



Innovative Medicines Initiative

New ways of sharing knowledge

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efpia

www.imi.europa.eu

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



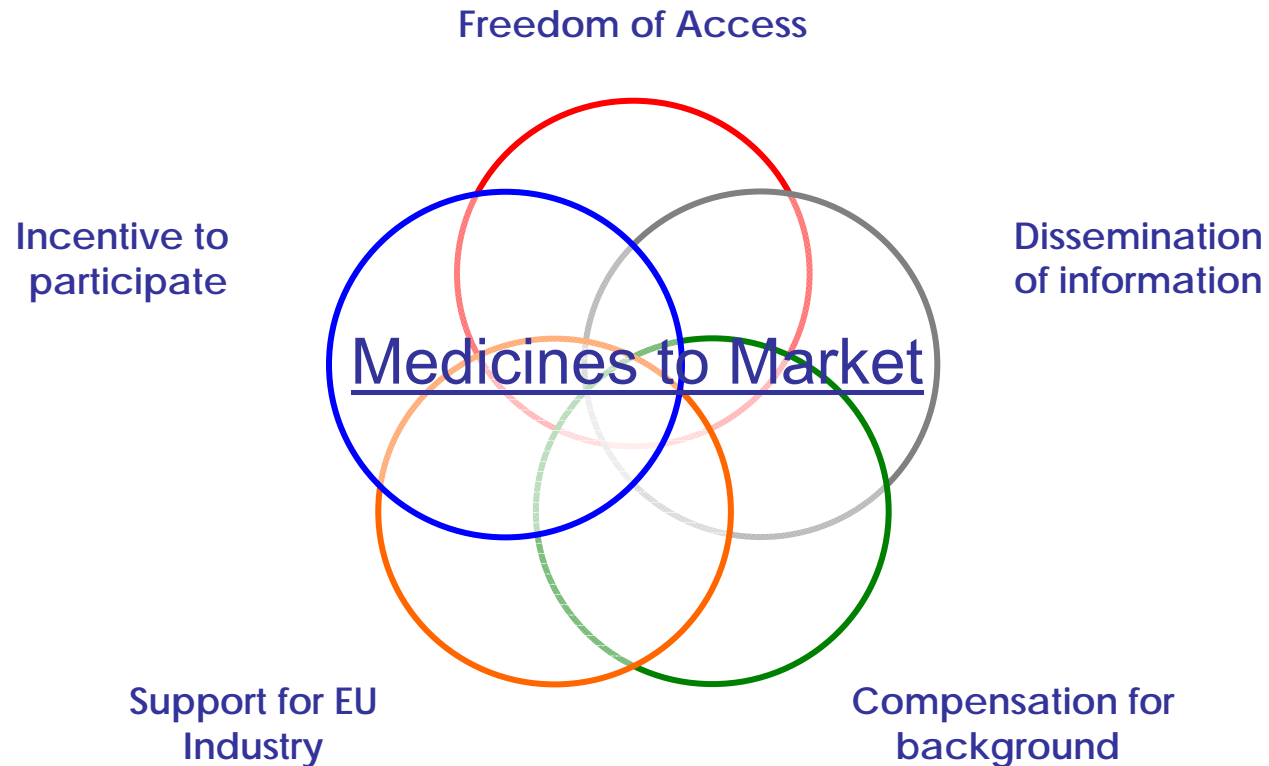
Guiding principles



- 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)



One policy, multiple interests....



Working basis



- IP Policy set up in August 2007
- Grant Agreement adopted in March 2009
- Explanatory note of IPR Helpdesk (2008)
- Clarification Note published end of 2009



Working basis



- IP Working Group
 - with representatives from EC, EFPIA and Member/Associated States
 - 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

----- *Start of the Project* -----



Useful definitions (2/3)



----- *Start of the Project* -----

- **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

----- *End of the Project* -----



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 **commercialization** or to commercialize 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



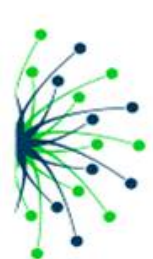
- Shall **remain** the exclusive property of each Participant
- Possibility to **freely license**, assign or otherwise dispose of its ownership rights in Background
- Has to be **identified** in the Project Agreement
- **Prior legal restrictions to be specified** in the Project Agreement



Quid of Foreground



- **Belongs** to the Participant who generated it
 - **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**
- **No sub-licences** unless otherwise agreed
- Not affected by the termination of participation

- Guiding framework between participants, affiliates and third parties
- Royalty-free basis, or fair and reasonable terms or to be negotiated



Access Rights (2/2)



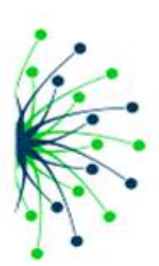
Access rights granted by a Participant to/on	Background (necessary and identified)	Foreground	Sideground
Participants for completion of the Project	Royalty-free	Royalty-free	N.A.
Participants and affiliates for Research Use	Royalty-free OR Fair & reasonable terms for Background needed for using Foreground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



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



One policy, multiple interests....



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

Incentive to
participate

Freedom of Access

Research Use for
project participants
Fair and reasonable
terms for others

Dissemination
of information

Medicines to Market

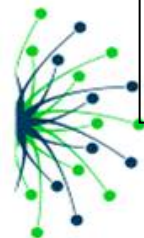
Data in public
domain within
a year

Support for EU
Industry

Compensation for
background

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

Only necessary background included
Compensation within fair and
reasonable terms





Thank you

