

PROJECT AGREEMENT FOR

“Open PHACTS”

**AN OPEN, INTEGRATED AND SUSTAINABLE
CHEMISTRY, BIOLOGY AND PHARMACOLOGY
KNOWLEDGE RESOURCE
FOR DRUG DISCOVERY**

IMI Project Agreement

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THIS AGREEMENT dated [] 2010 is made
BETWEEN:

- (1) **Pfizer Limited (Pfizer)**, whose administrative offices are at Ramsgate Road, Sandwich, Kent, CT13 9NJ, UNITED KINGDOM
- (2) **Universität Wien (UNIVIE)**, whose administrative offices are at Dr Karl Lueger Ring 1, Vienna 1010, AUSTRIA
- (3) **Technical University of Denmark (DTU)**, whose administrative offices are at Anker Engelundsvej 101, DK-2800 Kgs. Lyngby, DENMARK
- (4) **University of Hamburg, Center for Bioinformatics (UHAM)**, whose administrative offices are at Moorweidenstr. 18, 20148 Hamburg, GERMANY
- (5) **BioSolveIT GmbH (BIT)**, whose administrative office is located at An der Ziegelei 79, 53757 St. Augustin, GERMANY
- (6) **Consorti Mar Parc de Salut de Barcelona (PSMAR)**, whose administrative offices are at Passeig Marítim 25-29, 08003 Barcelona, SPAIN
- (7) **Academisch Ziekenhuis Leiden**, also acting under the name **Leiden University Medical Centre (LUMC)**, whose administrative offices are at Albinusdreef 2, Leiden, 2333 ZA, NETHERLANDS
- (8) **Royal Society of Chemistry (RSC)**, whose administrative offices are at Thomas Graham House, Science Park, Milton Road, Cambridge, CB4, 0EF, UNITED KINGDOM
- (9) **Vereniging voor Christelijk Hoger Onderwijs, Wetenschappelijk Onderzoek en Patientenzorg (VUA)**, whose administrative offices are at Boelelaan 1083a, 1081 HV Amsterdam, THE NETHERLANDS
- (10) **Spanish National Cancer Research Centre (CNIO)** for the purposes of this Agreement represented by Juan Arroyo Muñoz, Managing Director, and with administrative offices at C/ Melchor Fernández Almagro, 3, E-28029 MADRID
- (11) **University of Manchester (UNIMAN)** established in Oxford Road, Manchester M13 9PL, UNITED KINGDOM
- (12) **Maastricht University (UM)** having its principal offices at Minderbroedersberg 4-6, 6211 LK Maastricht, THE NETHERLANDS
- (13) **Academic Concept Knowledge Limited - ACKnowledge (ACK)** whose administrative offices are at Suite 5, Denham House, Norman Avenue, Epsom, Surrey, KT17 3AB, UNITED KINGDOM

- (14) **Universidade de Santiago de Compostela (USC)**, whose administrative offices are at Pazo de San Xerome, Praza do Obradoiro s/n, 15782 Santiago de Compostela, SPAIN
- (15) **Rheinische Friedrich-Wilhelms-Universität Bonn (UBO)**, represented by the rector, he in turn represented by the chancellor, Regina-Pacis-Weg 3, 53113 Bonn, GERMANY
- (16) **AstraZeneca AB (AZ)**, whose administrative offices are at Västra Mälarehamnen, SE-151 85 Södertälje, SWEDEN
- (17) **GlaxoSmithKline Research & Development Limited (GSK)**, whose administrative offices are at 980 Great West Road Brentford, TW8 9GS Middlesex, UNITED KINGDOM
- (18) **Laboratorios del Dr. Esteve, S.A. (Esteve)** whose administrative offices are at Avda. Mare de Déu de Montserrat 221, Barcelona 08041, SPAIN
- (19) **Novartis Pharma AG (Novartis)**, whose administrative offices are at Lichtstrasse 35, Basel, 4056, SWITZERLAND
- (20) **Merck KGaA (ME)**, whose administrative offices are at Frankfurter Strasse 250, 64293 Darmstadt, GERMANY
- (21) **H. Lundbeck A/S (HLU)**, whose administrative offices are at Ottiliavej 9, Valby DK-2500, DENMARK
- (22) **Eli Lilly and Company Limited (Lilly)**, whose registered offices are at Lilly House, Priestley Road, Basingstoke, Hampshire RG24 9NL, UNITED KINGDOM

WHEREAS:

The IMI-JU has announced its intention to make a grant in respect of the project entitled “*Open PHACTS*” subject to the terms of the Grant Agreement, and subject to the Participants entering into an agreement governing their collaboration “the Project Agreement”. The aim of the Open PHACTS Project is to develop an open pharmacological space (the “OPS system”) for information exchange in drug discovery, which will be beneficial to patients, healthcare providers, the pharmaceutical industry and society. The core OPS system will contain data and technology for semantic information exchange. The Participants acknowledge the intention to make the core OPS system publicly and openly available free of charge, as further set forth in Clause 16 of this Project Agreement. The Project will also develop value added services and scientific research to demonstrate the effectiveness and applicability of the pharmacological space.

This Agreement governs the Participants’ collaboration in relation to that Project.

Participants will accede to the Project Agreement through the respective Form of Accession for each as described herein. For the avoidance of doubt, such accession is intended to accommodate the efficiencies required for processing signatures of the Project Agreement to facilitate initiation of the Grant Agreement and the Project start. All Participants acceding to the Project Agreement in this manner shall be entitled to all rights and are subject to all obligations under this Project Agreement as though each Participant separately executed this Project Agreement otherwise through their respective signatory.

THEREFORE IT IS AGREED AS FOLLOWS:

1. DEFINITIONS

Any word(s) or expression(s) appearing in this Project 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 the rights to use as envisaged by Clauses 10-17 of this agreement;

“Affiliated Entity” means any legal entity that is under the direct or indirect control of a Participant, under the same direct or indirect control as a Participant, or is directly or indirectly controlling a Participant, 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;

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“Allocated Work” means the research work and the related activities and services allocated to a Participant in accordance with Annex I of the Grant Agreement;

“Associated Partners”, as identified in Article 5, means an external group of organizations linked to the Project through contribution of data, tools and services, but who do not receive funding.

“Background” means information, including data and know-how which is held by a Participant prior to, on or after the accession to the Grant Agreement, as well as copyrights (including that subsisting in computer models and software) or other intellectual and industrial property rights pertaining to such information, and which is introduced into and necessary for carrying out the Project and which is defined in Appendix 3 to this Project Agreement;

“Coordinator” means in accordance with the Grant Agreement the Participant acting as the co-ordinator of the consortium;

“Confidential Information” means any and all written information communicated between the Participants in the framework of the Project clearly identified or marked as being confidential at the moment of its disclosure, except for the information which the Recipient Participant can prove (a) is, at the time of communication, in the public domain, (b) after the communication, becomes part of the public domain by publication or otherwise, except by breach of this agreement by the Recipient Participant, (c) is obtained from a third party not in breach of any obligation of confidentiality, (d) is known by the Recipient Participant or any of its Affiliated Entities prior the date of the communication, (e) is required to be disclosed by the Recipient Participant pursuant to any applicable law or judicial or governmental order, provided that the Recipient Participant shall give immediate written notice of such requirement to the Disclosing Participant with the view to agreeing the timing and the content of such disclosure. Whenever Confidential Information is communicated orally, its confidential nature shall be confirmed in writing by the disclosing party within thirty (30) days after such disclosure;

“Defaulting Participant” means a Participant in breach of any obligation(s) under this Project Agreement;

“Direct Exploitation” means to develop for commercialization or to commercialize Foreground itself;

“Eligible Costs” means those costs incurred by each Participant in carrying out its Allocated Work under the Project; the nature of such costs is more particularly detailed in Article II.14 of the Grant Agreement;

“EFPIA members” means members of the European Federation of Pharmaceutical Industries and Associations;

“Executive Committee” or “EC” means a committee comprised of the Coordinator, his deputy, the Managing entity of the IMI JU funding, and his

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deputy, each individually having one vote. Other non-voting representatives with rights to attend the EC meetings include the Project Manager, chairs of the Technical Task Force and Scientific Task Force, Chair of the Scientific Advisory Board and Work Package Leaders. The Executive Committee is chaired by the Coordinator and shall have those responsibilities as described in Article 5 of this Project Agreement;

“Foreground” means the results, including data, know how and information, whether or not they can be protected, which are generated under the Project and excluding Sideground. Such results include rights related to copyright (including that subsisting in computer models and software); design rights; patent rights; or similar forms of protection;

“Form of Accession” means the form of deed which all additional Participants to this Project Agreement must sign before becoming a Participant, as more particularly set out in Appendix 4;

“Government Official” means (i) any elected or appointed government official (e.g., a member of a ministry of health) of a government entity; (ii) any employee or person acting for or on behalf of a government official, agency, or enterprise performing a governmental function (including, but not limited to, doctors employed by state-owned hospitals and employees of state-owned universities); (iii) any political party, officer, employee, or person acting for or on behalf of a public international organization (e.g., the United Nations or European Commission), or (v) any person otherwise categorized as an official of a governmental entity or government-owned entity under local law.

