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, Linked Third Parties or Sub-Contractors become subject of such debarment, disqualification, blacklisting or banning proceeding.

## **21. TRANSPARENCY**

21.1 Each Beneficiary acknowledges and agrees that in the interest of transparency, EFPIA Beneficiaries and its 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 applicable by law (e.g. Physician Payments Sunshine Act (US Sunshine Act), Loi Bertrand (French Sunshine Regulation)), the "EFPIA Code on Disclosure of Transfers of Values from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations" adopted by the EFPIA Statutory General Assembly of 24 June 2013 (the "EFPIA Disclosure Code"), and the national EFPIA member organizations implementation of the EFPIA Disclosure Code, respectively, or any other regulations.

## **22. APPENDICES**

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

Appendix 1	Name and addresses of Beneficiaries and Beneficiaries' representatives
Appendix 2	Actions involving Personal Data and/or Human Samples
Appendix 3	Animal Welfare
Appendix 4	Background & Materials (identified prior to signature of Grant Agreement)
Appendix 5	Additional Background (identified after signature of Grant Agreement)
Appendix 6	Additional data, know-how, or information (identified after signature of Grant Agreement)

Appendix 7	Data management plan (if applicable)
Appendix 8	Contracts under Mandate: One-sided CDA
Appendix 9	Contracts under Mandate: Two-sided CDA
Appendix 10	Contracts under Mandate: Advisory Agreement
Appendix 11	Form of Accession
Appendix 12	Communication Guidelines

**SIGNATURES**

**IN WITNESS WHEREOF**, the Parties have executed this Consortium Agreement, together with its Appendices, to be duly signed by their authorized representatives as follows, in [XX] originals, on the dates indicated below

**THE COORDINATOR** (give name)

Authorised to sign on behalf of:

Signature .....

Name .....

Title .....

Date .....

Stamp (if applicable)

**THE PROJECT LEADER** (give name)

Authorised to sign on behalf of:

Signature .....

Name .....

Title .....

Date .....

Stamp (if applicable)

**[add a page for each additional Beneficiary]**

**THE BENEFICIARIES** (give name)

Authorised to sign on behalf of:

Signature

.....

Name

.....

Title

.....

Date

.....

Stamp (if applicable)

**Appendix 1: Names and addresses of Beneficiaries and Beneficiaries' representatives**

## Appendix 2: Actions involving Personal Data and/or Human Samples

### 1. APPLICATION

Beneficiaries will have to comply with the following principles and applicable laws and regulations when collecting, processing, storing, using or transferring any Personal Data and/or Human Samples for activities conducted, sponsored, supported or funded pursuant to the Action.

### 2. DEFINITIONS

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

**“Human Samples”** shall mean any human tissue or human biological material of a natural person (“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, or any derivative of such human biological material such as stem cells, cell lines or xenograft tissues; and any human biological product, including, but not limited to, hair, nail clippings, teeth, urine, faeces, breast milk, and sweat.

**“Personal Data”** shall mean any information relating to an identified or identifiable natural person (“Donor”); an identifiable 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.

**“Processing”** shall mean any operation with regard to Personal Data and/or Human Samples irrespective of the means and procedures applied, in particular the obtaining, collection, recording, organizing, storage, holding, use, amendment, adaption, alteration, disclosure, dissemination or otherwise making available, aligning, combining, retrieval, consultation, archiving, transmission, blocking, erasing or destruction of Personal Data and/or Human Samples.

**“Processor”** shall mean any Beneficiary that Processes Personal Data and/or Human Samples on behalf and according to the instructions of a Controller.

