



The Innovative Medicines Initiative – Europe's partnership for health

Meeting SGPP – 28 September 2018





What is IMI and why do we need it?

IMI – Why Europe's partnership for health?

Because drug development is very...



Because...

- Biological mechanisms underlying disease are complex
- Clinical trial designs need to be adapted to scientific knowledge
- Regulatory pathways should be adapted due to scientific drivers



IMI – Why Europe's partnership for health?

Because despite decades of research we still don't have...



- supporting projects across the whole spectrum of medical R&D and drug development, incl. understanding diseases;
- identifying & developing potential drugs;
- testing safety / efficacy;
- improving clinical trial design...



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 key concepts

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 through IMI funding

Outcomes should be transformative for the industry as well as having a clear "public" value



IMI 2 budget (2014 – 2020)







IMI 2 Strategic Research Agenda

- Antimicrobial resistance
- Osteoarthritis
- Cardiovascular diseases
- Diabetes
- Neurodegenerative diseases
- Psychiatric diseases
- Respiratory diseases
- Immune-mediated diseases
- Ageing-associated diseases
- Cancer
- Rare/Orphan Diseases
- Vaccines









How does IMI work? Two stage procedure



A typical IMI consortium











Improving the current drug development process

Medicines safety – the challenge

- A major challenge in drug development is finding medicines that treat the disease but are not toxic to vital organs like the heart, liver, kidneys, etc...
- Too often, toxicity issues are only picked up late in drug development, when vast amounts of time and money have been spent on a drug.

IMI projects are developing simple tests to detect to toxicity issues earlier in drug development.



Medicines safety – an IMI success

lnput = 2D

structure of a

possible drug

What eTOX did Pharma data + Public data = One big database underlying multiple computer-based tools

- Project partners using tools
- Reducing animal testing

Output = possible effect on heart – ECG result!

Example: Will this be toxic to the heart?

H₃C

CH₃

CH₂

Medicines development – the challenge

- High Throughput Screening (HTS) = researchers screen large collections of chemical compounds in hunt for molecules that could be potential drugs or be used in drug development in other ways.
- Pharmaceutical companies have huge compound collections, but access to these is usually tightly restricted...
- Public compound collections exist, but are small and expertise is scattered across many institutions.

Through its European Lead Factory project, IMI has created a state-of-the-art compound collection & screening centre that is delivering results for academics, SMEs & pharma



Medicines development – an IMI success



Joint European Compound Collection

320 000 cpds from 7 pharma companies

200 000 cpds from public partners European Screening Centre

Advanced, ultra high throughput screening facilities & expertise on logistics, medicinal chemistry, etc. 'Access to the European Lead Factory has fast-forwarded our drug discovery programme in the field of oncology by several years.' – Huib Ovaa, Netherlands Cancer Institute

'ELF support & its high quality compound library ... will allow Effecta Pharma to expand its drug discovery efforts for dengue and gives an *important boost* to tackling this viral disease.' – Effecta Pharma, UK biotech company

- ✓ Leading role for SMEs
- ✓ Quality & diversity of compounds recognised
- ✓ Award-winning IP solution
- ✓ Happy users!







Fighting AMR and Dementia: two examples of current IMI programmes

Antimicrobial resistance – a growing threat





IMI New Drugs for Bad Bugs programme

Challenge 1: Getting the drug into the bug

TRANSLOCATION: Addressing scientific challenge of penetration barriers & efflux

Challenge 2: Translation from early discovery to clinic

ENABLE: Combine academia / industry expertise to work on early-stage novel molecules

Challenge 3: Clinical dvpt long, costly & often inefficient

COMBACTE family, iABC:

Creating sustainable clinical investigator / laboratory / epidemiology networks; clinical studies Challenge 4: Low return on investment

DRIVE-AB: Options for a new economic model of antibiotic development & stewardship. Buy in from all stakeholders

Impact and Results

- The New Drugs for Bad Bugs (ND4BB) programme has delivered screening data on the antimicrobial activity and toxicity of several compounds;
- The COMBACTE family of projects is building self-sustaining, pan European antibacterial development networks and using them to run high-quality clinical studies addressing antimicrobial resistance. To date, there are 7 clinical trials and studies running;
- COMBACTE-NET trained 598 people on the creation of a high quality clinical network of investigators supported by laboratory network to conduct high quality studies;
- 46 (of 70 total) applications to enter ENABLE with a new development programme came from SMEs;



Alzheimer's disease – a major unmet need

Alzheimer's disease in numbers...

- 46.8 million affected globally
- 10.5 million
 in Europe
- Global cost
 EUR 732 billion





IMI neurodegenerative diseases portfolio

Challenge 1: What are the underlying causes of dementia?

AETIONOMY: Identifying subgroups of dementia, based on underlying genetic / molecular causes, to allow tailored treatments Challenge 2: Who is at greatest risk of developing dementia?

EMIF: Linking & analysing data from many studies to identify markers of risk

Patients involved

Challenge 3: How can we improve clinical trial design?

EPAD: Setting up innovative clinical trials that allow multiple treatments to be tested at same time

Challenge 4: Can brain scans aid research & treatment?

AMYPAD: Studying how brain scans of 'amyloid plaques' could aid diagnosis, treatment & research

Impacts and results

- IMI projects are creating environments for early interventions in dementia
- EPAD is setting up an unprecedented pan-European platform for clinical trials of novel treatments designed to prevent the onset of dementia;
- AETIONOMY discovered 180 putative disease mechanisms for Alzheimer's and Parkinson's diseases, of which 6 have been selected for further validation;
- EMIF has opened up access to the EMIF Data Catalogue to the wider research community. The online catalogue currently (early 2017) includes 14 population-based data sources (e.g. electronic health records, regional databases) and 46 cohorts.



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