“Grant Agreement” means Grant Agreement No **(115191)**, (including its annexes and any amendments thereto), to be entered into between the Participants and the IMI JU for the undertaking by the Participants of the Project;

“IMI JU” means the Innovative Medicines Initiative Joint Undertaking, a community body established by Council Regulation No 73/2008 of 20 December 2007;

“Materials” means chemical and/or biological materials;

“Managing entity of the IMI JU funding” means the appointed Participant to manage the allocation of the IMI JU funding and who will act in accordance with article II.2.3 of the Grant Agreement and also this Project Agreement;

“Participant” means a party to this Project Agreement and “Participants” shall be interpreted accordingly;

“Project” means the research activities carried out by the Participants as defined in Annex I of the Grant Agreement;

“Project Agreement” means this Agreement and all of its appendices, together with amendments validly agreed in writing amongst the Participants;

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“Project Deliverables” means reports, including progress reports and certified audit reports generated under the Project;

“Project Management Unit” or “PMU”, as defined in Article 5, describes the composition and responsibilities of a management team composed of a Project Manager or PM (whose role is identified and defined hererin in Article 5.26) and a project management office to be located at the Managing entity of the IMI JU funding (UNIVIE);

“Project Objectives” means the objectives which are defined in Annex I of the Grant Agreement;

“Project Share” means for each Participant that Participant’s share of the total cost of the Project as outlined in Annex I of the Grant Agreement and as shall be more specifically determined in accordance with the provisions of the Grant Agreement and this Project Agreement;

“Representative” means the person chosen by a Participant, who is employed by the Participant or by an Affiliated Entity, to represent it on the Steering Committee;

“Research Use” means the use of Foreground or Background necessary to use Foreground for all purposes other than for completing the Project or for Direct Exploitation. An example of Research Use is the application of Foreground as a tool for research and clinical research in the discovery, development or commercialisation of pharmaceutical products by for-profit institutions and organisations.

“Scientific Advisory Board” or “SAB”, as defined under Article 5, means an external body of experts in computational life sciences and/or drug discovery domain representing the global scientific user community, selected from the global scientific user community for the purpose of giving advice to the EC and SC on matters related to the Project;

“Scientific Task Force” or “STF”, as defined under Article 5, means a group of Representatives which comprises scientists from all core disciplines, for the purpose of coordinating broad scientific initiatives related to the Project, including but not limited to semantic approaches, bioinformatics, cheminformatics and medicinal chemistry;

“Sideground” means the results, including data, know how and information, whether or not they can be protected, which are generated by a Participant under the Project but outside of the Project Objectives and which are not needed for undertaking and completing the Project or the research use of Foreground. Sideground specifically excludes Foreground.

“Sub-contractor” means a Third Party which has entered into an agreement on business conditions with one or more Participants, in order to carry out part of

the work of the Project without the direct supervision of the Participant and without a relationship of subordination.

“Steering Committee” or “SC” whose responsibilities are defined in Article 5 of this Project Agreement means a committee comprised of, collectively, the Representatives. The SC shall be the ultimate decision-making body within the Project.

“Technical Task Force” or “TTF” , as defined under Article 5, means a core group of Representatives, including the CTO and TPL (as both are defined herein under Articles 5.28 and 5.30 respectively) which monitors, guides, and coordinates the technical implementation of the Project as outlined in the respective WP’s goals.

“Third Party” means any legal entity which is not a Participant. Contributions from third parties such as subcontractors do not qualify them as Participants.

“Third Party Collaborator” means a Third Party which has entered into an agreement on business conditions with a Participant in order to perform certain aspects of Research Use. For the avoidance of doubt, a Third Party Collaborator is not a Sub-contractor.

“Work Packages” or “WP’s”, as defined in Article 5, means a group of tasks as defined in Annex I to the Grant Agreement.

“Work Package Leaders” or “WPLs”, as defined in Article 5, means an EFPIA Representative and an academic Representative with overall responsibility for the day-to-day management of their respective Work Packages.

“Work Package Leader Group” or “WPLG”, means all Work Package Leaders responsible for the proper execution of the Work Packages as outlined in Annex 1 to the Grant Agreement.

2. PURPOSE

- 2.1 The purpose of this Project Agreement is to facilitate the completion of the Project by the Participants 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 Participants amongst each other in relation to, inter alia, financial provisions, the performance of the Project, issues relating to intellectual property rights, and access to arising Foreground and Background by the Participants and Third Parties (as defined in this Agreement) and the liability and indemnification of the Participants amongst each other.
- 2.2 This Project Agreement is not intended, and nothing contained herein shall be deemed, to create any partnership, agency or joint venture amongst the Participants or any of the Participants, nor to establish any other legal entity constituted amongst any or all of the Participants.

3. VALIDITY AND ENTERING INTO FORCE

- 3.1 This Project Agreement shall be deemed to have been validly entered into between the Participants, and to be legally binding, when signed on behalf of each Participant by the appropriate authorised signatories, as of the date that the Grant Agreement comes into effect.
- 3.2 As soon as reasonably practicable following the signing by all Participants of the Project Agreement, the Coordinator and the Managing entity of the IMI JU funding shall enter into the Grant Agreement with the IMI JU which shall provide for the start date of the Project. The Grant Agreement will become effective with respect to each Participant, following their accession by signature of Form A, Annex III of the Grant Agreement, countersigned by the Coordinator.
- 3.3 This Project Agreement shall remain in force until the Project has been completed and the Participants have performed their obligations, unless earlier terminated in accordance with this Project Agreement and the Grant Agreement.

4. UNDERTAKING THE PROJECT

- 4.1 Each Participant shall carry out the tasks specifically allotted to it in the Project, both in relation to the completion of each such Participant's Allocated Work, and in relation to all other undertakings and obligations pursuant to the Grant Agreement and the Project Agreement.
- 4.2 Without limitation to the generality of Clause 4.1, each Participant shall promptly, at the request of the Coordinator or as may be otherwise specified in this Project Agreement, 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 Project Agreement, (and in particular the provisions of Clause 8), or under the Grant Agreement.
- 4.3 Although each Participant will use reasonable endeavours to carry out its Allocated Work, no Participant undertakes that any research will lead to any particular result, nor does it guarantee a successful outcome to the Project.
- 4.4 Where a Participant intends to sub-contract a share of its Allocated Work to a Sub-contractor, pursuant to Annex I of the Grant Agreement, such Participant shall be liable for the acts and omissions of its Sub-contractor as if those acts and omissions have been performed by such Participant and, as such, shall remain responsible for the implementation of such share and for the satisfaction of all obligations relative to such share arising under this Project Agreement and under the Grant Agreement. Other than to the extent provided in the Project, or as may be otherwise expressly permitted either under the Grant Agreement or pursuant to any provision of this Project Agreement, no Participant shall be entitled to sub-contract any part of its Allocated Work to a Sub-Contractor

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unless the prior written approval has been obtained from the Coordinator, who will ensure consent from the Steering Committee.

- 4.5 Each Participant represents and warrants that any human tissue or other biological samples and data obtained from donors of such tissue or samples required for use in the Project to be 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 use of personally identifiable information and that any Ethics Committee approvals and donor informed consents required will be obtained prior to the commencement of the respective part of the Project work. Each Participant agrees to permanently anonymise any data obtained from a donor of tissue or other biological sample prior to transferring such data to another Participant.
- 4.6 Unless otherwise required or prohibited by law, the Participants warrant, to the best of their knowledge, that in relation to the performance of this Project 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 Participants to their employees is safe for habitation. The Participants 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, 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.

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

- 4.7 With respect to the Allocated Work and payments or services provided under the Grant Agreement and Project Agreement, none of the Participants has taken and will not during the term of the Project and Grant Agreements take any action directly or indirectly to offer or pay, or authorize the offer or payment of, any money or anything of value in order to improperly or corruptly influence any Government Official or to otherwise obtain an improper advantage from such Governmental Official.
- 4.8 The Participants shall perform their obligations and exercise their rights under this Project Agreement and the Grant Agreement in accordance with all applicable laws and regulations.

5. PROJECT MANAGEMENT

In order to achieve the goals of the Project, the management structure is organised into the various committees and representatives including but not limited to the task forces, advisory boards, and management units referenced in this Article 5.

