Die Strategische Forschungsagenda der IMI2 und Ausblick auf Call 1 und 2
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Current EU pathways are expensive and slow in getting new therapies to patients.

New therapies don’t reach patients until here.

General response rates to modern medicine:

Patients can respond differently to the same medicine:

- Anti-depressants (SSRIs)
- Asthma drugs
- Diabetes drugs
- Arthritis drugs
- Alzheimer’s disease
- Cancer drugs

Percentage of the patient population responds to medicine.

Science offers new opportunities:

Molecular diagnosis based on biological knowledge.

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

We treat a targeted population. They all respond.
IMI - tool for implementation of research, regulatory and industrial policy agendas

Reduce Attrition and Time to Market

**What**: Decrease risk by developing improved tools and methodologies

**How**: Large scale industry collaboration and engagement with scientific community

Since 2008

Increase uptake of innovation

**What**: align on healthcare priorities

**How**: Engage with regulators and payers

Since 2011

Adapt regulatory framework

**What**: adaptive development based on real life data and patient needs

**How**: Collaborate with regulators and payers

Since 2012

R&D model revamp

Global dimension

Industrial policy

R&D productivity
Objectives of IMI2 – what the Regulation says

- increase the success rate in clinical trials
- where possible, reduce the time to reach clinical proof of concept in medicine development
- develop new therapies for diseases for which there is a high unmet need and limited market incentives
- develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators;
- reduce the failure rate of vaccine candidates in phase III clinical trials through new biomarkers for initial efficacy and safety checks;
- provide support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products.
IMI2 Strategic Research Agenda (SRA)

Comprehensive framework for a 10-year programme

Prepared with input from 80+ organisations (internet and targeted)

Project ideas from industry and third parties will be screened against it

http://goo.gl/jqMP9g
Therapeutic areas covered by the IMI2 SRA

WHO 2013 report on priority medicines for Europe and the World
Percentage of DALYs for top 20 high burden diseases and conditions

Therapeutic Areas in IMI2 SRA
(no priority order)

6. EUROPEAN HEALTH PRIORITIES
   6.1. Antimicrobial resistance
   6.2. Osteoarthritis
   6.3. Cardiovascular diseases
   6.4. Diabetes
   6.5. Neurodegenerative diseases
   6.6. Psychiatric diseases
   6.7. Respiratory diseases
   6.8. Immune-mediated diseases
   6.9. Ageing-associated diseases
   6.10. Cancer
   6.11. Rare/Orphan Diseases
   6.12. Vaccines
The right prevention and treatment to right patient at the right time
# IMI2 Scientific Programme: The Need for Focus

## Therapeutic Areas and Cross-cutting Themes

1. **Neuro-degeneration**
   - Successfully prevent and treat dementia and other neurodegenerative diseases

2. **Prevention and treatment of immune-mediated disease**
   - Advance immunological understanding to deliver new treatments and develop new and better vaccines for non-infectious diseases

3. **Metabolic disorders**
   - Tackle all phases of disease and its complications, including prevention and early interception

4. **Infection control**
   - Address multidrug resistance and create incentives for reinvestment (including antimicrobials, antivirals, vaccines) and develop new and better prophylactic vaccines

5. **Translational Safety**
   - Identification of predictors of safety and development of point of care for safety biomarkers and development of new human biology platform to predict toxicity and safety during early drug development

## Differentiating Enablers for all Themes

Towards early and effective patient access to innovative prevention and treatment solutions (MAPPs):

- Target validation based on human biology
- Stratified medicine, precision medicine
- Innovation in clinical trials
- Data generation and interpretation (knowledge management)
- Prevention, disease interception, patient adherence (incl. societal acceptance of vaccines)
- Effect on medical practice and outcomes (health/disease management)
- Regulatory framework (including pharmacovigilance)
- Patient access
First projects under IMI2

Current projects for 1\textsuperscript{st} Call – \textit{launched 9 July}

\begin{itemize}
  \item Translational approaches to disease modifying therapy of Type 1 Diabetes Mellitus
  \item Discovery and validation of novel endpoints in retinal diseases
\end{itemize}

Postponed to 2\textsuperscript{nd} Call

\begin{itemize}
  \item RADAR: Remote assessment of disease and relapse (\textit{real world} data - in support to all priority areas and new R&D models)
\end{itemize}
Call 1 – Topic 1

Translational Approaches to Disease Modifying Therapy of Type 1 Diabetes Mellitus (T1DM)

- Increasing prevalence of T1DM, but no prevention or cure so far
- Deeper insight into the heterogeneous, phenotypic characteristics of people either at risk of developing T1DM or having manifest disease required → needs a multi-stakeholder approach,
- Key deliverables: 1) pan-European clinical trial and translational research network including a T1DM patient registry; 2) Innovative clinical trial paradigms; 3) Stronger patient involvement via a Patient Advisory Committee
- EFPIA partners: Sanofi (coordinator), Juvenile Diabetes Research Foundation (JDRF) (co-coordinator), Novo Nordisk, Eli Lilly, GSK, Helmsley Charitable Trust.
- Indicative budget: 17.63 mio Euro over 7 years
Discovery and Validation of Novel Endpoints in dry Age-related Macular Degeneration (dryAMD) and Diabetic Retinophathy (DR)

- No satisfying treatments available for dryAMD and DR
- Clinical endpoints beyond BCVA and predictive markers needed
- Multi-stakeholder approach needed including imaging companies
- Key deliverables: Development of novel methods (e.g. imaging, proteomics, metabolomics, genomics, epigenetics; animal models, and tools as e.g. disease/endophenotype specific patient reported outcome tools or novel visual function testing protocols) and their clinical validation.
- EFPIA partners: Bayer HealthCare (coordinator), Sanofi, Novo Nordisk, Zeiss
- Indicative budget: 7 mio Euro over 5 years
Call 2 – Potential Topic

Remote Assessment of Diseases And Relapse (RADAR)

* A better, more frequent monitoring of changes in disease state would offer great opportunities; in principal possible via novel technologies, but validation needed.

Goals of the project:

* Develop and validate the science of using biosignatures to characterise disease and predict changes in disease state through observational studies (various disease areas)

* Encourage innovation and development of novel biosensors and the associated knowledge management technology

* Understand the regulatory pathways for using remote assessment in healthcare

* Develop standards for Information Exchange that enable seamless integration of sensor, data capture, data management, & analysis technologies
Continuous flow of topics

★ It is expected to have ~ 2 calls per year

★ Topics will come from the priority areas / Strategic Governing Groups but also address other fields in the scope of the Strategic Research Agenda

★ Ideas from third parties are always welcome
Contact points


- Network of national contact points [http://ec.europa.eu/research/participants/portal/desktop/en/support/national_contact_points.html](http://ec.europa.eu/research/participants/portal/desktop/en/support/national_contact_points.html)

- IMI partner search tool for help finding collaboration partners [http://www.imi.europa.eu/content/partner-search](http://www.imi.europa.eu/content/partner-search)

- IMI Executive Office [infodesk@imi.europa.eu](mailto:infodesk@imi.europa.eu)
IMI and IMI2: from science to patients - together

SUCCESS

- New model developed & published
- Setting new standards
- In house implementation by industry
- Impact on regulatory practice
- Better drugs & impact on med. practice

Thank you for your attention!