### 3. PERSONAL DATA AND HUMAN SAMPLES COLLECTION AND INFORMED CONSENT

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

- (1) the Personal Data and the Human Samples are Processed in accordance with all laws, rules, regulations and guidelines applicable to their collection, use, handling, disposal and further Processing, including – without limitation – data protection legislations, such as the EU Data Protection Directive 95/46/EC or succeeding regulations as the General Data Protection Regulation 2016/679 and the Standards for Individually Identifiable Health Information (45 CFR Parts 160 and 164, the "HCALL ORDERA Privacy Regulation") promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 all as updated from time to time (“Data Protection Legislation”), as applicable,

- (2) if applicable, the Personal Data and Human Samples are collected with voluntarily given informed consent of the Donors of the Personal Data and Human Samples covering the activities of the Action, including the collection, processing, storage, use and transfer including the addressees of the transfer of the Personal Data and Human Samples as provided for under the Action, such informed consent must be revocable any time with effect for the future,<sup>6</sup>
  - (3) the responsible ethics committee/Institutional Review Board (IRB) has given its approval to the collection, processing, storage, use and transfer of the Personal Data and Human Samples under the Action, and
  - (4) if applicable, the Donors of the Personal Data and Human Samples have not withdrawn their informed consents.
- 3.2 Beneficiaries shall ensure that employees dealing with the Processing of Personal Data and Human Samples have been obliged to data secrecy in writing and that they are informed about the Data Protection Legislation and contractual provisions regarding data protection.
- 3.3 To the extent a Sub-Contractor Processes Personal Data and Human Samples, the appointing Beneficiary will select such Sub-Contractor considering the adequacy of the technical and organizational measures for the protection of Personal data and Human Samples implemented by the Sub-Contractor and will oblige such Sub-Contractor in accordance with this Consortium Agreement. If the Sub-Contractor and/or its Processing is located in countries outside the European Economic Area which do not offer an adequate level of protection, the appointing Beneficiary is obliged to agree on applicable standards to implement an adequate level of protection, e.g. where applicable by executing model clauses in the form issued by the European Commission.
- 3.4 Beneficiaries will not introduce to the Action Personal Data and Human Samples that are collected for reasons unrelated to the Action, unless (i) all legal requirements under applicable Data Protection Legislation for the collection, processing, storage, use and transfer of the Personal Data and Human Samples under the Action (such as that the informed consent allows for such use) are fulfilled, and (ii) prior written approval of the competent ethics committee/IRB is obtained. When a Beneficiary obtains Personal Data and/or Human Samples 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 and/or Human Samples.
- 3.5 To the extent a Beneficiary introduces to the Action Personal Data and Human Samples and thereby enables other Beneficiaries to access and Process such Personal Data and Human Samples within the Project independent from specific instructions regarding the handling of

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<sup>6</sup> The Beneficiaries should consider to agree on a data protection concept including the minimum requirements for informed consents, such as that (i) the purpose of use in informed consent must cover activities under the Action, including genetic tests and whole genome analysis, (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.

Personal Data (“**Controller to Controller**”), the introducing Beneficiary and the accessing Beneficiary are additionally obliged as follows:

- (1) Personal Data and Human Samples shall be accessed only for the purpose of the Project and the corresponding agreements, i.e. the Grant Agreement and the Consortium Agreement. Further Processing of such introduced Personal Data and Human Samples by the accessing Beneficiary for own purposes or for purposes of Third Parties is not permitted, unless expressly permitted in the informed consent.
- (2) The Personal Data and Human Samples being introduced to the Action or Processed shall be adequate in relation to the purpose of the transfer and the Processing. No Personal Data or Human Samples shall be transferred and Processed if it is not necessary for the stated purpose.
- (3) Personal Data and Human Samples shall be retained by the accessing Beneficiary in accordance with applicable laws and regulations and shall not be retained longer than necessary for the purposes of the Project, within the limitations of applicable laws.
- (4) The introducing Beneficiary shall inform the Donor about the transfer of their Personal Data and Human Samples to and the Processing by the accessing Beneficiary and if applicable Third Parties in accordance with Data Protection Legislation. The accessing Beneficiary shall provide the introducing Beneficiary with all information about the accessing and Processing of the Personal Data and Human Samples which the introducing Beneficiary requests in order to inform the Donor according to applicable law.
- (5) The introducing Beneficiary remains the responsible contact for any requests by the Donor, e.g. for information, correction or deletion of the Personal Data or Human Samples or for an objection to the Processing.
- (6) The accessing Beneficiary 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 and Human Samples [as specified in Schedule W].
- (7) The introducing Beneficiary is entitled to perform an audit if the accessing Beneficiary Processes Personal Data and Human Samples in accordance with the foregoing. For this purpose the accessing Beneficiary will inform the introducing Beneficiary upon request and provide necessary documents and information to the introducing Beneficiary. The accessing Beneficiary is obliged to perform internal audits to ensure compliance with its obligations.