For the avoidance of doubt, prior to the engagement of any and all Third Parties for any reason for the purposes of this Project as may be contemplated under this Project Agreement, each such Third Parties shall first execute a separate legally written binding confidentiality agreement made effective only upon collection of the signatures of all Participants, the terms of which shall be equivalent to those terms described under Article 8 of this Project Agreement. Each such confidentiality agreement shall be contemplated on a needs basis subject to oversight and approval by the Steering Committee and negotiated and executed on a party-by-party basis. To the extent the Participants wish to engage any Third Parties to provide services, each such Third Party shall first enter into a separate legally binding written agreement with the Participants on such terms that are acceptable to the Participants. Such agreement shall be made effective only upon the collection of the signatures of all Participants. For the avoidance of doubt, such requirements for separate confidentiality obligations with respect to Third Parties contemplated here will not be required to the extent such confidentiality obligations are satisfied under Article 8.

Executive Committee (EC)

- 5.1 The EC shall be responsible for the operative work of the Project and the day to day coordination between the meetings of the Steering Committee.
- 5.2 The EC will be made up of the Coordinator, his deputy, the Managing entity of the IMI JU funding and his deputy. The Executive Committee will be chaired by the Coordinator.
- 5.3 Members of the EC will each have one vote in the EC. For clarity, 75% of the voting members of the EC must be present for quorum, and decisions will be taken by a simple majority. If consensus cannot be achieved, the Coordinator will have a casting vote.

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- 5.4 Also attending the EC, but in a non-voting role are the Project Manager, the chairs of the Technical Task Force and Scientific Task Force, and the chair of the Scientific Advisory Board. The EC may also call specific or all Work Package leaders for a meeting if a wider consensus on scientific issues are needed. For the avoidance of doubt, only the EC will have voting rights.
- 5.5 The EC will report to the SC during its regular meetings. The EC shall propose or decide on the following matters, provided such matters and their implementation are in compliance with the terms of the Grant Agreement:
- (a) Receiving, reviewing and preparing all Project Deliverables required for approval by the SC;
 - (b) Deciding upon the technical roadmaps with regard to the Project;
 - (c) Reviewing budget assignments within the Project to ensure they are in agreement with the corresponding SC decisions;
 - (d) Proposing changes to the work plan, funding, Project and to the composition of the consortium to the SC;
 - (e) Receiving a priori information of all publications related to Foreground intended by Participants, and subsequently informing the rest of Participants, according to Section 19.
- 5.6 The EC will participate in meetings every two (2) weeks by tele-conference and four (4) times a year in face-to-face meetings, at venues to be agreed. Face-to-face meetings of the EC will be convened with at least twenty-one (21) days written notice in advance. That notice must include an agenda. Minutes of the meetings of the EC will be prepared by the chair of the meeting and sent to each of the EC meeting participants within fourteen (14) days after each meeting.

Steering Committee (SC)

- 5.7 The Project shall have an SC. The SC shall be responsible for the determination of policies and decision making in relation to the overall management of the Project and the initial arbitration of any disputes between the Participants relating to the execution of the Project.
- 5.8 The SC will be made up of one Representative nominated by each of the Participants. If necessary, in the event that an SC member cannot attend a scheduled meeting, each Participant shall also be entitled to nominate a replacement Representative. Contact details of Representatives from each Participant are listed in Appendix 1. In the event a Representative on the SC resigns and is not replaced as contemplated by this Article 5.8, the remaining members will solicit nominations for the SC position from the Participants to maintain the balanced mix of academic and EFPIA members. For the avoidance of doubt, no Participant has any authority to make any representation or commitment, or to incur any liability, on behalf of another (absent) Participant.

- 5.9 Any experts or qualified persons may be invited by any Representative of the SC to attend meetings of the SC with a role of non-voting advisor. Prior to their first participation in a meeting of the SC or their first receipt of Confidential Information, any Third Party expert or qualified person shall first enter into a suitable confidentiality agreement with the Participants, which enables the Participants to comply with the provisions of Article II.9 of the Grant Agreement. For the avoidance of doubt, such experts or qualified persons may be employees of Participants other than Representative.
- 5.10 The SC will be jointly chaired by the Coordinator and the Managing entity of the IMI JU funding (the “Co-Chairs”). The Co-Chairs shall:
- (a) be responsible for the preparation and distribution of the agenda and minutes for meetings of the SC;
 - (b) chair meetings of the SC.

Where the Co-Chairs cannot attend a SC meeting, they shall nominate a replacement to chair the meeting for the purposes of such meeting of the SC only, provided that the replacement must be a Representative.

- 5.11 The SC 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 Coordinator in fulfilling its obligations towards the IMI JU;
 - (b) monitoring the progress of the Project based on input from the EC;
 - (c) making proposals to the Participants (other than a Defaulting Participant) in relation to the service of notice on a Defaulting Participant in accordance with Clause 22 and the reassignment of that Defaulting Participant 's Allocated Work;
 - (d) the inclusion of a new Participant in the Project;
 - (e) agreeing press releases and (without prejudice to Clause 19) publications by the Participants with regard to the Project;
 - (f) agreeing (without prejudice to Clause 19) on procedures and policies in accordance with the Grant Agreement, Article II.34 for dissemination of Foreground from the Project;
 - (g) agreeing adequate management procedures and standards for the Project;
 - (h) analysing and approving the Project Deliverables;
 - (i) during the Project, receiving all requests for Access Rights to Background and/or Foreground which a Participant may wish to make, and forwarding, as appropriate, to the concerned Participant;
 - (j) deciding upon measures in the framework of controls and audit procedures to ensure the effective day-to-day coordination and monitoring of the progress of the technical work affecting the Project as a whole;

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- (k) agreeing when and where SC meetings should be held, and providing the Coordinator with agenda items for such meetings;
 - (l) taking all necessary decisions with regard to its responsibilities without undue delay and for the best of the Project;
 - (m) without limitation to any of the foregoing responsibilities, proper management and administration of the Project and implementation of the provisions contained in the Grant Agreement and in this Project Agreement.
 - (n) approval of Participants' subcontractors as set forth in Clause 4.4.
 - (o) making the open source Foreground publicly available following the authorisation to publish procedure that the SC will decide on
- 5.12 Any Representative of the SC may participate in meetings of the SC by tele-conference, video-conference or any other technology that enables everyone participating in the meeting to communicate interactively and simultaneously with each other if technically possible at the meeting facilities.
- 5.13 The Participants will ensure that the SC meets at least every six (6) months at venues to be agreed, or at any other time at the request of any of the Participants. Meetings of the SC will be convened with at least twenty-one (21) days written notice in advance. That notice must include an agenda. Minutes of the meetings of the SC will be prepared and sent to each of the Participants within fourteen (14) days after each meeting. Comments to the minutes will be accepted until fourteen (14) working days after they have been submitted, whereafter they will be considered final.
- 5.14 Following expiry or early termination of the Project, the SC shall remain in force for at least one year solely for the purpose of receiving and reviewing intended Publications from Participants in accordance with clause 19.1.
- 5.15 Each Participant will, through its Representative or his alternate, have one vote in the SC. Decisions will be taken by a two-thirds majority. The Coordinator will inform the IMI JU of any such decision.
- 5.16 In order for an SC meeting to be quorate no fewer than 75% of all Representatives shall be present physically, or via tele-conference, video-conference or other technology.
- 5.17 Where an SC meeting shall be inquorate, the Coordinator shall reconvene the Representatives at a date no later than three weeks from the date of the original meeting, and shall advise the Representatives accordingly by notice in writing.
- 5.18 The Participants agree to abide by all decisions of the SC, provided always that a Participant whose scope of work, time for performance, costs or liabilities are changed from those shown in the Project and/or Project Agreement, or whose Confidential Information, including without limitation any Background or Foreground, is to be published, disclosed or disseminated or whose name is to be included in a press release, may veto such decisions. In case of exercise of

veto, the SC shall make every effort to resolve the matter which occasioned the veto to the general satisfaction of all the Participants within 14 days from the lodging of such veto.

Associated Partners (AP)

5.18 AP's will comprise Third Party organisations engaged in the Project through contributions of data, tools or services but not receiving IMI JU funding. The AP shall ensure any outputs of the Project, not limited to but including scientific approaches, methodologies, best practices and semantic standards will be followed and adopted by the global scientific community.

5.19 Subject to Article 5.9, AP representatives will be invited to attend SC meetings as non-voting observers.

Scientific Advisory Board (SAB)

5.20 The SAB is an external and independent body of experts in the computational science and/or drug discovery domain, representing the global scientific user community, in particular, USA and Asia. The experts of the SAB will act as non-voting advisers to the SC and EC on matters relating to the Project, including dissemination activities.

5.21 SAB representatives will be comprised of both academic and industry advisors with outstanding scientific expertise in the computational science and/or drug discovery domain. The SAB, including the chair of the SAB will be appointed by SC Representatives by consensus vote at the first SC meeting of the Project.

5.22 Subject to Clause 5.9, the SAB chair will be invited to attend all SC meetings and ad-hoc EC meetings as a non-voting observer.

Project Management Unit (PMU)

5.23 The PMU comprising a "Project Manager" ("PM") and a management office, will be located at the Managing Entity of the IMI JU funding (UNIVIE).

