

November 2010

**Innovative Medicines Initiative (IMI)
Intellectual Property (IP) Policy**

Guidance Note for IMI Applicants and Participants

1. INTRODUCTION

The purpose of this guidance note¹ is:

- to clarify the IMI IP Policy, and in doing so
- to highlight the flexibility provided therein, and
- to explore ways to handle IP related issues and pitfalls that participants may encounter during the preparation, negotiation and completion phases of the Grant Agreement and Project Agreement.

This Guidance Note follows discussions of the Intellectual Property Working Group (IPWG), composed of representatives from the European Federation of Pharmaceutical Industries and Associations (EFPIA), the European Commission (EC) and the IMI States Representatives Group (SRG).

2. OBJECTIVES OF IMI AND THE IMI IP POLICY

OBJECTIVES OF IMI

The Innovative Medicines Initiative (IMI)² has been set up with the objective to significantly improve 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, small and medium size enterprises (SMEs) and others as appropriate. The expected outcomes are new approaches, methods and enabling technologies which address IMI objectives.

The legal provisions³ which underpin IMI state that distinct rules on IP will be adopted that serve IMI's key objectives, in particular to ensure that intellectual property generated is protected and that the results are used and disseminated⁴. Furthermore these rules⁵ state the rationale for objectives and principles of the

¹ This note updates and supersedes the Clarification Note issued in 2009.

² Established by Council Regulation (EC) No 73/2008 O.J. L 30 4.2.2008 2.38

³ Article 15 of the Council Regulation

⁴ For this reason, the IMI IP Policy is unique and clearly distinct from the general FP7 IP Rules.

⁵ Article 22 of the Council Regulation

IMI IP Policy and make it clear that rules must be incorporated in the Grant and Project Agreements.

OBJECTIVES OF THE IMI IP POLICY

Based on the IMI objectives and nature of pre-competitive collaboration, the IMI IP Policy has the explicit objective to promote knowledge creation together with its disclosure and exploitation, to achieve fair allocation of rights and to reward innovation and to achieve a broad participation of private and public entities. The main principles regard ownership of Background and Foreground IP, access rights which differ depending on the entity that requests them and the purpose for which they are to be used, dissemination of the Foreground and confidentiality.

Flexibility is therefore provided for and will be maintained for participants to establish the most appropriate agreements serving each individual project objective and to be consistent with the IMI IP policy and the wider IMI objectives.

The IP policy does not foresee all details and does not aim to provide answers to all possible practical situations participants may be faced with.

3. ISSUES TO BE CONSIDERED IN THE PROJECT AGREEMENT

3.1 INTRODUCTION TO THE PROJECT AGREEMENT

The Project Agreement is a private agreement concluded amongst the participants of an IMI project in order to implement the provisions of the Grant Agreement and to regulate internal issues related to work organisation and objectives for each participant such as consortium governance, intellectual property, financial and other matters.

As a result, the Project Agreement is the document in which the agreed outcomes of the IP negotiations are legally documented. Any template shall be seen as a starting point for negotiating each individual Project Agreement and needs to be adapted to suit the individual circumstances of each project.

The Project Agreement may be amended during the life of the project according to the needs and the possible evolution of the project's activities if required and without obligation. Any amendment should be agreed in writing by all the participants and must be in line with the provisions of the Grant Agreement.

In effect, while the provisions of the Grant Agreement constitute mandatory provisions that cannot be ignored and/or modified, these provisions can be explained further and/or detailed in the Project Agreement.

Other agreements, separate from the Project Agreement (e.g. material transfer agreement, non-disclosure agreement) may have been concluded before the signature of the Grant Agreement and possibly after, each governing a different aspect of IP. Impact of this must be taken into account in the Project Agreement.

3.2. BACKGROUND

DEFINITION

Background comprises information and IP rights relating to such information held by participants before accession to the Grant Agreement and necessary for carrying out the Project⁶.

To be considered as Background, this information must be identified as Background in the Project Agreement⁷. Information not identified expressly as Background in the Project Agreement is not therefore Background and not subject to access rights.

IP rights applied for after the project starts but relating to Background information that has been already identified in the Project Agreement are also considered as Background⁸.

Additional information which could be useful to carry out the project may be introduced (i.e. added to the Background list in the Project Agreement) as Background at any time by the participant owning the information, at his/her sole discretion. This additional information will then also be considered as Background.

