Industry Perspective of IMI2
The right prevention and treatment, to the right patient, at the right time

Salah-Dine Chibout
EFPIA Research Directors Group member, Novartis
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IMI delivers on Innovation and Health

- Established robust validated models for Alzheimer, Diabetes, Schizophrenia, Asthma
- Developed clinically relevant biomarkers for Alzheimer, Diabetes, Schizophrenia, Asthma
- Established Robust tools for drug safety prediction, prevention and monitoring
- Establishment and regulatory submission of key standards and tools for drug development in infectious diseases, COPD, diabetes
- Improved clinical trial design and process in schizophrenia, pain, autism
- Co-funding by EU of antibiotics development
- Projects launched and planned on use of real life data and alignment of regulators and payers data requirement

Many of the above pave the way for new regulatory pathways aligned with science and technology development and creating pull incentives
- Uptake by Regulators has started (guidance, biomarkers)
Evolution of IMI – the road to IMI2

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

SRA – Strategic Research Agenda
Current EU pathways are expensive and slow in getting new therapies to patients.

New therapies don’t reach patients until here.

Total Cost: $2 -

General response rates to modern 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.
IMI2 vision – towards integrated healthcare solutions

- Addressing healthcare priorities identified by the WHO 2013 report
- Strategic Research Agenda aimed at progressing the vision of stratified medicines: prevention, treatment and health management
- Entire product cycle from discovery, through development to healthcare delivery and access models
- Collaboration across sectors to harness all knowledge and technologies which can contribute to IMI2 vision - diagnostics, imaging, IT, medical devices, …
IMI2 Strategic Research Agenda

- Priorities: WHO report on priority medicines
- Input: 70+ scientific, research, patient, regulatory organisations
- Endorsed by the IMI Scientific Committee

The right prevention and treatment for the right patient at the right time
Strategic Research Agenda for Innovative Medicines Initiative 2
Therapeutic areas covered by the IMI2 SRA

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
Major Axis of Research

Biomarker identification/validation (precision medicine)

- 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

Target & Biomarker Identification (safety & efficacy)

- Innovative clinical trial paradigms
- Benefit/Risk Assessment
- Adoption of innovative clinical trial designs
- Innovative methodologies to evaluate treatment effect

European Health Priorities

- Innovative Medicines
- Patient tailored adherence programmes
- Healthcare delivery: focus on the treatment programmes not just the medicine
- Discovery and Development of novel preventative and therapeutic agents

Innovative adherence programmes

DRIVE CHANGE IN DELIVERY OF MEDICAL PRACTICE
# IMI2 scientific programme: First five big themes

## Therapeutic Areas and Cross-cutting Themes

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<tr>
<th>Theme</th>
<th>Description</th>
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<tr>
<td><strong>1. Neuro-degeneration</strong></td>
<td>- Successfully prevent and treat dementia and other neurodegenerative diseases</td>
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<tr>
<td><strong>2. Prevention and treatment of immune-mediated disease</strong></td>
<td>Advance immunological understanding to deliver new medicines and new and better vaccines</td>
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<td><strong>3. Metabolic disorders</strong></td>
<td>- Tackle all phases of disease and its complications, including prevention and early interception (type 2 diabetes, obesity, dislipidemia, hypertension)</td>
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<td><strong>4. Infection control</strong></td>
<td>- Address big societal problem related to multidrug resistance and create incentives for reinvestment (including antimicrobials, antivirals, vaccines) and develop new and better vaccines</td>
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<td><strong>5. Translational Safety</strong></td>
<td>- Identification of predictors of safety and development of point of care for safety biomarkers &amp; Development of new human biology platform to predict toxicity and safety during early drug development</td>
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## Differentiating Enablers for all themes

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

- 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
Outputs expected from the new SGG process

**Strategic Governing Groups:**
- Will ensure a coordinated strategic approach
- Will improve efficiency of idea generation
- Will allow more coherent planning and exploitation of results
- Provide a structure for review and integration of proposals from industry and third parties
- Allow improvement of internal processes for getting commitment and speeding up the idea generation process
- Will provide a more structured engagement with other sectors, key stakeholders

**Therapeutic focus areas**
- **Neurodegeneration**
  - Leads: Janssen, Lilly, Abbvie
- **Immunology**
  - Leads: GSK
- **Diabetes/ Metabolic Disorders**
  - Leads: Sanofi, Lilly, Servier
- **Infection control**
  - Leads: AstraZeneca
- **Translational safety**
  - Leads: Sanofi, Bayer, Janssen, Novartis

**Cross cutting themes**
- **Data and Knowledge Management**
  - Leads: Janssen, Pfizer
- **Medicines Adaptive Pathways to Patients (implemented as Coordination and Support Action)**
  - Leads: Amgen, Janssen
First five big themes

* Prioritisation/selection criteria
  - Field of unmet need
  - Patient-centric approach
  - The science appears ready to make a big change over the next decade
  - Added value of PPP to make a difference (including collaboration with other industry sectors/technologies)
  - Synergies/complementarity with similar initiatives

* While keeping focus on prioritised questions, there is sufficient room for other projects within the SRA
  - e.g. Oncology; Rare/Orphan Diseases; Psychiatric Diseases; Respiratory Diseases
IMI2 idea generation
Conclusions

★ Focused: stratified medicines and healthcare priorities
★ Healthcare solutions: prevention and treatment
★ End-to-end: R&D, regulatory, access/healthcare practice
★ Multi-sector: within and beyond life sciences – there is room for win-win collaborations

★ Submit your ideas: http://imi.efpia.eu/