3.6 To the extent the Beneficiary introduces to the Action Personal Data and Human Samples 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 and the accessing Beneficiary are additionally obliged as follows:<sup>7</sup>

- (1) The accessing Beneficiary shall Process personal Data and Human Samples exclusively in the name of and in accordance with the instructions of the introducing Beneficiary (Commissioned Data processing). The introducing Beneficiary remains the Controller and responsible for the legality of Processing Personal Data and Human Samples.
- (2) The Processing of the Personal Data and Human Samples by the accessing Beneficiary shall exclusively and entirely occur in the type and extent and for the purposes and shall exclusively relate to the type of data and samples and the circle of affected persons as described in the additional Schedule X.
- (3) The accessing Beneficiary shall be regarded as Processor and shall not acquire any rights with respect to the Personal Data.
- (4) With respect to Personal Data as per Schedule X, additionally the terms and obligations as per Schedule Y apply including the obligations of the accessing Beneficiary to provide for the technical and organizational measures as per Schedule Z.

3.7 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. USE OF PERSONAL DATA AND HUMAN SAMPLES IN THE ACTION**

- 4.1 Beneficiaries are responsible for their Processing, storing, using and transferring of Personal Data and/or Human Samples in compliance with the applicable Data Protection Legislation and for purposes that are consistent with the consent obtained, if applicable.
- 4.2 The Beneficiary introducing the Personal Data and Human Samples to the Action shall immediately inform the other Beneficiaries in writing in case that Donors have withdrawn their consent.
- 4.3 Additional individual Donor consent and ethics committee/IRB approval must be obtained when the research use intended is inconsistent with or beyond the scope of the original consent.
- 4.4 Additional consent should also be obtained if the original consent did not include analysis of DNA and other genetic tests (if relevant to the research proposal) or use of any associated medical information (if relevant to the research proposal).

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<sup>7</sup> Clause 3.6 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 3.6 would apply. Please also note that the prerequisites established in this Clause 3.6 may have to be supplemented with additional wording according to the national legal requirements for commissioned data processing.

- 4.5 In circumstances where individual re-consent cannot practicably be obtained, approval of an ethics committee or IRB (if permissible under applicable Data Protection Legislation) must be sought to determine whether the research can proceed in the absence of individual consent, as permissible under the applicable laws and regulations.

### **Appendix 3: Animal Welfare**

Beneficiaries agree to comply and further agree to oblige their Affiliated Entities, Linked Third Parties 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. In conducting any research involving the use of animals, the Beneficiaries further agree to comply and oblige their Affiliated Entities, Linked Third Parties and Sub-Contractors to comply with the “3R” Principles- reducing the number of animals used, replacing animals with non-animal methods whenever possible 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, Linked Third Parties 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, Linked Third Parties 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, Linked Third Party and/or Sub-Contractor concerned take) reasonable and practical corrective measures to remedy any such material deficiencies.

#### Appendix 4: Agreement on Background pursuant to Clause 6.1.1 of the Consortium Agreement

The Beneficiaries to this Action hereby identify and agree on the Background for this Action pursuant to Clause 6.1.1 of the 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.

Furthermore, the Beneficiaries acknowledge that the IMI-2 JU has agreed to exclude the below Background identified under Section 4.2. to be wholly or partially excluded from Access Rights by Third Parties, per Article 25.4 of the Grant Agreement.

Section 4.3 lists the Materials Needed to carry out the Action. For the avoidance of doubt, as indicated in the Consortium Agreement, unless they are also listed as Background, no Access Rights are granted on such Materials.