As is current practice, 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 models material, compounds, clinical data and the like.

OWNERSHIP REGIME

Ownership of Background is not affected by participation in an IMI project.

IDENTIFICATION OF BACKGROUND

Participants shall clearly and fully identify the Background they bring into the project and which is deemed necessary to carry out the project (for example, by foreseeing an annex to the Project Agreement)⁹. By identifying Background the participants agree to grant access rights to it under the negotiated conditions.

The participants may consider defining in more detail in the Project Agreement the concept of necessity related to the granting of access rights for completing the Project.

As indicated above, additional elements of Background may be included on a voluntary basis during the implementation of the project, should this be deemed

⁶ Article II.1.3 of the IMI model Grant Agreement

⁷ Article II.1.3 of the IMI model Grant Agreement

⁸ Footnote 1 of the IMI IP Policy

⁹ Article II.1.3 of the IMI model Grant Agreement

necessary by the participants. The process by which such addition will be made should preferably be clearly defined by the participants in the Project Agreement.

Before the signature of the Grant Agreement, participants may exclude elements of the Background from the set for which they are otherwise obliged to grant access rights to third parties for Research Use¹⁰. Approval of such exclusion(s) by the IMI Office shall only occur under exceptional circumstances (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 clinical or regulatory practice) and should not affect the achievement of the Project Objectives¹¹.

Before signing the Grant Agreement, each participant shall also communicate any legal restrictions of which it is aware that may affect the use of Background for completing the project or for Research Use purposes¹² to the other participants and the IMI Office. Legal restrictions do not only include restrictions derived from the law but also from prior contractual agreements (e.g. non-disclosure agreements or material transfer agreements). Any such restrictions will be identified in the Project Agreement.

Clear and complete identification of included and/or excluded (third party and legal restrictions) Background is therefore a key aspect of the IP negotiation process in order to avoid uncertainties and ensure transparency notably with regards to the other participants.

3.3. FOREGROUND

DEFINITION

Foreground is the term to describe the results and IP rights relating to such results, which are generated under the Project and which lie within the scope of the Project Objectives¹³.

It is therefore very important to understand and clearly define what the Project Objectives are in order to understand what the Foreground will be.

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 models and the like and where mentioned, "including data, know-how and information" should not be interpreted as restricting the scope of "results".

OWNERSHIP REGIME

The general rule is that Foreground belongs to the participant that generates it¹⁴.

¹⁰ Article II.31.4 of the IMI model Grant Agreement

¹¹ The term "Project Objectives" is defined as the objectives which are defined in the Description of Work (Annex I to the IMI Grant Agreement).

¹² Article II.25.2 of the IMI model Grant Agreement

¹³ Article II.1.9 of the IMI model Grant Agreement

However, a different allocation of ownership may be agreed between the participants in the Project Agreement¹⁵.

Derogations, decided on a case-by-case basis, may concern a specific Foreground and/or a limited number of participants within the same project.

This is based on the premise that the participants understand and define the nature of Foreground that may be generated and that the derogations reflect the willingness of the concerned participants.

JOINT OWNERSHIP

The IMI IP Policy provides for joint ownership in the cases where two or more participants have jointly generated specific Foreground¹⁶. Joint ownership may also be agreed by the participants as the result of derogation from the basic ownership regime (see above).

If a number of participants in a project jointly own Foreground, they shall define how they intend to organise this joint ownership (certain national legislations already provide criteria for organising joint ownership arrangements). One possibility would be that shares are divided equally between all the concerned participants. Other options may be agreed which consider the relative investment in terms of time and resources of each participant concerned.

If nothing has been agreed upon by the Participants concerned in the Project Agreement, each joint owner has the right to use the jointly-owned Foreground, including the right to grant non-exclusive licenses, provided that:

- A) Prior notice (preferably in writing) is given to the other joint owners, and
- B) Fair and reasonable compensation is provided to the other joint owners.

The joint owners must therefore determine fair and reasonable terms. This could be done from the outset or at a later stage when the joint Foreground and its use are clearly identified. Fair and reasonable terms may be determined considering, for example, information regarding the granted license, including any direct or indirect benefits given in return.

TRANSFER OF OWNERSHIP

Each Participant has the right to assign or dispose of its ownership rights in Foreground¹⁷:

- A) either as expressly permitted in the Grant or Project Agreement,
- B) or after obtaining consent of all Participants which can only be withheld where they can demonstrate that their rights would be adversely affected.