5.24 The PMU shall be responsible for the following tasks:

- (a) financial tracking and reporting, project secretariat, and 'back office' support.
- (b) providing support to the Coordinator and all committees in the day-to-day Project management including the organisation of meetings and the facilitation of communication among Participants.
- (c) . maintaining Project web-pages.
- (d) maintaining contact with the IMI JU and providing legal support for intellectual property issues in accordance with clause 5.26 below.

5.25 The PMU shall:

- (a) maintain an ongoing list of Foreground generated under the Project based on the information provided by the Participants.
- (b) ensure Participants review and update their Background listed in Appendix 3, on an annual basis.
- (c) subject in all respects to clauses 8 and 19, manage the dissemination of knowledge within and outside the consortium including publication strategy and intellectual property rights and propose a publication and IPR strategy to the SC and the EC which is consistent with the terms of this Project Agreement.

5.26 The Project Manager (PM) shall be responsible for the following tasks:

- (a) managing the Project with respect to checking timelines and Project Deliverables;
- (b) preparing agendas and assisting chairs in the dissemination of minutes following EC and SC meetings;
- (c) taking a leading role in the management of the online workspace.

Technical Task Force (TTF)

5.27 The TTF has overall responsibility for the technical integration of the WP's and to guide the development of all the software outlined in the respective WP's goals. This includes prototyping, beta-testing, implementation and release of the overall Project software, architecture, platform and the exemplar services.

5.28 TTF members will be nominated by the Participants and endorsed by the EC. The TTF will be made up of six (6) – eight (8) Representatives split equally between EFPIA members and academia. The TTF chair will be appointed by the EC after consultation with the TTF and will effectively operate as the Chief Technology Officer (“CTO”) of the Project.

5.29 The CTO will attend EC meetings to represent technical components of all WPs, and offer technical advice to voting EC Representatives. For the avoidance of doubt, Representatives cannot be a member of two committees at the same time.

5.30 Each WP will be monitored and technically supervised by a Technical Project Leader (TPL), who form the core of the TTF. TPLs are responsible for the tactical technical aspects of the WPs and assist in translating the long term goals of the WP into practical steps to be implemented.

5.31 Each TPL will provide regular reports about the technical progress of their respective WP to the TTF.

Scientific Task Force (STF)

- 5.32 The STF has responsibility for coordinating the broad scientific initiatives under the Project ranging from data mining, annotation, small molecule data storage and manipulation, target related bioinformatics, pathway annotation, protein structure analysis, massive daily *in silico* reasoning and meta-analysis, chemical biology, cheminformatics and medicinal chemistry.
- 5.33 STF members will be nominated by the Participants and endorsed by the EC. The STF will be made up of six (6) – eight (8) Representatives split equally between EFPIA members and academia. The STF chair will be appointed by the STF members
- 5.34 The STF chair will attend EC meetings and offer scientific advice to voting EC Representatives.
- 5.35 The STF will meet regularly for the first eighteen (18) months of the Project, which will reduce in frequency for the remainder of the Project.

Work Packages (WPs) and Work Package Leaders (WPLs)

- 5.36 All WPs will be jointly coordinated by an EFPIA Representative and an academic Representative, and will be known as the WPLs.
- 5.37 The WPLs shall be responsible for the following tasks:
- (a) day-to-day management and coordination activities of their respective WP;
 - (b) production of Project Deliverables and delivery of WPs;
 - (c) monitoring the progress of the WP and reporting back to the SC and EC;
 - (d) coordinate with the TTF for technical implementation of the prototypic outputs of their WP.
- 5.38 The WPL's will participate in regular meetings by tele-conference and at least twice a year in face-to-face meetings, at venues to be agreed.
- 5.39 Any issues that cannot be resolved by WPLs will be referred back to the EC or WPLG as appropriate.

Work Package Leaders Group (WPLG)

- 5.40 The WPLG is composed of all WPLs and will be responsible for tactical issues relating to interdependence between WPs.
- 5.41 The WPLG will be a forum for WPLs to report progress of their WPs and request additional support if appropriate, in order to deliver the WP.

- 5.42 The WPLG will participate in regular meetings four (4) times a year in face-to-face meetings, at venues to be agreed. Meetings will be chaired by the Coordinator. EC members will attend WPLG meetings on an ad-hoc basis.

The Coordinator

- 5.43 The Coordinator is and shall be the single point of contact between the Participants and the IMI JU. Other than where expressly provided in this Project Agreement, any information, report or other correspondence which a Participant, pursuant to the provisions of this Project Agreement or of the Grant Agreement, shall be required to communicate to the IMI JU, shall be provided to the Coordinator for onward transmission. The Coordinator shall forward any such correspondence promptly upon receipt. The Coordinator shall be the leader of the consortium.

- 5.44 The Coordinator will perform certain duties as part of the general management of the Project, as provided for in the Grant Agreement. In particular, the Coordinator shall be responsible for:

- (a) instructing the Managing entity of the IMI JU funding of the allocation and distribution of the IMI Financial Contribution among Participants eligible to receive IMI JU funding, in accordance with the Grant Agreement and the decisions taken by the consortium;
- (b) reviewing and submitting the Project Deliverables to the IMI JU;
- (c) monitoring the compliance by Participants with their obligations under the Grant Agreement
- (d) instructing the Participants of due dates for Project Deliverables and collecting them from each Participant;
- (e) implementing the decisions of the SC and EC;
- (f) the transmission of any documents and information connected with the Project to and between the Participants concerned;
- (g) coordinating on a day-to-day basis the progress of the technical work under the Project;
- (h) overseeing the contractually agreed audit regime that enables the IMI JU to proceed to audits, dealing with technical, financial, technological (innovation impact) and ethical aspects;
- (i) working with Participants to prepare and negotiate any non-disclosure agreements that may be required;
- (j) ensuring that each Participant is in a position to accede to the Grant Agreement and accept its associated special clauses by updating the Participants as to the progress of, and is able to comment on the content of, the Grant Agreement negotiations.

- 5.45 The Coordinator shall neither be entitled to act or to make legally binding declarations, on behalf of any other Participant nor to enlarge his role beyond

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the one described herein and in the Grant Agreement, without the prior written consent of the Participants.

- 5.46 The Coordinator shall not be entitled to make any representation or commitment on the part of the Participants or any of the Participants other than to the extent expressly authorised in the Grant Agreement or in this Project Agreement.
- 5.47 If the IMI JU and/or any of the Participants raise serious concerns regarding the financial soundness of any of the Participants, the Coordinator has the authority to require an appropriate letter of comfort to substantiate that the corresponding Participant is able to fulfil its financial obligations with regard to the Grant Agreement and this Project Agreement. Until this is provided, the Coordinator shall be entitled to instruct the Managing entity of the IMI JU funding to refuse the disbursement of the IMI JU financial contribution to such Participant eligible to receive IMI JU funding.
- 5.48 The Coordinator has the right to instruct the Managing entity of the IMI JU funding to withhold any payment if a Participant eligible to receive IMI JU funding is late in submitting or refuses to provide Project Deliverables as required under the Grant Agreement and this Project Agreement. For the avoidance of doubt, such a Participant will be given ten (10) days notice by the Coordinator prior to withholding of the funding.
- 5.49 If one or more of the Participants is late in submitting Project Deliverables, or any other information or material required under the Grant Agreement or under this Project Agreement, the Coordinator shall submit the other Participants' Project Deliverables to the IMI JU without the contribution of the defaulting Participants and report the delay of these Participants to the IMI JU.

Managing entity of the IMI JU funding

- 5.50 The Managing entity of the IMI JU funding shall be responsible for:
- (a) receiving all payments made by the IMI JU;
 - (b) taking instruction from the Coordinator as to the amounts of, and distribution of, IMI JU funding to Participants eligible to receive IMI JU funding;
 - (c) ensuring that all the appropriate payments are made to the Participants eligible to receive IMI JU funding without unjustified delay
 - (d) keeping accurate accounts of the amounts of, and distribution of, IMI JU funding to Participants eligible to receive IMI JU funding;
 - (e) informing the Coordinator and the IMI JU of the distribution of IMI JU funding and the dates of such transfer to Participants eligible to receive IMI JU funding.

