

## IMI Intellectual Property Policy

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### I. Objective

The objective of this IMI intellectual property policy (IP Policy) is to promote knowledge creation, together with its disclosure and exploitation, to achieve fair allocation of rights, to reward innovation, and to achieve a broad participation of private and public entities (including, but not limited to, participating research based pharmaceutical companies that are full members of EFPIA, academic groups and small and medium-sized enterprises) in projects.

### II. Definitions

1. "Access Rights" shall mean the rights to use.
2. "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.
3. "Background" shall mean data, know how and information which is held by a Participant prior to the accession to the Grant Agreement, as well as copyrights or other intellectual and industrial

property rights pertaining to such information<sup>1</sup>, and which is necessary for carrying out the project and identified in the Project Agreement.

4. "Confidential Information" shall mean 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 receiving party 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 receiving party, (c) is obtained from a third party not in breach of any obligation of confidentiality, (d) is known by the receiving party prior the date of the communication, (e) is required to be disclosed by the receiving party pursuant to any applicable law or judicial or governmental order, provided that the receiving party shall give immediate written notice of such requirement to the disclosing party 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.
5. "Direct Exploitation" shall mean to develop for commercialization or to commercialize Foreground itself.
6. "Dissemination" shall mean disclosure by any appropriate means other than that resulting from the formalities for protection, and including the publication in any medium.
7. "Executive Office" shall have the same meaning as in the Statutes.
8. "Fair and reasonable terms" shall mean appropriate conditions including financial terms (where appropriate) taking into account the actual or potential value of the Foreground or Background to which access is requested and other characteristics of the Research Use envisaged.
9. "Foreground" shall mean 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; design rights; patent rights; or similar forms of protection.
10. "Grant Agreement" shall mean the agreement between the IMI Joint Undertaking and the Participants. The Grant Agreement shall be consistent with this IP Policy.

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<sup>1</sup> For the avoidance of doubt, it also includes rights the subject-matter of which has been generated before accession to the Grant Agreement even if applications for registration of such right are made thereafter.

11. "Participant" shall mean a legal entity that participates in the Project as defined in the Grant Agreement. Contributions from third parties such as subcontractors do not constitute participation.
12. "Project" shall mean the research activities carried out by the Participants under the IMI Joint Undertaking as defined in the Grant Agreement.
13. "Project Agreement" shall mean the agreement between the Participants for the implementation of the Grant Agreement. The Project Agreement shall be consistent with the Grant Agreement and this IP Policy.
14. "Project Objectives" shall mean the objectives which are defined in the Grant Agreement. The Project Objectives shall not include the direct development and/or commercialization of marketable pharmaceutical or diagnostic products and the Grant Agreement shall not permit such direct development and/or commercialization.
15. "Research Use" shall mean use of Foreground or Background necessary to use Foreground for all purposes other than for completing the project or for Direct Exploitation<sup>2</sup>.
16. "Sideground" shall mean 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.
17. "Third Party" shall mean any legal entity which is not a Participant.

### **III. Identification, ownership and transfer**

#### **III.1. Background**

1. Each Participant shall remain the exclusive owner of its Background.
2. The Background to be included in the Project shall be identified in the Project Agreement.

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<sup>2</sup> An example of Research Use will be 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

The Participants shall identify in the Project Agreement any legal restrictions which exist relating to the use of such Background for Research Use or for completing the Project, and of which they are aware. The Executive Office shall be informed of any such restrictions prior to execution of the Grant Agreement and shall consider the impact of any such restrictions in achieving the Project objectives and the objectives of IMI as described in the Statutes.

Participants shall be entitled but not obliged to introduce into the Project and to designate as Background data and information as well as know-how, copyrights or other intellectual property rights pertaining to such information and which is generated or held or acquired by a Participant after the accession to the Grant Agreement.

3. Each Participant shall remain free to license, assign or otherwise dispose of its ownership rights in Background, subject to any rights and obligations of the Grant Agreement and the Project Agreement.

Where a Participant transfers ownership of Background, it shall pass on its obligations regarding that Background, as defined in the Grant Agreement and Project Agreement, to the assignee including the obligation to pass those obligations on to any subsequent assignee.

Notwithstanding the above, a Participant may - without the permission of the other Participants, but provided that other Participants are informed and that the assignee agrees in writing to be bound by the Grant Agreement, the Project Agreement and this Policy - assign its Background to (i) its Affiliated Entity; or (ii) any purchaser of all or substantially all of its assets; or (iii) any successor entity resulting from the merger or consolidation of such party with or into such entities.

### **III.2. Foreground**

1. Ownership of the Foreground belongs in the first instance to the Participant(s) who generated it. The Participants may agree on a different allocation of ownership in the Project Agreement. If employees or any 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 Project Agreement.
2. Where several Participants have jointly carried out work generating Foreground and where no individual Participant can be identified as its owner, such Participants shall, unless otherwise agreed in the Project Agreement, have joint ownership of such Foreground.

In case of joint ownership, unless otherwise agreed in the Project Agreement, each joint owner shall have the right to use such jointly owned Foreground, including the right to grant nonexclusive licenses, with the following conditions:

- Prior notice must be given to the to any other joint owner(s);
  - Fair and reasonable compensation must be provided to the other joint owner(s).
3. Each Participant shall remain free to license, assign or otherwise dispose of its ownership rights in Foreground:
- Either as expressly permitted in the Grant Agreement and/or in the Project Agreement;
  - Or after obtaining the consent of all Participants, which may only be withheld where they can demonstrate that their rights would be adversely affected.

