Innovative Medicines Initiative 2
2009-2014

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Make Drug R&D processes in Europe more efficient and effective and enhance Europe’s competitiveness in the Pharma sector

The Evolution of IMI: From bottlenecks in industry – to bottlenecks in Industry and Society

Primary focus of early IMI calls 2007 SRA
Shift to also addressing challenges in society and healthcare 2011 SRA
IMI 2 includes real life medical practice 2013 SRA
The premises

- Alignment with **Horizon 2020** objectives of the Health challenge
- Addressing healthcare priorities identified by the WHO 2013 report on priority medicines for Europe and the world
- Strategic Research Agenda aimed at progressing the vision of personalised medicines, for both prevention and treatment
- Collaboration across sectors to harness all knowledge and technologies which can contribute to IMI2 vision - diagnostics, imaging, IT, medical devices, …
IMI2: Major Axes of Research

- Reclassification of disease by molecular means
- Target Identification and validation (human biology)
- Determinants of drug/vaccine safety and efficacy
- Innovative drug delivery methodologies
- Manufacturing for personalised medicines
- Discovery and Development of novel preventative and therapeutic agents
- Innovative Medicines
- Innovative clinical trial paradigms
- Innovative methodologies to evaluate treatment effect
- Adoption of innovative clinical trial designs
- Benefit/Risk Assessment
- Healthcare delivery: focus on the treatment programmes not just the medicine
- Innovative adherence programmes
- Innovative clinical trial paradigms
- Biomarker identification/validation (precision medicine)
- Innovative Medicines
- Innovative medicines initiative

Drive change in delivery of medical practice
IMI2 - Broad participation to be able to set ambitious goals

IMI is evolving, with a stronger focus on the needs of patients and society and with simpler rules and procedures

Evolution in scientific focus
• Stronger focus on needs of patients and society, including unmet needs
• Increased emphasis on improving patient access to innovative medicines (in addition to medicines development)
• Focus on personalised medicine (the right treatment for the right patient at the right time)
IMI2 - Broad Participation to achieve ambitious goals:

**Bigger budget:** 3,45 Billion Euro, equally shared by EU and industry

- **Not limited to EFPIA members:** open for other industries / companies, which can contribute to the PPP goals (Healthcare IT, medical devices,…) giving them the opportunity to establish their own projects

- The principle of large companies providing an inkind contribution matched by IMI funding for public beneficiaries will be retained.
IMI2 - Broad Participation to achieve ambitious goals:

**Specified Budget:** 225 million Euros reserved for non-EFPIA led projects (to be matched by inkind contributions)

- Objectives, deliverables and timelines determined by the company(ies) proposing the project

- Inkind contribution determined by the company(ies)

- Once approved by IMI’s Governing Board the Programme Office will launch a call for proposals to identify public partners for the project

- The call process and review of submitted proposals will be independent of the company(ies)
## IMI projects including biobanking activities

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<tr>
<th>Project</th>
<th>Area</th>
<th>PROJECTS description</th>
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</table>
| NEWMEDS     | schizophrenia and depression  | Develops biomarkers to allow better treatments for schizophrenia and depression  
 Biobank of DNA samples  
 Has assembled the largest known repository of antipsychotic clinical trial data  
 The database contains information on 23 401 patients from 67 industry sponsored studies. |
| U-BIOPRED   | asthma                         | Towards a new taxonomy of asthma:  
 Creates a biobank containing samples from more than 800 adult and children patients suffering from asthma.                                                                                                                                                                                                                                            |
| EU-AIMS     | autism                         | Towards new treatment for autism spectrum disorders (ASD): Develops new tools to study the pathogenesis of ASD and test the efficacy of innovative therapies  
 Creates an European clinical investigator network  
 Establishes a biobank of DNA samples to investigate genetic predisposing factors (CNVs).                                                                                                                                                                                                                                               |
| DIRECT      | diabetes                       | Towards personalised therapy of diabetes: Aims to identification of biomarkers to predict evolution of diabetes and responses to drugs  
 Creates a large European diabetes repository of blood, urine and DNA samples  
 5000 patients with type 2 diabetes to be enrolled.                                                                                                                                                                                                                                                                 |
| BIOVACSAFE  | Vaccines                       | Establishing the safety of vaccines: Develops cutting edge tools to improve the testing and monitoring of vaccine safety  
 Creates a large repository of samples to store information and explore factors involved in reactions to vaccines.                                                                                                                                                                                                                                                                 |
| BT-CURE     | rheumatoid arthritis           | Biobanks to improve rheumatoid arthritis management  
 Creates the largest biobank of pre-disease RA samples in the world, with more than 800 000 patients and 2 million samples.                                                                                                                                                                                                                                                                                       |
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<td>STEMBANCC</td>
<td>Stem cells</td>
<td>Aims to derive and biobank 1500 different iPSC lines from homogeneous patient cohorts covering five major disease groups (peripheral neuropathies, neurodegenerative disorders, neurodysfunctional disorders, diabetes, and adverse drug responders).</td>
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<tr>
<td>EBISC</td>
<td>Stem cells</td>
<td>European bank of induced pluripotent iPS cells — Generation and distribution of iPS cells along with detailed stem cell bank geno- and phenotypic data for key patient cohorts covering a broad range of therapeutic areas/patient diseases,</td>
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## BBMRI as participant to IMI projects

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<td>EMTRAIN</td>
<td>Education and training</td>
<td>European Medicines Research Training Network aiming at establishing a pan-European platform of excellence for education and training covering the whole life-cycle of medicines from basic research through clinical development to pharmacovigilance.</td>
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“ESFRI has called for the construction of thirteen pan-European research infrastructures. Several of these are strategically important for biomedical research among which BBMRI for biobanking and biomolecular resources. Cooperation between these frameworks and with the newly proposed PPP will strengthen Europe’s impact in the area of biomedical research and further enhance attractiveness for global cooperation and collaboration and ensure efficient use of available research funding. Research infrastructures can also strengthen the European position by encouraging mobility and improving education and training”.
Thank you

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