

## **CLARIFICATION NOTE – IMI IP POLICY**

### **Objectives – clarify why IMI Intellectual Property (IP) policy is distinct from the FP7 IP rules**

The Innovative Medicines Initiative (IMI) (established by Council Regulation (EC) No 73/2008 O.J. L 30 4.2.2008 2.38) has been set up with the objective to improve significantly the efficiency and effectiveness of the drug development process with the long-term goal that the pharmaceutical sector produces more effective and safer innovative medicines. IMI also has the objective of increasing investment in the biopharmaceutical sector in Europe. Hence IMI supports pre-competitive collaborative research to address bottlenecks in drug discovery and development. This research will be undertaken by industry-academia consortia and include other stakeholders such as patient groups, regulators, SMEs etc as appropriate. The expected outcomes are new approaches, methods and enabling technologies which address these needs.

The Council Regulation setting up IMI establishes in its article 15, that the IMI Joint Undertaking will adopt distinct Intellectual Property (IP) rules that best serve IMI's key objectives and ensure that intellectual property generated is protected and that the results are used and disseminated. Article 22 of the IMI Statutes, part of the IMI Regulation, further establishes that general rules governing the IMI IP Policy will be incorporated in the Grant Agreement and Project Agreements.

### **Definition of Background – clarify the scope of information included in the Background definition**

Background comprises, like in FP7, information and IP rights pertaining to such information, held by participants before accession to the Grant Agreement and needed for the Project. To be considered as Background, information must be identified in the Project Agreement. Contrary to FP7, IP rights applied for after the project starts but pertaining to Background information already identified in the Project Agreement are also included. Additional information which could be useful to carry out the project may be brought into the Project at any

time by the owning participant, at his sole discretion however. This additional information will also be considered as Background. As is current practice under FP6 and FP7, the word "information" should be interpreted in a broad sense to include, but not be limited to, knowledge, data, know-how, methods, tests, experimental procedures, including knowledge, data and know-how relating to samples, cell lines, transgenic mice material, compounds, and the like.

#### **Definition of Foreground – clarify the scope of the Foreground definition**

Foreground is, like in FP7, results and IP rights pertaining to such results, generated under the Project in the scope of the Project Objectives. Contrary to FP7, not all results and IP rights are considered Foreground as Sideground results are excluded (**note:** Sideground has a specific meaning in IMI – see below). The word "results" should be interpreted in a broad sense to include, but not be limited to, knowledge, data, know-how, material, compounds, methods, tests, experimental procedures, samples, cell lines, transgenic mice and the like and the mention "including data, know-how and information" should not be interpreted as restricting the scope of "results".

#### **Definition of Sideground – clarify the scope of the Sideground definition**

Sideground is specific to IMI and does not exist in FP7. Moreover, the Sideground definition of IMI should not be confused with the definition of sideground used in the FP7 IPR guide. In IMI, Sideground is results generated under the Project but outside the Project Objectives and which are not needed for undertaking and completing the Project or for the Research Use of the Foreground. Namely, any result generated under the Project which is needed for undertaking and completing the Project or for the Research use of Foreground and is within the Project Objectives is Foreground. As an example to illustrate what is meant by Sideground, if a specific Project Objective relates to the development of a particular cell line “X”, Sideground could be a new method of storing cells developed while carrying out the Project but which can be applied to cells other than cell line ‘X’. The scope of Sideground is the application of the new method to cells

other than cell line 'X'. Since Sideground is defined with reference to the Project Objectives, the importance of careful drafting of the Project Objectives, which are part of the Annex I ("description of work") of the Grant Agreement, is emphasized.

### **Definition of Research Use – clarify the scope of the Research Use definition**

In IMI, the FP7 term “Use” is divided into:

- “Research Use”, which is the use of Foreground or Background necessary to use Foreground for purposes other than for completing the Project or for Direct Exploitation, and
- “Direct Exploitation”, which is to develop for commercialization or to commercialize the Foreground itself

The definition of Research Use is specifically tailored to IMI objectives of fostering the accessibility of enabling technologies for drug research and development purposes. It should be noted that the "Research Use" definition of IMI intentionally goes beyond the legal concepts of the research use or research exemption in most patent laws or the acceptance of this term for purely academic research. As stated in the footnote linked to the IMI definition of Research Use in the IMI IP policy, an example of Research Use is the application of Foreground (*e.g. a cell, an animal model or a molecule that can be isolated from an organism and which is an indicator of a biologic state (biomarker)*) as a tool for research and clinical research in (i.e. during) the discovery, development or commercialization (e.g. phase IV clinical trials or post marketing study commitments and the like) of pharmaceutical products by for-profit institutions or organizations. The field of IMI Research Use should therefore be understood as to include without limitation all pre-clinical research and development activities, all human clinical studies, all activities relating to developing the ability to commercialize any drug substance or drug product (including process development work), and all activities relating to seeking, obtaining and/or maintaining any regulatory approvals from Regulatory Authority<sup>1</sup>. It might prove useful for Participants to a Project to segment the field of IMI Research Use in the Project Agreement in order

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<sup>1</sup> For clarification purposes Regulatory Authorities include also reimbursement agencies undertaking Health Technology Assessment decisions directing government purchasing of drugs for national health institutions

to set the most appropriate terms and conditions for access, provided always that this segmentation does not limit the scope of Research Use.