6. FINANCIAL PROVISIONS

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- 6.1 Each Participant shall maintain financial records in relation to its activities within the Project, including its Sub-contractors.
- 6.2 The Coordinator shall give each Participant a minimum of forty-five (45) days prior notice of the deadline to produce a specific cost statement as prescribed in the Grant Agreement and each Participant shall be responsible for the preparation and obtaining of an audit certificate/report for each of the cost statements as may be required by the Grant Agreement. The Coordinator must receive these within sixty (60) days of the period end.
- 6.3 The IMI JU financial contribution shall be of indicative value only. The Participants eligible to receive IMI JU funding agree that their respective entitlements to the IMI JU financial contribution 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 the Participants shall determine the Project should proceed and the consequent allocation of costs amongst them. Accordingly, no Participant eligible to receive IMI JU funding shall be entitled to receive specific IMI JU financial contribution other than in accordance with the Grant Agreement and this Project Agreement.
- 6.4 The Managing entity of the IMI JU funding shall receive all payments made by the IMI JU. The Managing entity of the IMI JU funding undertakes to transfer, in accordance with the Grant Agreement and as instructed by the Coordinator, the appropriate sums to the respective Participants eligible to receive IMI JU funding with minimum delay, but not later than thirty (30) calendar days from its receipt thereof from the IMI JU. The Managing entity of the IMI JU funding will notify each of the other Participants eligible to receive IMI JU funding promptly of the date and amount transferred to its respective bank account and shall give the relevant references.
- 6.5 Bank deposit details of each Participant eligible to receive IMI JU funding shall be provided to the Managing entity of the IMI JU funding within thirty (30) days of each such Participant's signature of this Project Agreement.
- 6.6 For the avoidance of doubt, the provisions of this Clause 6 shall apply in relation to any proportion of a Participant's Allocated Work which such Participant shall have properly, in accordance with the Grant Agreement and/or this Project Agreement, sub-contracted to a Third Party, as if such Participant had undertaken such proportion on its own account.

7. LIABILITIES OF THE PARTICIPANTS

To each other

- 7.1 In respect of information (including software and computer models) or Materials supplied by one Participant to another hereunder or pursuant to the Grant Agreement, the supplier Participant 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 proprietary rights of third parties or the other Participants. Participants, by the use of such information and materials and the recipient Participant shall in any case be entirely responsible for the use to which it puts such information and Materials.

- 7.2 Each Participant “the Indemnitor” shall indemnify each other Participant (“the Indemnitee” and hold each such Indemnitee harmless from and against all loss, damage, cost, expense, liability or injury incurred by such Indemnitee resulting from any claim, suit, complaint, proceeding or cause of action brought by a Third Party alleging or arising out of our connected to the (i) gross negligence or wilful misconduct of the Indemnitor or (ii) infringement of Third Party intellectual property rights by itself, its employees, Sub-contractors or Affiliated Entities or its agents; provided always that the foregoing obligation to indemnify shall not extend to claims for indirect, incidental, special, punitive or consequential loss, expense or damage, including but not limited to loss of profit, revenue, business, goodwill or contracts, and provided that the total limit of liability of any Participant to the other Participants collectively in respect of any one claim or series of connected claims, shall not exceed that Participant’s Project Share.
- 7.3 Nothing in this Project Agreement may be construed to limit (i) the right of any Participant 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 Participant for personal injury or death resulting from the negligence of such Participant or its employees, officers, directors, agents, or representatives (as applicable) or (iii) with prejudice to clause 7.3 (ii), the liability of any Participant in the event of such Participant’s gross negligence or wilful misconduct.
- 7.4 The Indemnitee shall immediately advise the Indemnitor of any such 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 set out in clause 7.2. The Indemnitee shall reasonably co-operate with the Indemnitor and its legal representatives in the investigation and defence of any such claim. The Indemnitee shall refrain from making any admission of liability or any attempt to settle the claim without the Indemnitor’s prior written consent. The Indemnitee may obtain representation by separate legal counsel, at its own expense.
- 7.5 If any refund or reimbursement of monies (including without limitation in respect of overpayment or failure in performance of work) is requested by IMI JU in respect of a Participant’s works under the Project, that Participant shall be solely liable to IMI JU in respect of such sum, and shall indemnify the other Participants from any and all liability of such other Participants to IMI JU.

Towards Sub-contractors

- 7.6 Subject always to such other undertakings and warranties as are provided for in this Project Agreement and the Grant Agreement, each Participant shall be solely liable for any loss, damage or injury to Sub-contractors resulting from

carrying out its Allocated Work and from its use of Foreground and/or Background, or from entering into or defaulting under any contractual or other relationship with any such Sub-contractor(s).

Freedom to Operate

7.7 Without prejudice to any of the foregoing provisions of this Clause 7, each Participant acknowledges that it shall be solely responsible for ensuring that it has all necessary licences under intellectual property owned by Third Parties (that are not Affiliated Entities of a Participant) to enable it to complete the Project and make any Research Use of Foreground or undertake the Direct Exploitation of Foreground whether owned by it or to which is has been granted Access Rights hereunder.

8. CONFIDENTIALITY

8.1 No Confidential Information disclosed by one Participant ("Disclosing Participant") to another Participant ("Recipient Participant") under this Project Agreement may be disclosed by the Recipient Participant to any Third Party other than in those circumstances permitted below; provided that, in such permitted circumstances, it shall nevertheless be a condition of disclosure that such Third Party shall, as appropriate, be made aware of the confidential nature of the information disclosed and shall be bound to comply with confidentiality provisions no less onerous than those provided in this Project Agreement. Any disclosure of Confidential Information to an Affiliated Entity and/or a Sub-contractor of a Participant shall be regarded as a disclosure to that Participant. The Recipient Participant shall be responsible to the Disclosing Participant for any disclosure by any such Third Party which shall be inconsistent with the terms of this Project Agreement. Permitted disclosure under this Clause shall be as follows:

- (a) to employees, Affiliated Entities, agents, officers, directors, auditors, advisers, partners, consultants, licensees, sub-licensees, students, or Sub-contractors of the Recipient Participant requiring the Confidential Information for the purposes of this Project Agreement;
- (b) if the Recipient Participant 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 Participant with a view to agreeing the timing and the content of such disclosure, and to enable the Disclosing Participant to seek a protective order or otherwise try to prevent disclosure of such information. Any Participant disclosing information under this Clause 8 must use all reasonable endeavours to ensure that persons receiving Confidential Information from it do not disclose the same.

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- 8.2 No Confidential Information of the Disclosing Participant may be used by the Recipient Participant for any purpose other than the performance of the Recipient Participant's obligations or the exercise of the Recipient Participant's rights under this Project Agreement.
- 8.3 The provisions of this Clause 8 shall not apply to Confidential Information which:
- (a) is, at the time of communication, in the public domain;
 - (b) after the communication, becomes part of the public domain by publication or otherwise, except by breach of this Project Agreement by the Recipient Participant ;
 - (c) is obtained from a Third Party not in breach of any obligation of confidentiality; or
 - (d) is known by the Recipient Participant prior to the date of the communication; or
 - (e) was in the Recipient Participant's possession before receipt hereunder and/or was independently developed by any student, employee, agent, officer, auditor, advisor, partner, consultant, licensee, sub-licensees or Sub-contractor of the Recipient Participant who had no access to the Confidential Information and where the independent development can be proven.
- 8.4 The Recipient Participant shall return to the Disclosing Participant or destroy all documents or other materials containing any of the Disclosing Participant's Confidential Information which are in its possession, power or control or in the possession, power or control of persons who have received such Confidential Information from it pursuant to this Clause, whenever requested to do so by the Disclosing Participant, where such Confidential Information is not required by the Recipient Participant for the use or exercise of (i) Access Rights for completing the Project or (ii) other rights or licences contemplated in this Project Agreement, provided, however, that the Recipient Participant shall be entitled to keep one (1) copy of the Confidential Information in its confidential files solely for the purpose of ensuring its compliance with this Project Agreement.
- 8.5 In the event that a Participant intends to exchange personally identifiable information prior to disclosure, the Participants concerned will enter into an appropriate data transfer agreement in order to comply with their obligations under applicable laws including European Parliament and Council Directive 95/46.
- 8.6 Subject to Clause 19.2, the obligations of confidentiality and non-use in this Clause 8 will survive the expiry or earlier termination (for whatever reason) of this Project Agreement, or the termination of the participation of a Participant, for a period of five (5) years from such expiry or termination, or such longer

period as agreed between the Participants. In the Grant Agreement the IMI JU undertakes to preserve the confidentiality of Confidential Information until five (5) years after the completion of the Project. Upon a duly substantiated request by a Participant, the IMI JU may agree to extend this period regarding specific Confidential Information.

