Guiding principles

• Aligned with IMI objectives as a public-private partnership

• Adapted to specific research needs and challenges

• To achieve a broad participation of:
  - private and public entities in IMI projects (academic institutions; small biopharmaceutical companies; large biopharmaceutical companies)
  - patients’ organisations and regulatory agencies
Guiding principles

- To promote knowledge creation, together with its disclosure and exploitation
- To achieve fair allocation of rights
- To reward innovation
- To provide some scope of flexibility for participants to establish the most appropriate agreements serving the project objectives (-> Project Agreement, i.e. agreement between the participants)
Working basis

• IP Policy set up in August 2007

• Grant Agreement adopted in March 2009

• Explanatory note of IPR Helpdesk published in 2008

• Guidance Note of October 2010 (including Clarification Note of 2009)
IP Working Group

- Set up by the IMI Governing Board
- Composed of representatives from EC, EFPIA and Member/Associated States
- With the objectives:
  - to exchange views on the IMI IP Policy
  - to coordinate a targeted dialogue between interested parties
  - to consider concrete feedback and experiences
Useful definitions (1/3)

• **Background**
  – data, know how, patents, copyrights and other intellectual property which is held by a Participant *prior to the accession* to the Grant Agreement, and which is necessary for carrying out the Project and identified in the Project Agreement

• **Foreground**
  – results, patentable or not, which are generated by a Participant *under the Project* excluding Sideground

• **Sideground**
  – results, patentable or not, 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
Useful definitions (2/3)

Start of the project

Implementation

End of the project

Background

Foreground

// Sideground //

possible access rights
Useful definitions (3/3)

- **Research Use**
  - use of Foreground or Background necessary to use Foreground for all purposes other than for completing the Project or for Direct Exploitation

- **Direct Exploitation**
  - to develop for commercialisation or to commercialise Foreground itself

- **Dissemination**
  - disclosure by any appropriate means other than that resulting from the formalities for protection, and including the publication in any medium
Quid of Background

- Shall remain the exclusive property of each Participant
- Possibility to freely license, assign or otherwise dispose of its ownership rights in Background
- Has to be identified in the Project Agreement
- Prior legal restrictions to be specified in the Project Agreement
Quid of Foreground

• Belongs to the Participant who generated it, unless otherwise agreed

• Joint ownership
  - if generated by several Participants, except otherwise agreed in the Project Agreement
  - each joint owner shall have the right to use such jointly owned Foreground, provided that prior notice is given to the other joint owners, and fair and reasonable compensation are provided to the other joint owners

• Possibility to freely license, assign or otherwise dispose of its ownership rights in Foreground if:
  - expressly permitted in Grant Agreement and/or Project Agreement
  - after obtaining the consent of all Participants
Transfer of Back/Fore-ground

- Possible transfer of ownership subject to pass on its IP obligations under the Grant Agreement and the Project Agreement regarding that Back/Fore-ground

- Transfer to affiliates, any purchaser of all or substantially all of assets, and any successor entity resulting from the merger or consolidation of such party without prior agreement
Access Rights (1/2)

- Granted on written request, unless otherwise agreed
- Non-exclusive basis approach
- No sub-licences, unless otherwise agreed
- Not affected by the termination of participation

- Guiding framework between/for participants, affiliates and third parties
- Terms: royalty-free basis / fair and reasonable / to be negotiated
## Access Rights (2/2)

<table>
<thead>
<tr>
<th>Access rights granted by a Participant to/on</th>
<th>Background (necessary and identified)</th>
<th>Foreground</th>
<th>Sideground</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants for completion of the Project</td>
<td>Royalty-free</td>
<td>Royalty-free</td>
<td>N.A.</td>
</tr>
<tr>
<td>Participants and affiliates for Research Use</td>
<td>Royalty-free OR Fair &amp; reasonable terms for Background needed for using Foreground as determined in Project Agreement</td>
<td>Royalty-free OR Fair &amp; reasonable terms as determined in Project Agreement</td>
<td>N.A.</td>
</tr>
<tr>
<td>Third Parties for Research Use after the Project</td>
<td>Fair &amp; reasonable terms for Background needed for using Foreground as determined in Project Agreement</td>
<td>Fair &amp; reasonable terms as determined in Project Agreement</td>
<td>N.A.</td>
</tr>
<tr>
<td>Participants and affiliates or Third Parties for Direct Exploitation</td>
<td>To be negotiated</td>
<td>To be negotiated</td>
<td>N.A.</td>
</tr>
</tbody>
</table>
Dissemination

- Obligation to disseminate the Foreground
- As soon as reasonably practicable
- But no later than one year after the termination or expiry of the Project

- Description of the material to be disseminated in the Project Agreement
To be considered

- Background
- Foreground
- Sideground
- Access rights
- Dissemination
- IP Committee
One policy, multiple interests

Direct exploitation rights (academia/SME)
Terms known at outset (Pharma)

Incentive to participate

Research Use for project participants
Fair and reasonable terms for others

Dissemination of information

Data in public domain within a year

Innovative Medicines

Freedom of Access

Support for EU Industry

Compensation for IP

Only necessary background included
Compensation within fair and reasonable terms

Terms accommodate a the needs of a spectrum of interests - large and small
Thank You!

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