#### 4.1. BACKGROUND TO BE SUBJECT OF ACCESS PURSUANT TO CLAUSE 6.1.1 OF THE CONSORTIUM AGREEMENT

N° Beneficiary	Owner (Beneficiary acronym)	Background (with the exclusion of Materials)	Type of Background <sup>8</sup>	Beneficiary who needs access to the Background <sup>9</sup>	Related WP or task	Is there any legal restriction to the use of your Background? <sup>10</sup>
[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]

<sup>8</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>9</sup> Please indicate which IMI project partner(s) would need to access this knowledge (for carrying out the project or for further research)?

<sup>10</sup> If there is any restriction, please precise this restriction (legal, regulatory, patent, business model, etc.) e.g. Limited to Research Use only, during and after Project, for any purpose.


**4.2. SPECIFIC ELEMENTS OF BACKGROUND WHICH ARE WHOLLY OR PARTIALLY EXCLUDED FROM ACCESS RIGHTS BY THIRD PARTIES**

[IDENTIFY AND LIST – ON A PER BENEFICIARY BASIS - THE BACKGROUND FOR WHICH SUCH EXCEPTION WAS GRANTED BY THE IMI2 JU PER CLAUSE 25.4 OF THE GRANT AGREEMENT]

- 1.
- 2.

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

[IDENTIY AND LIST – ON A PER BENEFICIARY BASIS - THE MATERIALS NEEDED]

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

\*Standard use: The standard MTA provisions of Article 9 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 from Article 9 shall apply.

## Appendix 5: Additional Background identified by Beneficiaries during the Action pursuant to Clause 6.1.2 of the Consortium Agreement

During the Action, Beneficiaries may add certain Background by identifying such additional Background 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 additional Background.

Furthermore, the Beneficiaries acknowledge that the IMI-2 JU has agreed to exclude the below additional Background identified under Section 5.2. to be wholly or partially excluded from Access Rights by Third Parties, per Article 25.4 of the Grant Agreement.

### 5.1.ADDITIONAL BACKGROUND TO BE SUBJECT OF ACCESS PURSUANT TO CLAUSE 6.1.2 OF THE CONSORTIUM AGREEMENT

N° Beneficiary	Owner (Beneficiary acronym)	Background (with the exclusion of Materials)	Type of Background <sup>11</sup>	Beneficiary who needs access to the Background <sup>12</sup>	Related WP or task	Is there any legal restriction to the use of your Background ? <sup>13</sup>
[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]

<sup>11</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>12</sup> Please indicate which IMI project partner(s) would need to access this knowledge (for carrying out the project or for further research)?

<sup>13</sup> If there is any restriction, please precise this restriction (legal, regulatory, patent, business model, etc.) e.g. Limited to Research Use only, during and after Project, for any purpose.

**5.2.SPECIFIC ELEMENTS OF ADDITIONAL BACKGROUND WHICH ARE WHOLLY OR PARTIALLY EXCLUDED FROM ACCESS RIGHTS BY THIRD PARTIES**

[IDENTIFY AND LIST – ON A PER BENEFICIARY BASIS - THE BACKGROUND FOR WHICH SUCH EXCEPTION WAS GRANTED BY THE IMI2 JU PER CLAUSE 25.4 OF THE GRANT AGREEMENT]

- 1.
- 2.



**Appendix 6: Additional data, know-how or information entered into the ACTION.**

During the Action, a Beneficiary may contribute additional data, know-how or information pursuant to Clause 6.1.4 of the 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.

