Industry Perspectives on IMI 2

Magda Chlebus, Director Science Policy, EFPIA
IMI 2 Info Day – Brussels, 30 September 2014
Make Drug R&D processes in Europe more efficient and effective and enhance Europe’s competitiveness in the Pharma sector.

Evolution of IMI – the road to IMI2

Idea generation
Basic research and non-clinical testing
Human testing
Regulatory Approval
HTA and Pharmacovigilance
Daily Medical practice

Primary focus of early IMI calls
2007 SRA

Shift to also addressing challenges in in society and healthcare
2011 SRA

IMI 2 includes real life medical practice
2013 SRA

SRA – Strategic Research Agenda
The pathways to patients are expensive and slow.

"The average drug developed by a major pharmaceutical company costs at least $4 billion, and it can be as much as $11 billion."
Modern Medicines – non-responder rates

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Anti-depressants (SSRI’s)</td>
<td>38%</td>
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<tr>
<td>Asthma Drugs</td>
<td>40%</td>
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<tr>
<td>Diabetes Drugs</td>
<td>43%</td>
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<tr>
<td>Arthritis Drugs</td>
<td>50%</td>
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<tr>
<td>Alzheimer’s Drugs</td>
<td>70%</td>
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<tr>
<td>Cancer Drugs</td>
<td>75%</td>
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Percentage of the patient population for which a particular drug in a class is ineffective, on average.
The Vision for IMI2 (and the Pharma industry)

From population

Molecular diagnosis based on biological knowledge

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

We “treat” a targeted population They all respond
Science is driving advances in diagnosis: breast cancer is actually 10 different diseases

“A landmark study has reclassified the country’s most common cancer in breakthrough research that could revolutionise the way we treat breast tumours… scientists found breast cancer could be classified into 10 different broad types according to their common genetic features.”

Unmet medical needs

- Burden of disease on patient and society = total cost of disease for healthcare and social security
- Unmet need:
  - No treatment
  - Inadequate treatment (resistance or treating symptoms, not cause)
  - Inadequate formulation for specific population (geriatric, pediatric, etc)
- Barriers and incentives
Strategic Research Agenda

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

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: First five big themes

## Therapeutic Areas and Cross-cutting Themes

<table>
<thead>
<tr>
<th>Theme</th>
<th>Details</th>
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<tbody>
<tr>
<td><strong>1. Neuro-degeneration</strong></td>
<td>Prevent and treat dementia and other neurodegenerative diseases</td>
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<tr>
<td><strong>2. Immune-mediated disease</strong></td>
<td>Advance immunological understanding to deliver new medicines and new and better vaccines</td>
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<tr>
<td><strong>3. Metabolic disorders</strong></td>
<td>Tackle all phases of disease and its complications, including prevention and early interception</td>
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<tr>
<td><strong>4. Infection control</strong></td>
<td>Multidrug resistance (including antimicrobials, antivirals, vaccines) and develop new and better vaccines</td>
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<td><strong>5. Translational Safety</strong></td>
<td>Predictors of safety and development of point of care for safety biomarkers, 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 (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
Success will be driven by

- Focusing on the challenges of the future
- Leveraging the value added for working together, across sectors, effectively use resources and expertise
- Focusing on strategic, game changing, think big – around broader therapeutic areas
- Change in research, regulatory, and healthcare practice
Objectives – extract from IMI2 Regulation:

- 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;
- develop tools, standards and approaches to assess efficacy, safety and quality of regulated health products.
http://imi.efpia.eu/
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
- Submit your ideas: [http://imi.efpia.eu/](http://imi.efpia.eu/)
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