IMIDIA – Intellectual Property and Open Innovation in IMI projects

Bernd Stowasser, PhD, MS
Head of European Public Private Partnerships
Sanofi
Agenda

• Open Innovation – why do we need it?

• Collaboration – what does this mean?

• Sustainable win win situations – examples how to put this into practice (Intellectual Property aspects)

• Short summary
Open innovation (for better health)

• Integrate (external) problem solvers in the innovation and development process
  o Select the right problem solving team = heterogeneous group of different stakeholders (with different interests)
  o Removing (internal & external) project barriers
  o Develop sustainable win win for all parties
  o Enable the collaboration towards common goals

• Bridge different (company / management / scientific) cultures

• (Alliance / consortium / project) management is key towards delivery
Why are Public Private Partnerships essential for Sanofi?

Global challenge: Innovate on innovation to the benefit of the patient

- Key to change how we search for innovation
- Disease management – new rule book (e.g. Personalized Medicine)
- Create, evaluate and implement new operational models (e.g. pooling of screening resources across companies)
- Enable the environment to effectively engage with policy makers

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Collaboration is a mind set towards success

The iterative process of giving and taking

Opportunities

Rewards

Harvest the value – e.g. Publications

Solution / Implementation

Project & processes

Interest & Needs – Risks & Hurdles: Dissemination & Value protection

Intellectual Property (IP) management to accompany the project planning and implementation process

- Planning first – common understanding
- Definition of (IP) needs
- Alignment & communication
  - Different levels: Scientists, Patent, Legal, Finance etc.
  - “Glue” function
- Balance and Relevance

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Dissemination strategy – the right tool for the right scenario

- Development
- Translation
- Research

Pubslications (Low IP relevance)

Patents! HIGH IP relevance (then wider publication)

Process
Best practices

Tools

Compounds

IMI - Putting Policy into Practice
IMI Project IMIDIA
IMPROVING BETA-CELL FUNCTION AND IDENTIFICATION OF DIAGNOSTIC BIOMARKERS FOR TREATMENT MONITORING IN DIABETES

- **Focus:** patient centric validated disease models / Biomarker / improved disease management

- **Challenge:** Value perception (innovation – application – development)
  - Considerable knowledge brought into the project, e.g. via SME (beta cell candidates)

- **Solution:**
  - Added value based on Pharma validation within IMIDIA
  - Fair and reasonable terms for research use outside of project
  - Stringent protection by Material Transfer Agreements

- **Success:**
  - Highly collaborative incl. SME
  - First validated human beta cell lines
  - First (Imaging) Biomarker Candidates

**Financial Overview:**

**FINANCING:**
- IMI funding: € 7,074,760
- Other contributions: € 3,750,920
- Pharma costs: € 15,081,800
- TOTAL PROJECT COST: € 25,907,480

**Starting Date:** 1.2.2010
**Duration:** 60 months
IMI Project COMPACT
Collaboration on the optimization of macromolecular pharmaceutical access to cellular targets

- **Focus:** Transport pathways across biological barriers, non-invasive delivery of biopharmaceuticals

- **Challenge:** Translation/dissemination of results
  - Wide spectrum of Foreground
    (from basic research results on membrane transport up to improved formulations for biopharmaceuticals)
  - Different participant’s expectations and concerns

- **Solution:**
  - Never give up to find the best compromise, don’t exclude key contributors on majority votes
  - Different terms on access rights (research use) for EFPIA companies and academics to ensure effective dissemination of basic research results as well as fair participation on development aspects

7 Pharma Companies:  
- Sanofi (Coordinator)  
- GSK (Dept. Coordinator)  
- Abbott  
- Novo Nordisk  
- Merck  
- Boehringer  
- Pfizer

16 Academic Partners & Biotech:  
- Utrecht University (Science)  
- Utrecht University (Veterinary Science)  
- University of Copenhagen  
- Helmholtz Institute for Pharmaceutical Research  
- Cardiff University  
- Stockholm University  
- Southampton University  
- University of Vienna  
- LMU  
- University of Zurich  
- Ghent University  
- Pharmacoidea  
- Bioneer:FARMA  
- University of Helsinki  
- Leiden University  
- University of Oxford

**STARTING DATE:** 01.11.2012  
**DURATION:** 60 months

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Focus: Discovery of novel small molecule candidates as starting points for subsequent optimisation to drug candidates, provide high-quality compound collection for drug discovery platform

Challenge: Generate value from compound screening results ("qualified hit list")
  - Align patentability and development issues with IMI access and publication policy
  - Increase likelihood to develop innovative drugs to reach the patient from this initiative

Solution:
  - Use flexibility of IPR policy (foreground ownership)
  - Setup adjusted dissemination policy
(Call topic under preparation)

- **Focus:** Increase the probability of success of developing the next generation of antibiotics by PPP with multidisciplinary teams with different skills sets and expertise

- **Challenge:** Execute PPP in highly IP relevant and competitive research and development environment
  - Define effective collaboration framework
  - Need to engage different (company) functions efficiently (scientific unit, BD, Legal, Contracting, IP)

- **Proposed solution**
  - Setup binding collaboration framework
  - Use flexibility of IPR policy (foreground ownership)
  - Pre-defined process for potential commercial exploitation
    (Elaborate compensation schemes for participants generating Foreground with respect to development results)
Setting-up IMI projects with considerable competitive aspects in Sanofi
(in restricted areas of high medical and society needs such as AMR)

- IMI Call Text Preparation
  - Scientific content, structure and WP definition, EFPIA contribution, deliverables, financial and IP framework
- Bilateral Framework Agreement (competitive part of collaboration)
  - Frame of collaboration, governance, IP and access rights, IP rules after project completion, financial contribution

**IMI Process – RGD, Consultation, Approvals**
- Crucial to align content and activities

**IMI PM**
- Contracting
- Scientific Expert
- Legal (Contract)
- IP (Contracts)
- BD

**Sanofi**

**IMI Coordinator Team**
- Scientific Expert
- Unit Management
- Legal (IMI)
- IP (IMI)

**Sanofi**
Dissemination strategy – the right tool for the right scenario

IMI - Putting Policy into Practice
Summary

- Open innovation – sustainable win win situation
- Project determines the dissemination channel for results to secure the value for all participants
  - Publication
  - Patent – then publication
- Complexity and diversity are opportunities and not a pain
  - needs to be managed, but not in isolation
- Results depend on longer breath and many short sprints – but they will come!