As an example, nothing could preclude a joint owner from assigning its ownership rights on Foreground to a start-up company who would then take on

¹⁴ Article II.26.1 of the IMI model Grant Agreement

¹⁵ Reference to "in the first instance"

¹⁶ Article II.26.2 of the IMI model Grant Agreement

¹⁷ Article II.26.3 of the IMI model Grant Agreement

the obligations of the joint owner and therefore would be the entity granting access rights to the other Participants & Third Parties, as specified in the Project Agreement, either for Research Use or Direct Exploitation.

Where a Participant transfers ownership of Foreground¹⁸, 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. Recalling the above mentioned example, the start-up would then take on the obligations of the joint owner and therefore would be the entity granting access rights to the other Participants & Third Parties, as specified in the Project Agreement, either for Research Use or Direct Exploitation.

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.

PROTECTION OF FOREGROUND

No specific allocation of responsibility for the protection of the results is foreseen in the IMI IP Policy.

According to normal practices, the responsibility for protection lies with the owner(s) of the Foreground, unless otherwise agreed.

The Participants may also determine, in the Project Agreement, the action to take when the owner of an IP asset is not interested in formally protecting a Foreground.

3.4. SIDEGROUND

DEFINITION

Sideground has a specific meaning in IMI. *Sideground* is defined as 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^{19,20}. This is contrary to Foreground which are results generated under the Project which are needed for undertaking and completing the Project or for the Research use of Foreground and which are within the Project Objectives.

¹⁸ *Background can also be assigned.*

¹⁹ *Article II.1.20 of the IMI model Grant Agreement*

²⁰ *Results generated in parallel with a project are neither Foreground, nor Sideground according to the IMI IP Policy. No access rights thereto are foreseen. However, the participants often agree to refer to results generated in parallel with a project as Sideground in the Project Agreement.*

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 (and understanding) the Project Objectives, which are part of the Annex I ("description of work") of the Grant Agreement, must be emphasized.

OWNERSHIP REGIME AND ACCESS RIGHTS

Sideground belongs to the participant that generates it and there is no obligation to give access rights²¹.

The participants may however decide differently in the Project Agreement.

3.5. RESEARCH USE & DIRECT EXPLOITATION

In IMI, the term "Use" is divided into:

- "Research Use"²², 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"²³, which is the development of Foreground specifically for commercialisation or to commercialise the Foreground itself.

RESEARCH USE

The definition of Research Use is specifically tailored to the IMI objectives of fostering the accessibility of enabling technologies for drug research and development purposes. In this respect, 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 legislation or academic research.

As stated in the footnote linked to the IMI definition of Research Use in the IMI IP policy²⁴, 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 including clinical research in (i.e. during) the discovery, development or commercialisation (e.g. phase IV clinical trials or post-marketing study commitments and the like) of pharmaceutical products by for-profit institutions or organizations.

²¹ Article II.27 of the IMI model Grant Agreement

²² Article II.1.19 of the IMI model Grant Agreement

²³ Article II.1.5 of the IMI model Grant Agreement

²⁴ http://www.imi.europa.eu/content/documents#ip_policy - see footnote 1 to Section II.3 of the IMI IP policy

The field of IMI Research Use should therefore be understood as including, without limitation, all pre-clinical research and development activities, all human clinical studies, all activities relating to developing the ability to commercialise 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 Authority²⁵.

Understanding the definition of Research Use is crucial when identifying the Background, determining the Project Objectives and discussing the conditions for access rights, especially in relation to granting access rights to Background, to affiliates and Third Parties.

It might prove useful for Participants in a Project to segment the field of IMI Research Use in the Project Agreement in order to set the most appropriate terms and conditions for access, provided always that this segmentation does not limit the scope of Research Use.

DIRECT EXPLOITATION

Commercialisation of the Foreground itself, as well as activities linked to its development for commercialisation, is called "Direct Exploitation". Direct Exploitation should be interpreted in a broad sense to also include such exploitation through licensing activities.

An example of Direct Exploitation would be the development for commercialisation or the commercialisation 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 commercialisation or the commercialisation 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.

RESEARCH USE VS DIRECT EXPLOITATION

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

3.6. ACCESS RIGHTS

The provisions of the Grant Agreement constitute mandatory provisions that cannot be set aside or restricted further. However, additional access rights may be granted (for example to Sideground).

