IMI – The Innovative Medicines Initiative

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Summary of presentation today

- Some background - our current environment
- IMI – what it is and what it does
- Big Data examples in IMI projects
- Challenges
- Future Prospects
Some Background
What is the current environment for Healthcare Innovation?
Drivers for Change in Innovative Medicines

- Science and technology – the knowledge base is changing rapidly
- Huge challenges bringing this knowledge to patients
- Public Health challenges are increasing
  - Emerging diseases
  - Chronic diseases
- Demand on health provision is increasing
- Economic environments are more constrained
- Industry is adapting to a new ecosystem
Challenges in the Development of New medicines

- High Risk (large failure rate mostly due to unpredicted toxicity and lack of efficacy)
- Very inefficient process
- Duplication of effort amongst industry players
- Expensive
- Complex
- Long timelines
- Not enough science accompanying all development stages
- Clinical trial design not optimised for specific indications
- Regulatory pathways not always optimised for patient needs
All of this has a significant impact on the affordability and speed of access for innovation for patients.
The Innovative Medicines Initiative
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Through IMI projects we hope to:

- Share risk (amongst public and private players)
- Increase efficiency of drug development by developing common tools
- Reduce duplication of effort (especially at early stages)
- Incentivise companies to play in the non-competitive space
- Reduce timelines using a stratified approach (precision medicine)
- Integrate the latest science in real time during the development process
- Put patients at the centre
- **Use data and knowledge management to increase the efficiency of everything we do**
IMI – Europe’s partnership for health

IMI1: 2008-2013
€2 bn budget
59 projects

IMI2: 2014-2024
€3.3 bn budget
More ambitious
More open
Greater scope

> €5 bn

Partnership
2008 - 2024

€2.5 bn

EFPIA
€2.5 bn
IMI2 – building on successes of IMI1

- Focused: **stratified medicines** and healthcare priorities
- Healthcare solutions: prevention and treatment
- **End-to-end**: R&D, regulatory and access – move integration a step further
- Multi-sector: **within and beyond life sciences**

**European Commission From H2020**
€ 1638 M

**EFPIA & Partners in Research**
€ 1425 M

**Associated Partners**
€ 213 M

**IMI2**
€ 3276 M
The Vision for IMI2

Science is driving the manner in which we view disease

Population  Molecular diagnosis based on biological knowledge  Individual

We “treat” a population. Some respond and some don’t

We “treat” a targeted population. They all respond
Big Data examples in IMI projects
What types of Data are we talking about?

- Research Informatics “omics” and all analytical tools that are needed to create new knowledge

- Translational Informatics – needed to design clinical trials and validate tools (biomarkers) to speed up clinical development. Includes predictive toxicology work

- Real World Data – clinical data, pharmacovigilance data
Alzheimer’s disease – a major unmet need

Alzheimer’s disease in numbers…

- 46.8 million affected globally
- 10.5 million in Europe
- Global cost USD 818 billion (EUR 732 billion)
IMI action on Alzheimer’s disease

**PHARMA-COG**
Matrix of biomarkers
- Test efficacy of new treatments

**EMIF**
Linking & analysing data
- Identify those at risk

**AETIONOMY**
New classification of AD/PD
- Personalised treatments

**EPAD**
‘Adaptive’ clinical trials
- Faster drug development & patient access

*Total budget €169 million*
Sharing data to improve clinical trials for schizophrenia

By redesigning clinical trials, you could:

- make them **shorter** (6 weeks → 4 weeks)
- require **fewer people** (79 → 46 patients per arm)
- **cut costs** (savings of €2.8 million)
- gain **insights** into effects of treatment on negative symptoms (e.g. lack of emotion)

23 000 patients
67 studies
25 countries

1 database

23 000 patients
67 studies
25 countries

IMI
innovative medicines initiative
Development of reliable toxicity predictive systems

- Largest database on preclinical safety data providing access to unpublished safety data
- 90 in silico models for safety prediction delivered
- Regulatory dialogue on use of database and in silico tools
- First early candidate assessment based on eTOX database in member company allowed more targeted development process
- Development of data standards for ontologies with the potential to become regulatory practice
- Honest broker concept for secure data sharing developed, thereby broadening the pre-competitive space

Predicting cardiotoxicity
ONCOTRACK – a systems biology approach to model the tumour cell