9. MATERIAL TRANSFER OBLIGATIONS

If any Materials are transferred from one Participant (“Providing Participant”) to another Participant (“Receiving Participant”), or between their Sub-Contractors and/or Affiliated Entities, each Receiving Participant shall be bound by the following provisions and shall be responsible for ensuring that its Sub-Contractors and/or Affiliated Entities comply with such provisions:

- 9.1 The Receiving Participant has all the required authorisations under all applicable laws and regulations to perform the experimental work in vitro at the place of investigation using the Materials.
- 9.2 The Materials will be used in full compliance with all applicable laws and regulations.
- 9.3 The Materials will be used solely for performance of the Project in accordance with this Project Agreement. The Materials will under no circumstances be administered to humans unless this is specifically required in Annex I of the Grant Agreement. The Materials or animals treated therewith will under no circumstances be used as food for humans or animals.
- 9.4 The Materials will not be analyzed or modified except as necessary for the purpose of the Project.
- 9.5 The Materials will not be transferred or made available to any individual other than those under the supervision and control of the Receiving Participant, its Affiliated Entities or Sub-contractors. Upon completion of the Project, or the expiry or termination of this Project Agreement, any unused Materials will be either returned to the Providing Participant which made them available or disposed of/destroyed in accordance with all applicable laws and regulations.
- 9.6 All Materials are transferred with no warranties, express or implied, of merchantability or fitness for a particular purpose or otherwise. In particular, no Providing Participant represents or warrants that the use of the Materials will not infringe or violate any patent or proprietary rights of third parties.
- 9.7 The Materials are to be used with caution and prudence in any experimental work, since not all of the characteristics are necessarily known. The Receiving Participant using the Material shall bear all risk to it and/or any others resulting, directly or indirectly, from its use, application, storage or disposal/destruction of the Materials.

- 9.8 The Receiving Participant shall have no rights in the Materials except otherwise agreed under this Project Agreement or a respective Material Transfer Agreement. The Receiving Participant agrees that nothing in this Project Agreement and the transfer of Material shall be deemed to grant to the Receiving Participant any rights under any Providing Participant's patents/know-how or related industrial rights or any other rights to use the Material for any products or processes for profit-making and/or commercial purposes unless otherwise agreed upon.

10. OWNERSHIP OF BACKGROUND

- 10.1 Each Participant shall remain the exclusive owner of its Background and participation to the Project shall not affect such ownership rights in its Background, without prejudice to any rights and obligations under this Project Agreement and the Grant Agreement.
- 10.2 The Background shall be identified in the Project Agreement, as outlined in Appendix 3.

For the avoidance of doubt, any information, including data and know-how held by a Participant prior, on or after accession to the Grant Agreement, as well as copyrights or other intellectual and industrial property rights pertaining to such information, which is necessary or desirable for carrying out the project, but which is not defined in Appendix 3 shall not be considered Background (albeit ownership shall remain with the Participant or the originating party), and although such information may be used by or on behalf of the holding Participant in performing its Allocated Work under this Agreement, such information shall not be subject to Access Rights under this Agreement.

- 10.3 Each of the Participants have informed the Coordinator of any legal restrictions of which they are aware that may affect the use of their respective Background for Research Use or for completing the Project in accordance with Article II.25.2 of the Grant Agreement. The Coordinator shall inform the IMI JU of such restrictions and include such information in Appendix 3 of this Project Agreement.
- 10.4 Each Participant represents and warrants that it owns its Background and to its best knowledge has the right to grant the licenses set out and contemplated herein to its Background, save that UNIMAN represents and warrants that with respect to the Taverna software listed in Appendix 3, the other Participants do not need to enter into any publicly accessible software licenses beyond those described for each as further set forth in Appendix 3 in order to use such software as contemplated in this Agreement.
- 10.5 Each Participant may transfer ownership of its own Background following the procedures of the Grant Agreement Article II.25.
- 10.6 In the case of a transfer of ownership of Background to a Third Party the prior written consent of the other Participants is not required.

- 10.7 The transferring Participant shall, however, notify the other Participants of such transfer and shall ensure that the rights of the other Participants will not be affected by such transfer by making such transfer subject to the assignee agreeing in writing to be bound by the obligations applicable to such Background in the Grant Agreement and Project Agreement.

11. OWNERSHIP OF FOREGROUND

- 11.1 Subject to Clauses 11.2 to 11.6 below, Foreground shall belong to the Participants who generated it under the Project.
- 11.2 Where several Participants shall have generated Foreground and where it is not reasonably possible to distinguish their respective shares therein, such Foreground shall be jointly owned between/amongst them (the “Co-owners”). Such Co-Owners shall fully disclose any such joint interest to all other Participants through the SC.
- 11.3 In the case of joint ownership of Foreground, each Co-owner will be granted a non-exclusive, world-wide, fully paid up, royalty-free, perpetual, irrevocable licence to use the jointly owned Foreground for Research Use, including the right to grant non-exclusive sub-licences to its Affiliated Entities and to Third Party Collaborators 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 Foreground, including the right to grant non-exclusive licences subject to the following conditions:
- (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
- 11.4 Where a Participant in accordance with the Grant Agreement and/or this Project Agreement, has sub-contracted any part of such Participant’s Allocated Work, that Participant shall ensure that any Foreground arising thereunder will be owned in accordance with Clause 11.1
- 11.5 Each Participant may license, assign, or otherwise dispose or transfer ownership of its own Foreground or of jointly owned Foreground following the procedures of the Grant Agreement Article II.26. The other Participants hereby waive their right to object to such transfer if it is to its Affiliated Entity; any purchaser of all or substantially all of its assets; or any successor entity resulting from the merger or consolidation of such party with or into such entities. The transferring Participant shall, however, notify the other Participants of such transfer and shall ensure that the rights of the other Participants will not be affected by such transfer. The assignee shall agree in writing to be bound by the Grant Agreement and Project Agreement. These requirements to notify the other Participants and to secure the assignee’s agreement to be bound by the Grant Agreement and the Project Agreement shall not apply when the assignee is an

Affiliated Entity of the relevant Participant. Each Participant warrants that any assignee which is its Affiliated Entity at the time the Foreground is assigned, will comply with that Participant's obligations under the Grant Agreement and the Project Agreement to the extent that those obligations apply to the assigned Foreground.

- 11.6 If employees or any Third Party working on behalf of a Participant are entitled to claim rights to Foreground, the Participant shall ensure that it is possible to exercise those rights in a manner compatible with its obligations under the Grant Agreement and this Project Agreement.

12. OWNERSHIP OF SIDEGROUND

- 12.1 Ownership of Sideground belongs to the Participants who generated it.

13 GENERAL PROVISIONS APPLYING TO ACCESS RIGHTS

- 13.1 Participants, may, in their sole discretion, introduce into the Project any data, know-how, information, copyrights or other intellectual and industrial property rights pertaining to such information that are generated, held or acquired by it outside the Project after the date of this Project Agreement, by updating the details of Appendix 3.
- 13.2 All Access Rights granted pursuant to this Project Agreement shall be granted on a non-exclusive basis and shall not include any right to sub-license except to: (i) Sub-contractors for the purpose of performing the sub-contracted aspects of the Project; (ii) Affiliated Entities for Research Use; and (iii) Third Party Collaborators for Research Use in connection with work for, or for the benefit of, a Participant or a Participant's Affiliated Entities.
- 13.3 Foreground and Background shall be used only for the purposes for which Access Rights to the same have been granted and only for so long as is necessary for those purposes.
- 13.4 During the Project, all Access Rights under Clauses 16 and 17 shall be submitted as a written request to the granting Participant via the SC. Following the expiry or earlier termination of the Project, Access Rights shall be submitted as a written request directly to the granting Participant.

14. ACCESS RIGHTS TO PARTICIPANTS AND AFFILIATED ENTITIES FOR COMPLETING THE PROJECT

Foreground

- 14.1 During the Project, and subject to the provisions of this Project Agreement (including Clauses 8 and 13), each Participant and its Affiliated Entities are hereby granted Access Rights to the Foreground of any other Participants, solely for the purpose and to the extent necessary to undertake each such Participant's

own Allocated Work and also sub-contractable for each such Participant's Sub-contractor to perform such Allocated Work.

14.2 Such Access Rights are granted under Clause 14.1 on a royalty-free, fully paid up basis.

Background

14.3 During the Project, and subject to the provisions of this Project Agreement (including Clauses 8 and 13), each Participant and its Affiliated Entities are hereby granted Access Rights to the Background of the other Participants solely for the purpose and to the extent necessary to undertake each such Participant's own Allocated Work and also sub-contractable for each such Participant's Sub-contractors to perform such Allocated Work. As provided for in Article II.25 of the Grant Agreement, prior to the execution of the Grant Agreement, the Participants shall identify any limitation to the granting of Access Rights to Background or of any other restriction which might substantially affect the granting of Access Rights. Such restrictions shall be identified in Appendix 3.

14.4 Such Access Rights are granted under Clause 14.3 on a royalty-free, fully paid up basis.

15. ACCESS RIGHTS TO THE PARTICIPANTS AND AFFILIATED ENTITIES FOR RESEARCH USE

Foreground

15.1 During and after completion of the Project, and subject to the provisions of this Project Agreement (including Clauses 8 and 13), each Participant and its Affiliated Entities is hereby granted Access Rights to the Foreground of the other Participants, solely and to the extent necessary for the purposes of Research Use.

15.2 Such Access Rights to Foreground for the purposes of Research Use are granted under Clause 15.1 on royalty-free, fully paid up conditions. For the avoidance of doubt, such Access Rights to Foreground are granted to use for research and development purposes for the commercialization of pharmaceutical products.