25 For clarification purposes, Regulatory Authorities also include reimbursement agencies undertaking Health Technology Assessment decisions directing government purchasing of drugs for national health institutions

As a general remark, when discussing access rights, it is recommended for all the participants to have in mind the identified Background and to understand the nature of the foreseen Foreground.

EXCLUSIVE LICENSES

As a principle, access rights are granted on a non-exclusive basis as other Participants, affiliates and third parties may also request access rights.

However, as no mandatory access rights are foreseen for Direct Exploitation, exclusive licenses can be granted solely for this purpose, provided that this doesn't restrict the overall access rights for Research Use.

LEGAL RESTRICTIONS

As mentioned above in section 3.1, participants may have already concluded agreements (e.g. licensing, non-disclosure) relating to their Background before entering into collaboration with an IMI project, creating possible legal restrictions relating to its use for completing the project or for Research Use.

Any such legal restrictions shall be brought to the attention of the other participants and the IMI JU before the signing of the grant agreement²⁶.

The impact of such legal restrictions shall be analysed in detail also by the consortium, to make sure that they will not interfere with the proper implementation of the project, nor with the Research Use, nor with the exploitation and dissemination of the Foreground.

REQUESTING MODALITIES BETWEEN THE PARTICIPANTS

Access rights are granted on written request²⁷. The IMI IP policy does however foresee the possibility of the waiver of written request if so agreed between the participants in the Project Agreement.

Nevertheless, it is strongly recommended that the request for access rights for research use or Direct Exploitation by either a Participant, affiliate or a third party is made in writing.

Besides, the granting of access rights may be made conditional on the acceptance of specific conditions (e.g. subject to a separate written bilateral agreement) that apply equally to all requests for access rights²⁸.

Participants may decide to set up specific written request procedures e.g. for certain types of Background or Foreground, for a specific purpose only with regards to certain participants, or systematically when access rights are to be granted.

²⁶ Article II.25.2 of the IMI model Grant Agreement

²⁷ Article II.28.1 of the IMI model Grant Agreement

²⁸ Article II.28.2 of the IMI model Grant Agreement

SUB-LICENSES

As a principle, the granting of access rights does not include the right to grant sublicenses²⁹.

The participants may however agree, e.g. in the Project Agreement, that access rights do confer the entitlement to grant sub-licences.

If no deviating rules are agreed in the Project Agreement, then no license granted under the access rights regime contains the right to grant sublicenses. In the event the parties should want to make a general deviation from this principle, then it is advisable that the right of sublicensing and its scope are clearly defined in the Project Agreement in order to reduce legal uncertainty. Consequently, any discussion to include a right to sublicense should be viewed in connection with the requesting modalities. For example, if the participants agree to grant access rights without written request and with the right of sublicensing, access rights may be extended to any entity in the world, including competitors, without full traceability.

TIME-LIMITS FOR REQUESTING ACCESS RIGHTS

There is no time-limit foreseen by the IMI IP policy for requesting access rights to Foreground or to Background necessary for the Research Use and/or Direct Exploitation of Foreground.

Access rights for Research Use may be requested by participants (including respective affiliates) or third parties. There are no access rights for Direct Exploitation and therefore any request can be treated by the owners of those rights as they see fit and consequently can also be denied.

TIME-LIMITS FOR REQUESTING ACCESS RIGHTS BETWEEN PARTICIPANTS, INCLUDING AFFILIATES FOR RESEARCH USE

The objective is to allow participants to establish the most appropriate agreements based on the concrete purpose of each project (for example, an efficacy project may result in different arrangements to an education and training project) depending on:

- A) The nature of Foreground and/or necessary Background
- B) The purpose and duration of use
- C) The typology of requesting participant, including its affiliates

If no arrangements are made between the participants in the Project Agreement, the access rights from the Project can be requested by any participant for an indefinite period after the Project completion. Thus, participants should discuss whether under their Project, time-limits are appropriate given the flexibilities of "fair and reasonable terms".

²⁹ Article II.28.4 of the IMI model Grant Agreement

TIME-LIMITS FOR REQUESTING ACCESS RIGHTS BY THIRD PARTIES FOR RESEARCH USE

No time-limit has been specified concerning third party access rights as this would be inconsistent with the objectives of IMI to maximise dissemination and exploitation of Foreground.