### **Definition of Direct Exploitation – clarify the scope of the Direct Exploitation definition**

Commercialization of the Foreground itself as well as activities linked to its development for commercialization is called “Direct Exploitation”. Direct Exploitation should be interpreted in a broad sense to include also such exploitation through licensing activities.

An example of Direct Exploitation could be the development for commercialization or the commercialization of a molecule (*e.g. a nucleotide isolate X encoding a protein Y, an antibody which specifically binds to protein Y or a small RNA that interferes with the expression of protein Y*) or a cell (*e.g. a cell over expressing protein Y*) as a therapeutic, a diagnostic, a screening, an imaging or a recombinant production tool or the development for commercialization or the commercialization of an animal model (*e.g. an animal over expressing protein Y or an animal with a defective nucleotide X*) as a screening or a recombinant production tool.

### **Definition of Research Use and Direct Exploitation – clarify the distinction between Research Use and Direct Exploitation**

To illustrate the distinction between Research Use and Direct Exploitation: use of a biomarker in the conduct of a clinical trial would fall into Research Use; but the commercialization of the biomarker itself as a diagnostic kit, would be Direct Exploitation.

### **Executive Office – clarify the term "Executive Office" and how the Executive Office will handle requests of Background exclusion from access to Third Parties (art. IV.4.4)**

The term "Executive Office" used in articles III.1.2, IV.4.4 and VI should be understood as the IMI Joint Undertaking.

A specific note of procedure will be published by IMI JU on Background exclusion from access to Third Parties (art. IV.4.4) in accordance with the following principles. It is the aim of the IMI JU that the results of the IMI projects are widely used to ensure the rapid uptake of

the newly developed methods and technologies into industry and/or regulatory practice; hence the provisions for access rights to Third parties included in the IMI IP policy. Nevertheless, to preserve the participants' legitimate rights to exclude certain specific Background from the scope of access to Third Parties while ensuring that said Third Parties can still access to the Background necessary to use the Foreground, some conditions are foreseen to allow the IMI JU and the owning participant to confer together before specific Background is excluded..

**Confidentiality – clarify that article V applies to all participants and their subcontractors**

Confidentiality obligations apply to all participants, including subcontractors and any third parties involved through a participant in the Project. It is recommended that each participant treats confidential information with the same degree of care as their own confidential information and passes to their subcontractors and to involved Third Parties they are linked to on a strict need-to-know basis only and under appropriate agreements and other measures to ensure compliance with the provisions of the Grant Agreement, including the confidentiality provisions.

**Dissemination of Foreground – clarify that article V.2 applies to all Foreground**

Participants are expected to disseminate the Foreground, in particular through journals, lectures, etc. Dissemination activities by a participant as foreseen in article V.2 are not limited to that participant's own Foreground, unless agreed differently in the Project Agreement. However, other participants have the right to review the material to be published or otherwise disseminated, to exclude their confidential information. It is recommended that participants agree jointly on a dissemination strategy to follow in the Annex I of the Grant Agreement.

**Affiliated entities – clarify why the definition of "affiliated entities" is broader than in the context of FP7 and how to handle request for access right for Research Use**

The scope of the IMI definition of “Affiliated Entity” is broader than under the FP7 rules since it includes upward, downward and sideway companies including parents. It is furthermore not limited to entities established in EU Member States or countries associated to FP7. Nevertheless it should be highlighted that, contrary to FP7, the scope of access rights under IMI for Affiliated Entities is limited to Research Use only (although not subject to "a need to" basis as is the case in FP7), and no privileged or specific access for Direct Exploitation is provided beyond what is merely mentioned for Third Parties.

The IMI definition of Affiliated Entity is in line with the IMI objective to ensure the rapid uptake of the newly developed methods and technologies into industry and/or regulatory practice. Therefore, and considering the pre-competitive nature of IMI research projects, providing worldwide access to the IMI Project results is key to achieve these objectives. Moreover, this definition reflects the multinational profile of the health sector and many consortia under FP6 and FP7 have implemented a similar approach.

Companies generally apply safety measures when dealing with their affiliates and with the information provided to these affiliates, and therefore some guaranties may be obtained by the owning participant regarding the transfer of its information to affiliates. A participant may request a list of the affiliated entities of another participant at the date of signature of the Project Agreement or at later stage upon receipt of this other participant's request for access rights.

**Request for access rights – clarify that request for access rights is made in writing**

The IMI IP policy foresees the possibility of a waiver of written request if so agreed in the Project Agreement. However, it is strongly recommended that the request for access rights for research use or direct exploitation by either a Participant or a third party is made in writing. Besides, the conditions of article IV.1.2 i.e. the granting of access rights may be made conditional on the acceptance of specific conditions (e.g. subject to a separate written bilateral agreement) apply equally to all requests for access rights.

**Fair and reasonable – clarify the term "fair and reasonable"**

"Fair and reasonable" mean appropriate conditions taking into consideration the value of the Background/Foreground to which access is given and the scope of the intended Research Use. To determine the fairness of the proposed terms, general practice is to consider both the economic and competitive environment and the value of a technology relative to the next best alternative, as well as its contribution to the overall success of a project. For example, is the technology just one of a variety of accessible alternatives or the sole option, is it key to the speed or safety of a development process. Fair and reasonable terms may include financial terms and/or other conditions such as reciprocal access rights for example. These terms should be agreed upfront in the Project Agreement which can also include deciding on the appropriateness of the "Royalty Free" option. For any given technology what constitutes fair & reasonable will vary as between participants and third parties.