15.3 Any Research Use of the Foreground belonging to any other Participant pursuant to this Clause 15 shall acknowledge the ownership of such Participant and shall identify the Project as the source thereof.

Background to use Foreground

15.4 The Participants have listed or summarised in Appendix 3 certain Background which each such Participant shall offer Access Rights to in accordance with the provisions of this Project Agreement. Any limitation to the granting of Access Rights to Background or of any other restriction which might substantially affect the granting of Access Rights shall be identified in Appendix 3 as well.

15.5 During and after completion of the Project, and subject to the provisions of this Project Agreement (including Clauses 8 and 13), each Participant and its Affiliated Entities is hereby granted Access Rights to the Background of the other Participants but only to the extent reasonably required for and only for the purpose of the Research Use of Foreground.

15.6 Such Access Rights to Background for the purpose of Research Use of Foreground shall be granted on royalty-free, fully paid up conditions.

16. ACCESS RIGHTS TO THIRD PARTIES FOR RESEARCH USE

Foreground

16.1 After completion of the Project, subject to the provisions of this Project Agreement (including Clauses 8 and 13), Third Parties shall be entitled to receive under licence, Access Rights to the Foreground of the Participants, solely and to the extent necessary for the purposes of Research Use.

16.2 Such Access Rights to Foreground for the purposes of Research Use are granted under Clause 16.1 on a royalty free basis.

Background to use Foreground

16.3 After completion of the Project, subject to the provisions of this Project Agreement (including Clauses 8 and 13), Third Parties shall be entitled to receive under written licence, Access Rights to the Background of the Participants solely and to the extent necessary for the purposes of Research Use of Foreground. Before execution of the Grant Agreement, a Participant may identify specific elements of the Background and provide a reasoned request to the IMI JU that such elements shall be wholly or partially excluded from the obligations referred to in this section. The IMI JU shall only grant such request in exceptional circumstances and in making its decision shall consider the objectives of IMI as described in the Statutes. It may grant such a request on such conditions as it may agree with the Participant. Any exceptions shall be included in the Grant Agreement and cannot be changed unless such change is permitted in the Grant Agreement.

16.4 Such Access Rights shall be granted on fair and reasonable conditions..

17. ACCESS RIGHTS FOR DIRECT EXPLOITATION

17.1 Subject to Clause 11.3. Participants may use, exploit, sublicense or otherwise commercialise their Foreground, Background and Sideground as they see fit beyond the Research Use.

- 17.2 Where Direct Exploitation by a Participant or Third Party requires Foreground or Background necessary to use Foreground owned by another Participant, the Access Rights will be negotiated between the parties involved as they see fit.

18. ACCESS RIGHTS FOR NEW AND DEPARTING PARTICIPANTS

- 18.1 Participants joining the Project in accordance with the provisions of Clause 20, will be granted the Access Rights as provided for in Clauses 14 to 17 hereof as from the date of their signature of the Form of Accession as described in Appendix 4 of this Project Agreement. Such Access Rights will be retroactive to the date of the Project Agreement.

- 18.2 For Participants leaving the Project in accordance with the provisions of Clauses 21 and 22 hereof the following provisions will apply:

- (a) With the exception of the cases where the participation of a Participant 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 Project Agreement shall continue in full force and effect.
- (b) Defaulting Participants shall be obliged to continue to grant Access Rights pursuant to the Grant Agreement and this Project Agreement, but the Access Rights granted to the Defaulting Participant pursuant to this Project Agreement shall cease immediately upon termination of the participation of the Defaulting Participant as a Participant to this Project Agreement, or the Grant Agreement, if earlier.

19. DISSEMINATION

- 19.1 A Participant wishing to disseminate information relating to Foreground will inform the other Participants via the SC with prior written notice of any such proposed dissemination. Any Participant may object to a publication within thirty (30) days of notification, but will include a request for necessary modifications at the time of such objection. If this objection is upheld, the publishing Participant will:

- (a) extend the review period and delay the proposed publication for a period not exceeding ninety (90) days;
- (b) and/or modify the publication as requested for scientific or patent reasons;
- (c) and/or delete such other Participant's Confidential Information from the intended dissemination.

- 19.2 For the avoidance of doubt, a Participant may not publish or communicate Foreground generated by another Participant or any Background of such other Participant, even if such Foreground or Background is amalgamated with such

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Participant's Foreground, without the other Participant's prior written approval except for communication to its Sub-contractors.

- 19.3 Nothing in this Project Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Participants or any of their logos or trademarks without their prior written approval.
- 19.4 Unless the IMI JU requests otherwise, any publication or dissemination activity that shall arise from the Project shall include:
- (a) mentioning of the IMI JU and/or the IMI JU logo to the extent allowable and;
 - (b) a statement specifying that the Foreground in question was made with the assistance of financial support from the IMI with reference to the Grant Agreement Number. This statement shall also appear on any patent application or patent issued on Foreground of the Project.
- 19.5 Details of any publication and an electronic copy of the published version must be provided to the IMI JU within two months following publication.
- 19.6 Each Participant shall disseminate its Foreground within one (1) year of the end of the termination or expiry of the Project. If the Participants do not disseminate within such time period without good reason (e.g. patent application filings still pending), the IMI JU has the right to disseminate such Foreground in a manner consistent with the Grant Agreement.
- 19.7 In accordance with Article II.34 of the Grant Agreement, a description of the material which must be disseminated is outlined in Appendix 5.
- 19.8 In the event the thirty (30) day period, as mentioned in clause 19.1 above, elapses without notification from the other Participants or (in case the extended period applies) if the ninety (90) day period has elapsed, the publishing Participant shall be free to disclose the publication/ presentation.
- 19.9 In any event, the objections are deemed to be withdrawn in case the publishing Participant removes all the parts of the publication/presentation objected to.

20. ADDITIONAL PARTICIPANTS

- 20.1 Where, during the continuance of the Project, and with the prior approval of the IMI JU in accordance with the procedures specified in the Grant Agreement, the Participants shall agree to admit additional Participants to the consortium, each such additional Participant shall, as a condition of admission be required to accede to the Grant Agreement by completion of a Annex IV (Form B).
- 20.2 Each such additional Participant shall, at the same time as its execution of Form B, enter the consortium upon signature of the Form of Accession shown in Appendix 4 by the new Participant and the Coordinator. Such accession shall have effect from the date identified in the Form of Accession.

21. TERMINATION

- 21.1 The IMI JU may terminate the Grant Agreement in accordance with Article II.37 of the Grant Agreement by notifying the Coordinator of its intent to terminate. The Coordinator shall, on receipt of notice of termination from the IMI JU, forthwith provide each Participant with written notice to such effect. For the avoidance of doubt, the effective date of termination in any such instance shall be forty-five (45) days from the date of the Coordinator's receipt of notice of termination of the Grant Agreement from the IMI JU. This Project Agreement shall thereafter be deemed to have terminated on the same date as the effective date of termination of the Grant Agreement.
- 21.2 The Participants may together, pursuant to unanimous agreement reached in a SC meeting, give notice in writing to the Coordinator requiring that the Grant Agreement be terminated. The Coordinator shall provide to the IMI JU justification for termination and the reports and deliverables referred to in Article II.4 of the Grant Agreement relating to work carried out up to the date of such termination. Upon the IMI JU confirming to the Coordinator receipt of notice of termination, the Grant Agreement shall be terminated with effect from that date and this Project Agreement shall be deemed to have been terminated on the same date.
- 21.3 Any Participant may, after consultation with the SC, request that its participation in the Project be terminated ("Retiring Participant"). Such Retiring Participant shall provide the Coordinator with such documentation as specified in Article II.35.6 of the Grant Agreement for transmission to the IMI JU.
- 21.4 The Participants may in accordance with Article II.35 of the Grant Agreement, amongst themselves agree, (by unanimous agreement of all of the Participants excepting that Participant which is the subject of the proposed exclusion, hereinafter "the Excluded Participant"), that the IMI JU should terminate the participation of the Excluded Participant. At the same time as such agreement shall be reached, such Participants shall agree how they propose to reallocate the outstanding Allocated Work obligations of the Excluded Participant. Where those Participants shall have so determined, the Coordinator shall promptly forward such request, including the documents specified in Article II.35.6 of the Grant Agreement to the IMI JU.
- 21.5 In accordance with the provisions of Article II.36 of the Grant Agreement, any such notice to terminate as provided for in Clauses 21.3 or 21.4 shall be subject to the written confirmation of the IMI JU within thirty (30) days, the absence of a response from the IMI JU within 30 days of receipt of such a request constitutes approval.
- 21.6 Where the participation of any Participants under the Project and as a Participant to the Grant Agreement may be terminated by the IMI JU, pursuant to the Grant Agreement, the participation of that Participant's Sub-contractor(s)

under this Project Agreement shall be deemed to have been terminated on the same date as such termination by the IMI JU.

