IMI – The Innovative Medicines Initiative
Perspectives on future projects touching “adaptive pathways”

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IMI – Europe’s partnership for health

IMI mission

IMI facilitates open collaboration in research to advance the development of, and accelerate patient access to, personalised medicines for the health and wellbeing of all, especially in areas of unmet medical need.
IMI – Ecosystem for innovative collaborations

- Allow engagement in a cross-sector, multi-disciplinary consortium at the forefront of cutting-edge research
- Provide the necessary scale by combining funding, expertise, knowledge, skills and resources from public and private
- Build collaboration based on trust, creativity and innovative and critical thinking
- Learn from each other - new knowledge, skills, ways of working
- Take part in transformative research that will make a difference in drug development and ultimately patients’ lives

**IMI is a neutral platform where all involved in drug development can engage in open collaboration on shared challenges.**
Why do we need IMI?

Because despite excellent research we still don’t have…

- enough antibiotics in development
- a cure for diabetes
- a cure for schizophrenia
- a cure for dementia
- an Ebola vaccine

So IMI is…

- supporting projects across the whole spectrum of medical research, development & innovation, including drug development based on understanding the underlying mechanisms of disease
- identifying & developing potential diagnostics and drugs
- testing safety / efficacy
- adapting clinical trial design based on current scientific knowledge
- providing evidence supporting adaptation of regulatory pathways to scientific drivers
What does the typical IMI project look like?

Industrial partners align themselves around a real challenge for industry and agree to work together and commit resources.

New ideas from public sector, universities, SMEs etc. are needed to address the challenge.

Scale is a key to success and is provided by IMI funding and the outcomes should be transformative for the industry as well as having a clear “public” value.
Challenges

- The Public – Private Partnership space
  - Challenging to all stakeholders as out of everyone’s comfort zone (but realisation that more collaboration is needed)
  - Continued commitment from the public and private funders
  - Constant need for alignment between public and private
- Choosing the best topics that demonstrate the true value proposition of the model
- Bringing all stakeholders (e.g. payers, healthcare providers, ICT, diagnostic companies..)
- Defining impact indicators
- Using the multidisciplinary collaborative model optimally
- Learning from the programme in a continuous way
IMI 1 projects

Projects ending
What are the achievements – lessons learned

Sustainability
How to ensure sustainability of the assets

Uptake of the projects results
How to integrate project outputs into the product lifecycle
(i.e. on development, regulatory and clinical practices as relevant)
How to capitalise these results if further research needed

Impact of IMI projects and overall success of IMI 1 programme
How to measure the outcome/long term impact – what are the indicators?
“The IMI 1 projects reviewed were not designed to directly bring new medicines to market. Rather they will impact on new product development by acting on the medicines development process itself, usually in particular disease areas”

From the report of the IMI Socio-economic Impact Assessment Expert Group May 18th 2016. Available on IMI website
IMI2 overall objectives

- **improve the current drug development process** through development of tools, standards & approaches to assess **efficacy**, **safety** & **quality** of health products.

- **develop diagnostic & treatment biomarkers** for diseases clearly linked to clinical relevance & approved by regulators

- **reduce time to clinical proof of concept** (e.g. for cancer, immunological, respiratory, neurological/neurodegen. diseases)

- **increase success rate in clinical trials** of priority meds (WHO)

- **develop new therapies** for diseases with **high unmet need**, (e.g. Alzheimer’s) & **limited market incentives** (e.g. AMR)

- **reduce failure rate of vaccine candidates** in phase III trials through new biomarkers for efficacy & safety checks

- **IMI2 legislation, Article 2b**
IMI2 – Strategic Research Agenda
The right prevention and treatment for the right patient at the right time

Enablers to patient access to innovative medicines
ADAPT-SMART - A unique opportunity to fully analyse MAPPs and its possible implementation

One team

- Unique opportunity to bring all stakeholders under neutral platform; learn and trust each other and think outside the box;
- Sharing views and reach alignment
- Concrete/tangible results/recommendations
- Joint responsibilities at all levels and contribution of all needed: partners/advisors/stakeholders!
- Tight schedule & budget
- High visibility/political dimension

Keep focused on project objectives
Future projects touching “adaptive pathways”

- IMI2 projects/topics launched
  - PREFER (patients preference to inform benefit/risk assessment)
  - Big data for better outcome (BD4BO) programme projects
    ROADMAP (Alzheimer’s disease); HARMONY (haematologic malignancies), Topic on cardiovascular diseases)
  - RADAR-CNS (Remote Assessment of Disease and Relapse in Central Nervous System Disorders)
- IMI2 Call 10 for proposals launched in December 2016
  - BD4BO topic on prostate cancer
  - Patient perspectives in medicines lifecycle
  
  [http://www.imi.europa.eu/content/imi-2-call-10](http://www.imi.europa.eu/content/imi-2-call-10)
Future projects touching “adaptive pathways”

- 2017 IMI annual workplan

Scientific priorities

- Expansion of the BD4BO programme, incl Distributed Data Network (core distributed data infrastructure to allow real world evidence data repositories to be combined)
- Expansion of the RADAR programme
- Advanced therapies?

Key role for ADAPTSMArt to help shaping topics under consideration and/or inform potential future topics necessary to MAPPs implementation
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