Where a Participant transfers ownership of Foreground, it shall pass on its obligations regarding that Foreground, as defined in the Grant and Project Agreements, to the assignee including the obligation to pass those obligations on to any subsequent assignee.

Notwithstanding the above, a Participant may - without the permission of the other Participants but provided that other Participants are informed and that the assignee agrees in writing to be bound by the Grant Agreement, the Project Agreement and this Policy - assign its Foreground to (i) its Affiliated Entity; or (ii) any purchaser of all or substantially all of its assets; or (iii) any successor entity resulting from the merger or consolidation of such party with or into such entities;.

### **III.3. Sideground**

Ownership of the Sideground belongs in the first instance to the Participant(s) who generated it.

The Participants may agree on a different allocation of ownership in the Project Agreement.

## **IV. Access rights**

### **IV.1. Principles**

1. All requests for Access Rights shall be made in writing, unless otherwise agreed in the Project Agreement.
2. The granting of Access Rights may be made conditional on the acceptance of specific conditions aimed at ensuring that these rights will be used only for the intended purpose and that appropriate confidentiality obligations are in place.

3. The termination of the participation of a Participant shall in no way affect the obligation of that Participant to grant Access Rights to the remaining Participants and Third Parties.
4. Unless otherwise agreed by the owner of the Foreground or Background, Access Rights shall confer no entitlement to grant sub-licences. However, any person to whom rights for completing the Project or for Research Use have been made available under this IP Policy may authorise another party to exercise those rights on its behalf providing that that person shall be liable for the acts of that party as if those acts have been performed by this person.

#### **IV.2. Access Rights to the Participants for completing the Project**

1. **Foreground.** During the Project, Participants shall enjoy Access Rights to the Foreground of the other Participants solely for the purpose and to the extent necessary for undertaking and completing the Project.

Such Access Rights shall be granted on a royalty-free basis.

2. **Background.** During the Project, The Participants shall, unless prevented or restricted from doing so by obligations to others which exist at the date of accession to the Project Agreement, as identified in III.1(2), enjoy Access Rights to the Background of the other Participants solely for the purpose and to the extent necessary for undertaking and completing the Project.

Such Access Rights shall be granted on a royalty-free basis.

#### **IV.3. Access Rights to the Participants and Affiliated Entities for Research Use**

1. **Foreground.** During and after completion of the Project, Participants and their Affiliated Entities shall enjoy Access Rights to the Foreground of the other Participants for Research Use.

Such Access Rights shall be granted on a non-exclusive basis under Fair and reasonable terms or royalty-free, as determined in the Project Agreement.

2. **Background.** During and after completion of the Project, Participants and their Affiliated Entities shall enjoy 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.

Such Access Rights shall be granted on a non-exclusive basis under Fair and reasonable terms or royalty-free, as determined in the Project Agreement.

#### IV.4. Access Rights to Third Parties for Research Use

1. **Foreground.** After the completion of the Project, Third Parties shall have the right to request and receive under licence Access Rights to the Foreground of the Participants for Research Use.

Such Access Rights shall be granted on a non-exclusive basis under Fair and reasonable terms, as determined in the Project Agreement.

2. **Background.** After the completion of the Project, Third Parties shall have the right to request and receive under licence Access Rights to the Background of the Participants, but only to the extent reasonably required for and only for the purpose of the Research Use of Foreground.

Such Access Rights shall be granted on a non-exclusive basis under Fair and reasonable terms, as determined in the Project Agreement.

3. The terms for providing Access Rights under paragraphs 1 and 2 shall be included in the Project Agreement and referenced in the Grant Agreement. The proposed terms for Third Party Research Use for Foreground and Background necessary for the Research Use of Foreground shall be reviewed as part of the evaluation of the Project proposal.
4. Before execution of the Grant Agreement, a Participant may identify specific elements of the Background and provide a reasoned request to the Executive Office that such elements shall be wholly or partially excluded from the obligations referred to in this section. The Executive Office 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 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.

#### IV.5. Access Rights for Direct Exploitation

1. Participants may use, exploit, sublicense or otherwise commercialise their Foreground, Background and Sideground as they see fit beyond the Research Use rights described in this Policy.
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.

Participants may agree on such Access Rights in the Project Agreement.

## **V. Confidential Information**

1. The Participants covenant not to disclose and not to use the Confidential Information received from other Participants except as provided in and for the purposes of the Project Agreement and Grant Agreement.
2. Unless otherwise agreed in the Project Agreement, each Participant may disseminate (through journals, lectures, or otherwise) information relating to Foreground, provided that a copy of the proposed dissemination shall have been provided to the other Participants at least thirty (30) days prior to the submission of any written publication or any oral dissemination to allow the Participants to determine whether any invention or Confidential Information would be disclosed.

The reviewing Participants shall have the right to (a) require a delay in publication or presentation in order to protect patentable information, (b) require modifications to the publication for patent reasons or (c) require that Confidential Information be maintained as a trade secret.

The delay required by the reviewing Participants in publication or presentation in order to protect patentable information shall not exceed three months, unless agreed in the Project Agreement.

## **VI. Dissemination of Foreground**

1. The Participants undertake to disseminate the Foreground (as described in the Project Objective) as soon as reasonably practicable but not later than one (1) year after the termination or expiry of the Project.
2. The Project Agreement shall include a description of the material which must be disseminated in accordance with the IP Policy and referenced in the Grant Agreement.
3. If the Participants do not disseminate within such time periods without good reason, the Executive Office has the right to disseminate such results in a manner consistent with the Grant Agreement.