**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 & information]	[add type]	[All ] [Benf. of WPx]	[WP x]	[describe third party limitations on use or other restrictions imposed by appl. law]

**Appendix 7: Data management plan (if applicable)**

## Appendix 8: Contract 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:

[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: IMI) 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 Medicines Initiative 2 (“**IMI**”) for the purpose of establishing the project called “[*title of IMI Consortium*]” (IMI Grant Agreement No. [...]) (the “[X] **Action**”) and are parties to the [X] Consortium Agreement, as defined below, supported by the IMI2 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 Medicines Initiative (“IMI”)]* for the purpose of establishing the project called “[*title of Consortium*]” *[Delete if not applicable: (IMI Grant Agreement No. [...])]* (the “[Y] **Action**”) and are parties to the [Y] Consortium Agreement, as defined below, *[Delete if not applicable: supported by the IMI2 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 (each referred to as a “**Disclosing Party**” and collectively as the “**Disclosing Parties**”) to any Recipient that relates to the *[X]* Action.
- c) “*[X]* **Consortium Members**” shall mean the parties to the Innovative Medicines Initiative Consortium Agreement for *[title of IMI Consortium]* effective as of [...] (“*[X]* **Consortium Agreement**”) as listed at Exhibit 1.

*[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.]

## 2. 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 *[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 Recipient;

(the “**Purpose**”).

### **3. 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.

### **4. EXCLUDED INFORMATION**

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) 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 the provisions of the Freedom of Information Act 2000 or any equivalent law or regulation in any other applicable jurisdiction, the Recipient shall in all instances seek to apply the exemptions under that Act.

## **6. TERM**

This Agreement shall come into effect on the effective date. It may be terminated with respect to further disclosures upon thirty (30) days' prior written notice. This Agreement shall cover Confidential Information disclosed within a period of two (2) years from the effective date. After such period, the obligations accrued under this Agreement shall survive for a period of ten (10) years *[To be checked if this is sufficient for the Consortium Members and in line with the Consortium Agreement]*.

## **7. NO OTHER OBLIGATION; NO LICENSE**

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

## **8. NO REPRESENTATION OR WARRANTY**

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

## **9. RETURN OF CONFIDENTIAL INFORMATION**

At the request of the Disclosing Party or, at the latest, on completion of the Purpose, and in the absence of any further written agreement between the parties, the Recipient shall cease all use of the Confidential Information and shall promptly return to each Disclosing Party all of its Confidential Information which is in tangible form, except that the Recipient shall be permitted to retain one (1) copy of the Confidential Information so that any continuing

obligations may be determined. The return of the Confidential Information will not affect Recipient's obligation to observe the confidentiality and non-use obligations set out in this Agreement. The provisions of this clause 9 shall not apply to copies of electronically exchanged Confidential Information or copies thereof which must be stored by the Recipient according to the provisions of mandatory applicable law.

**10. NO PUBLICITY**

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

**11. RIGHTS OF THIRD PARTIES**

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

**12. ASSIGNMENT**

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

**13. SEVERABILITY**

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

**14. ENTIRE AGREEMENT; AMENDMENTS; WAIVER**

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

**15. GOVERNING LAW; 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.

REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK



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

*[name of authorized company or institution]      [Recipient, as the case may be:*

*(**[X]** Mandate Holder )                      „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 9: 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 MATERIAL CHANGES TO THE SUBSTANCE SHOULD NOT BE MADE WITHOUT CONSORTIUM APPROVAL, WHICH 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: IMI) 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 Medicines Initiative 2 (“**IMI**”) for the purpose of establishing the project called “*[title of IMI Consortium]*” (IMI Grant Agreement No. *[...]*) (the “*[X]* **Action**”) and are parties to the *[X]* Consortium Agreement, as defined below, supported by the IMI2 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 Medicines Initiative 2 (“IMI”)]* for the purpose of establishing the project called “*[title of Consortium]*” *[Delete if not applicable: (IMI Grant Agreement No. [...])]* (the “*[Y]*”)”)

**Action**”) and are parties to the *[Y]* Consortium Agreement, as defined below, *[Delete if not applicable: supported by the IMI2 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] Coordinating Team 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] Coordinating Team].* 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].*
- c) “*[X]* **Consortium Members**” shall mean the parties to the Innovative Medicines Initiative Consortium Agreement for *[title of IMI Consortium]* effective as of *[...]* (“*[X]* **Consortium Agreement**”) as listed at Exhibit 1.
- [Delete if not applicable:]*
- d) “*[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.