Moreover, as third parties are not parties to the Project Agreement or affiliated to any participant, such limitation of the rights assured under the Grant Agreement would clearly not be binding.

However, third parties should indeed keep in mind that time limits with respect to particular conditions for obtaining access are permissible. given the flexible nature of "fair and reasonable" terms. Moreover, request(s) for access rights may be valid only to the extent that the Foreground and/or necessary Background are still maintained (material embodiments e.g. cell lines, software) and free from any legal restrictions or rights.

ACCESS RIGHTS TO AFFILIATES

The scope of the IMI definition of "Affiliated Entity" includes 'upwards', 'downwards' and 'sideways' companies including parents³⁰. It is furthermore not limited to entities established in EU Member States or associated countries. 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 achieving 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.

Affiliated entities are not parties to the Grant Agreement but, by their affiliation with entities participating in the Grant Agreement, have certain access rights³¹.

Access rights indeed extend to affiliates or parent companies of the participants of IMI projects. This is a key feature of IMI which was specifically provided for to promote dissemination and exploitation of Foreground.

The scope of access rights under IMI for Affiliated Entities is limited to Research Use only (although not subject to "a need to" basis – see below), and no privileged or specific access for Direct Exploitation is provided beyond what is merely mentioned for Third Parties.

For transparency purposes only, the rights should be discussed for each participant to 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. This would help in identifying and clarifying which entities may benefit from access rights, notably if the affiliates are non-EU based.

³⁰ Article II.1.2 of the IMI model Grant Agreement

³¹ Article II.30 of the IMI model Grant Agreement

Companies generally apply safety measures when dealing with their affiliates and with the information provided to these affiliates (such as non-disclosure agreements), and therefore some guarantees should be obtained by the participant owning information regarding any transfer of this information to affiliates.

ACCESS RIGHTS FOR PARTICIPANTS FOR COMPLETING THE PROJECT

Access rights to a participant's Background or Foreground for the purpose of completing the project are to be granted by their owner non-exclusively on a royalty-free basis.

Such access rights are granted in order to allow a participant to perform its activities under the project³². Such access rights may not be interpreted as allowing a participant to use the Background or Foreground for activities outside the specific project.

ACCESS RIGHTS FOR PARTICIPANTS AND AFFILIATES FOR RESEARCH USE

Access Rights to Background & Foreground for Participants and affiliates for the purpose of Research Use of Foreground are to be granted non-exclusively and may be either on a royalty-free basis (which may mean free of charge –free of any payment- or not –e.g. technology transfer costs-) or under fair and reasonable terms. Neither of these constitutes a default position and the choice will be determined on a case by case basis by the Participants.

"Fair and reasonable"³³ means taking into consideration the value of the Background/Foreground to which access is given and the scope (including duration) of the intended Research Use, with consequent remuneration as defined below.

This terminology allows for any type of financial arrangements which best captures the actual or potential value of the specific Background provided for a defined project and Foreground. It may also include temporal conditions (see above).

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 project³⁴.

For example, in projects where the scientific contributions and possible benefits each participant can derive from the project are not level, fair and reasonable conditions, allowing for financial balance of this disparity via sharing of benefits, may be an appropriate starting point.

Fair and reasonable terms may include financial terms and/or other conditions such as reciprocal access rights for example. These terms should be agreed in the Project Agreement which can also include deciding on the appropriateness of the "Royalty Free" option. For any given technology what constitutes fair and reasonable may also vary between participants and third parties.

³² *Specific conditions aiming at ensuring that these rights will be used only for the intended purpose and appropriate confidentiality obligations may be set up – Article II.28.2 of the IMI model Grant Agreement*

³³ *Article II.1.7 of the IMI model Grant Agreement*

³⁴ *Possible technology transfer costs should be also considered.*

These conditions for access rights should be extensively discussed and agreed within the consortium and shall respond to a common need considering the IMI objectives to achieve fair allocation of rights and reward innovation and to achieve the project objectives.

In this regard, participants may agree on different terms depending on whether access rights will be granted to a Participant including Affiliate, on the nature of the Background and/or Foreground concerned and of the Research Use foreseen.