The premise: most attempts to identify novel biomarkers probably fail because the source data do not sufficiently represent the complexity of the tumour

- OncoTrack - An *in silico* model (ModCellTM) is being populated with genomic, transcriptome, genetic, biochemical and pathologic information derived from tumour samples (CTC, free circulating DNA, CSC, xenografts) collected prospectively from patients diagnosed with colon cancer

- This approach allows detailed analysis of signalling pathways in the tumour

- Major deliverable: Biological validation of the computational prediction of treatment response
eTRIKS - European Translational and Knowledge Management Services

- Supports collaborative projects
- Analysis needs of translational data
- Deploys open-source tranSMART
- Service with public data
- Ethics / data protection
- Standards research
- transMART Foundation
  - 35 transMART implementations
  - multiple development teams
  - commercial services

Abirisk
Oncotrack
U-BIOPRED
Predict-TB
RA-MAP ....

studies including omics
images clinical assessment
Efforts to Automate clinical research

1. DESIGN
   Feasibility Study

2. EXECUTION
   Patient Recruitment

   Protocol
   (CDISC PRM – SDM)

3. EXECUTION
   Data Collection

   Case Report Form
   (CDISC ODM)

FDA-EMA SUBMISSION

Regulators

- Trial Registry
- Document Management System
- Clinical Trial Management System (CTMS)
- Clinical Data Management System (CDMS)

CDISC PRM – SDM
CDISC ODM
Current Challenges and Approaches to Data and Knowledge Management
Challenge

- **Massive amounts** of diverse healthcare data currently exist:
  - inpatient and outpatient hospital data, prescription data, claims information and patient-reported data, sociodemographic data, clinical trial data, 'omic measurements etc..
- **Linking this data** could lead to many **powerful insights**
- Currently, no wide scale exploitation of these data
Big Data for better Outcomes (BD4BO) Programme Goals

- Exploit the opportunities offered by large data sets from variable sources to increase medical innovation and deliver better quality healthcare systems

- Support the evolution towards outcomes-focused and sustainable healthcare systems through engagement of key stakeholders
**BD4BO Programme Objectives**

1. **Design sets of standard outcomes and demonstrate value**
   - Sets of outcomes
   - Clinical endpoints
   - Alignment of HC stakeholders on the outcomes

2. **Increase access to high quality outcomes data**
   - Mapping of data sources and methods for harmonization
   - Governance and technical standards

3. **Use data to improve value of HC delivery**
   - Drivers of outcomes variation
   - Best clinical practices
   - Methodologies to predict outcomes

4. **Increase patient engagement through digital solutions**
   - Patient Reported Outcomes opportunities
   - Profiling patients behaviors
   - Tools to increase patient engagement
**BD4BO Programme Topics**

1. Design sets of standard outcomes and demonstrate value
   - **COORDINATION AND SUPPORT ACTION (CSA)** – Call 7
   - **DISTRIBUTED DATA NETWORK** – Planned for Call 9
2. Increase access to high quality outcomes data
   - **ROADS: ALZHEIMER'S DISEASE** – Call 6
3. Use data to improve value of HC delivery
   - **HEMATOLOGIC MALIGNANCIES** – Call 6
   - **CARDIOVASCULAR** – Call 7
4. Increase patient engagement through digital solutions

**Future topics**
Future Challenges

- How do we sustain valuable data rich assets developed during IMI projects?
- Who values these data sets? Who will use these data sets?
- Who will pay for their sustainability?

- What are the next challenges?
  - Data integration from multiple sources, multiple types etc
  - Data interfaces (Research/ Clinic) at scale and internationally
  - Data standards
Future Challenges (contd.)

- We need to engage with partners (ELIXIR, DG CNECT, Global initiatives)

- Institutional, Legal and Social issues related to the use of clinical data
  - Data privacy and the concerns around the use of personal clinical data

- Interoperability of systems globally
  - Global Alliance for Genomics and Health
The Innovative Medicines Initiative

**IMI as a productive public-private partnership for innovative medicines**

- IMI is a magnet for collaboration and co-investment.
- IMI facilitates end-to-end integration, from research to consumers of innovation (patients and payers).
- IMI is a neutral platform for pharmaceutical companies and others to collaborate and share data and knowledge.
- IMI is an open model that is attracting other disciplines (e.g. ICT).
Thank you

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