## 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**

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 the Freedom of Information Act 2000 or any equivalent law or regulation in any other applicable jurisdiction, Recipient shall in all instances seek to apply the exemptions under that Act.

## **6. TERM**

This Agreement shall come into effect on the effective date. It may be terminated with respect to further disclosures upon thirty (30) days' prior written notice. This Agreement shall cover Confidential Information disclosed within a period of two (2) years from the effective date. After such period, the obligations accrued under this Agreement shall survive for a period of ten (10) years. *[To be checked if this is sufficient for the Consortium Members and in line with the Consortium Agreement]*

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

## 11. RIGHTS OF THIRD PARTIES

Each *[X]* Consortium Member shall have a right to enforce the terms of this Agreement. *[Delete if not applicable: Each *[Y]* 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 *[X]* Consortium Members, whose consent may be withheld at the *[X]* 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.

REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK

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

*[name of authorized company or institution]*      *[Recipient, as the case may be:*

*(/X) Mandate Holder)*                                      *“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 10: Contracts under Mandate: Advisory Agreement

### Advisory Agreement

between *[X]* Consortium Members as listed in 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 Medicines Initiative 2 (“**IMI**”) for the purpose of establishing the project called “*[title of IMI Consortium]*” (IMI Grant Agreement No. *[...]*) (the “**Action**”). It consists of the participants listed in Exhibit 1 hereto (collectively the “**Participants**”), including *[name of authorized company or institution]* acting as the “**Project Leader**”. The Participants are parties to an IMI Consortium Agreement for *[title of IMI Consortium]* effective as of *[...]* (the “**Consortium Agreement**”).
- (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 Participant 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 Participant 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 Participant 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 Participant 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 Participant 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 Participants 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 Consortium Agreement expires or is terminated. *[To be checked if this is in line with the Consortium Agreement]*
- 3.6 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.

### **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 Participants in equal shares, and Advisor shall assign (or cause to be assigned) and does hereby assign fully to each of the Participants in equal shares all rights, title and interest in and to any Results, without payment of any additional compensation to Advisor. At a Participant’s request and expense, Advisor shall also reasonably assist such Participant in obtaining, perfecting, or defending such Participant’s rights, title, and interest in any Results, including, without limitation, the drafting, filing and prosecution of any patent applications. As between the Participants, such results shall be deemed to be *[allocate as suitable pursuant to Consortium Agreement terms, e.g. “Foreground”]* 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 Participants.

## 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 The terms set forth in Sections 3, 4, 6.2 and 7.1 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, IMI 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 Participant 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.

REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in *[insert number of necessary duplicates]* in their own name and in case of Project Leader in addition in the name and on behalf of the Participants as their duly authorized representatives.

*[name of authorized company or institution] [Advisor]*

**(Project Leader)**

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

**Acknowledged and agreed**

*[Participant 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 Participants]*

**Appendix 11: Form of Accession****FORM OF ACCESSION**

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

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

hereby consents to become a Participant 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 IMI2 JU of such accession by [OFFICIAL NAME OF THE NEW PARTY AS IDENTIFIED IN THE GRANT AGREEMENT].

[OFFICIAL NAME OF THE NEW PARTY 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 the Description of Work for the [insert Project title] project.

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 three (3) originals to be duly signed by the undersigned authorised representatives.

[Date and Place]

[INSERT NAME OF THE NEW BENEFICIARY]

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

Coordinator

Signature(s)

Name(s)

Title(s)

## Appendix 12: Communication Guidelines

### COMMUNICATION GUIDELINES

This Appendix governs Communication, by means other than Dissemination, by or on behalf of 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 list may be permissible, but are subject to the terms of the Consortium Agreement, including those on Dissemination and Confidential Information.

#### 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 IMI2 JU’s values and the IMI2 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 IMI2 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 IMI2 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 IMI2 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 privacy legislation, and the individual's written consent to use this is generally required.
- 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 posted without the express written consent of each of the depicted individuals and the photographer
- B. Names and other personally identifiable information of individuals may not be posted without the individual's express written consent



- 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
- D. Content from minors should not be posted 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.