ACCESS RIGHTS FOR THIRD PARTIES FOR RESEARCH USE³⁵

One of the key objectives of IMI is to deliver innovative medicines to patients in a faster way, by speeding up the discovery and development process. Therefore, the IMI IP Policy promotes swift disclosure and exploitation of Foreground, by foreseeing access rights for third parties for Research Use. Some third parties may indeed be in a better position to ensure a swift and appropriate dissemination and/or exploitation by way of Research Use in the discovery and development of new medicines.

Third parties have the right to request and receive access rights under fair and reasonable terms to be agreed on a case-by-case basis between the participants and the third party(ies) concerned.

The participants may already define in the Project Agreement basic criteria for negotiating the financial terms for example, based on the geographical location of the third party, the scope of its activities, possible future collaboration, exchange of know-how and knowledge, etc.

ACCESS RIGHTS FOR DIRECT EXPLOITATION

Participants are not required to grant access rights for Direct Exploitation to their Foreground and/or Background.

However should they decide to agree otherwise, then the particular terms and conditions attached to the granting of such access rights should be negotiated as and when appropriate. Therefore they may be the subject of more specific arrangements between the participants concerned (for example, in the Project Agreement, the participants may set up basic principles and granting conditions depending on whether the access rights are to be granted between themselves, to affiliates or to third parties).

They may also identify possible Direct Exploitation opportunities/activities for which they already agree on basic financial conditions.

³⁵ Article II.31 of the IMI model Grant Agreement

ACCESS RIGHTS TO SIDEGROUND

Participants are not required to grant access rights to their Sideground as it is outside the Project Objectives and is not needed for implementing the project or for Research Use.

However, by agreeing on appropriate clauses in the Project Agreement, the participants may decide to extend the obligation of granting access rights to identified Sideground. If they decide so in the Project Agreement, the Participants should then determine the types of access rights and the types of entities to whom access rights may be granted.

This may be agreed as a general principle, or on a case-by-case basis, considering the objectives of the project and the respective role of the participants during the completion of the project and after its end.

3.7. CONFIDENTIALITY

Confidentiality obligations apply to all participants, including subcontractors and any third parties, involved through a participant in the Project³⁶.

It is recommended that each participant treats confidential information with the same degree of care as their own confidential information and ensures that their subcontractors and involved Third Parties are linked to 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.

Exceptions to the general confidentiality obligations may be agreed between the participants in the Project Agreement.

Participants may precisely identify the information exchanged between themselves that is subject to confidentiality restrictions, or information for which confidentiality is not considered as an issue.

3.8. DISSEMINATION

Participants are expected to disseminate the Foreground, in particular through publications in scientific journals, reviews, books, lectures, websites, etc³⁷. Foreground must be disseminated as soon as reasonably practicable, but no later than one year after the termination or expiry of the Project.

The Project Agreement shall include a description of the material which will be disseminated.

³⁶ Article II.9 of the IMI model Grant Agreement

³⁷ Article II.34 of the IMI model Grant Agreement

Modalities for dissemination should be agreed between the participants in the Project Agreement. It is recommended that participants agree jointly on a dissemination strategy to follow in the Annex I of the Grant Agreement.

In principle, dissemination activities by a participant are not limited to that participant's own Foreground, unless agreed differently in the Project Agreement. Other participants may however have the right to review the material to be published or otherwise disseminated, to exclude their confidential information. For example, in the case of dissemination activities (e.g. planned publications) that imply disclosing Foreground to the public, participants may agree on publication procedures allowing for possible delay or modification.

The costs associated with dissemination activities may be also regulated by the participants in the Project Agreement.

3.9. THE IP COMMITTEE

Consortia may decide to set up a group specialised in IP issues. Its existence usually depends on the size and complexity of the project.

This IP Committee may have a consultative role and as an example:

- contribute to the IP strategy of the consortium as a whole or on a case-by-case basis;
- advise on possible impacts on the IP strategy and actions to be taken in case of minor scientific changes during the course of the project;
- provide support and/or advice in the resolution of disagreements between participants;
- assist in the negotiations of licensing agreements amongst participants and with third parties;
- help in reaching agreement on confidentiality;
- provide support and/or advice in the drafting of the plan for the research use and dissemination of Foreground³⁸, etc.

This IP Committee may be part of the highest decision-making body of a project, but may be also set up as a separate group.

It may also prove helpful in ensuring continuity after the end of the IMI project.

³⁸ Article II.4.2.b) of the IMI model Grant Agreement