- 21.7 Termination of a Participant under the Project or of such Sub-contractor's participation hereunder, pursuant to the foregoing provisions of this Clause 21, shall in each case be subject to the continuation in force of Clause 23.

22. TERMINATION FOR BREACH

- 22.1 Where there has been a breach of any obligation under the Grant Agreement by a Participant, (for the purposes of this Clause 22, a "Defaulting Participant"), the IMI JU may;
- (a) require that the Defaulting Participant remedy such breach within a period of no longer than thirty (30) days [of such request]; or
 - (b) immediately terminate the participation under the Grant Agreement of a Defaulting Participant in the circumstances permitted in the Grant Agreement.
- 22.2 Where the IMI JU shall require that the Participants remedy the relevant breach of obligation under the Grant Agreement, the Defaulting Participant shall, in any question amongst the Participants, be responsible for providing a solution acceptable to the IMI JU, notwithstanding the collective technical responsibility of all of the Participants for implementation of the Project. Such Defaulting Participant shall propose an effective and realistic solution, failing which, or in the event that the other Participants shall not agree with any such proposed solution, the other Participants shall determine, by agreement amongst themselves, how such breach may be remedied. Any such agreed recommendation made to the IMI JU on behalf of the Participants in such circumstances shall be binding on all Participants, including the Defaulting Participant.
- 22.3 The Participants, (with the exclusion of the Defaulting Participant), shall propose alternative arrangements for continuation of the Project, within the thirty (30) day period notified by the IMI JU, failing which the IMI JU shall be entitled to terminate the Grant Agreement. For the avoidance of doubt, in the event of termination by the IMI JU in such circumstances, no fault shall be attributed to any Participant, (without prejudice to any accrued rights of action against the Defaulting Participant), in relation to such termination.
- 22.4 Where the Coordinator shall receive notice of termination of the participation of a Defaulting Participant, from the IMI JU, the Coordinator shall promptly provide all other Participants with notice to that effect.
- 22.5 Where the IMI JU shall terminate the participation of a Defaulting Participant as aforesaid, subject to the continuation in force of Clauses 22.6 and 23 that Defaulting Participant's participation under, and as a Participant to, this Project

Agreement shall be deemed to have been terminated, by unanimous agreement of all of the Participants.

- 22.6 Where the IMI JU shall have requested that the Participants should provide appropriate solutions to any breach of obligation under the Grant Agreement, notwithstanding that costs incurred by the Participants eligible to receive IMI JU funding shall only be recoverable as Eligible Costs within the limits of the maximum IMI JU financial contribution set in the Grant Agreement, in the event that a solution acceptable to the IMI JU shall be found, the Participants, (including the Defaulting Participant unless the IMI JU shall have terminated the participation of the defaulting Participant with immediate effect), shall continue to undertake their respective Allocated Work in accordance with the Grant Agreement and this Project Agreement.

23. CONSEQUENCES OF TERMINATION

- 23.1 In the event of termination, under Clause 21, of this Project Agreement or of the participation of one or more Participants under this Project Agreement, (in either case, for the purposes of this Clause 23, “termination”), the departing Participants eligible to receive IMI JU funding shall be entitled to receive IMI 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 IMI JU shall refuse to accept any cost claimed by a departing Participant eligible to receive IMI JU funding, that departing Participant shall have no right to recover the same from any (other) Participant or from any IMI JU funding held or which may be received, unless the (other) Participant(s) unanimously agree otherwise in the SC.
- 23.2 A departing Participant shall, notwithstanding termination as aforesaid, remain bound to provide to the Coordinator, for onward transmission to the IMI 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 Participant would have been obliged to deliver had such termination coincided with the end of a reporting period.
- 23.3 Where, as a result of any delay on the part of a departing Participant in implementing the obligation included in Clause 23.2, (or any Participant in the event that the Grant Agreement shall be terminated in its entirety), the IMI JU shall decide to withhold IMI JU financial contribution, or to demand repayment of any IMI JU financial contribution which has been paid, such departing Participant eligible to receive IMI JU funding shall indemnify the other Participants 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.
- 23.4 The following Clauses shall survive termination, whether of the participation of any Participant in the Project and under this Project Agreement, or of the Grant

Agreement and this Project Agreement: Clauses 8 to 19, and this Clause 23 shall survive termination, whether of the participation of any Participant in the Project and under this Project Agreement, or of the Grant Agreement and this Project Agreement.

24. ASSIGNMENT

- 24.1 With the exception of Articles II.26.3 of the Grant Agreement and as otherwise expressly set out in this Project Agreement, no Participant shall assign any interest in this Project Agreement to any Third Party without the prior written consent of every other Participant and of the IMI JU and any such assignment shall be subject to such Third Party assignee agreeing in writing to (i) continue the performance of the Project undertaken by the assignor; and (ii) comply with the provisions of the Grant Agreement and this Project Agreement.
- 24.2 Where a Participant shall wish to assign its interest, as referred to in Clause 24.1, such Participant shall, within the limits of confidentiality, provide the remaining Participants and the IMI JU as the case may be, with such information as may be reasonably requested in connection with such proposed assignment and that Participant's Allocated Work, including, without limitation, the extent to which such Allocated Work has been completed and Eligible Costs incurred to date. That Participant shall, notwithstanding such assignment, remain liable under the Grant Agreement to the IMI JU for any additional information which the IMI JU may, either through the Coordinator or directly of such Participant, reasonably request regarding that Participant's Allocated Work and/or Eligible Costs.
- 24.3 Where a Participant shall have its request to assign any interest approved if needed, such Participant shall remain liable to all other Participants for all additional costs incurred by such other Third Party assignee in the performance of such assignor Participant'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 Participant's participation in the Project.
- 24.4 Where a Participant shall properly assign any or all of its interest in this Project Agreement in accordance with this Project Agreement, that Participant's participation in the Project and under this Project Agreement shall, to the extent of such assignment, be deemed to have terminated, and the provisions of Clause 23 shall apply.

25. FORCE MAJEURE

- 25.1 Where a Participant shall, be unable to perform, or shall be delayed in the performance of, any obligation hereunder or pursuant to the Grant Agreement, as a result of circumstances outside of its control and which it is not reasonably able to overcome, such non-performance or delay on the part of such Participant shall be deemed not to be a breach of such obligation on the part of such Participant. Notwithstanding the foregoing, the provisions of the Grant

Agreement, Article II.39 shall apply in any interpretation of whether specific circumstances shall constitute an event of force majeure as such term is defined therein.

- 25.2 Where a Participant shall be prevented or delayed in the manner referred to in Clause 25.1, such Participant shall promptly notify the Coordinator of such circumstance, the cause and anticipated duration thereof and any further information which the Coordinator may then, or during any such period of delay, reasonably require. The Coordinator shall promptly forward all such information to the other Participants and to the IMI JU.
- 25.3 Any default of a product or service or delays in making them available (unless due to force majeure) for the purposes of performing the Grant Agreement and affecting performance including anomalies in the functioning or performance of such product or service, labour disputes strikes or financial difficulties do not constitute force majeure.

26. DISPUTE RESOLUTION

- 26.1 All disputes or differences arising in connection with this Project Agreement which cannot be settled amicably initially by the SC shall be finally settled by arbitration in Brussels under the rules of arbitration of the International Chamber of Commerce by three arbitrators to be appointed under the terms of those rules. The chairman shall be of juridical education and the arbitrations proceedings shall be conducted in English. The award of the arbitration will be final and binding upon the Participants concerned.
- 26.2 The Participants concerned may, rather than arbitrate under Clause 26.1, instead elect to resolve by mediation a dispute or difference arising in connection with this Project Agreement which cannot be settled amicably. Such election shall be by unanimous written consent of the Participants involved in the dispute.

27. NOTICES

Any contractual, financial/administrative notice to be given under this Project Agreement shall be in writing and delivered to the relevant Participant at the address and marked for the attention of a named recipient, all as more specifically detailed in Appendix 2, or as a Participant shall under separate cover advise. A Participant may, by notice in writing to the Coordinator, amend its contact details as included in Appendix 2, 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 three (3) working days.

28. ENTIRE AGREEMENT

28.1 This Project Agreement, its Appendices (1-5) and the Grant Agreement and its Annexes (I-VI) constitute the entire agreement between the Participants in respect of the Project, and supersede all previous negotiations, commitments and writings.

28.2 Although the provisions of this Project Agreement have been drafted to reflect the provisions of the Grant Agreement as far as possible, in the event of any conflict between this Project Agreement and the Grant Agreement, (or any Annex), the Grant Agreement shall prevail.

28.3 Amendments or changes to this Project Agreement may be made only by written instrument signed by an authorised signatory of each of the Participants, other than where any such amendment shall relate solely to the contact details of a Participant, or shall otherwise be permitted under any provision hereof, in which event that Participant's written notice in accordance with the provisions of this Project Agreement shall suffice.

29. LAW

This Project Agreement shall be governed by and interpreted in accordance with the law of Belgium.