IMI: opportunities and challenges for immunologists

Michel Goldman, Executive Director
Public-Private Partnerships: Why?

- Developing incentives to address major unmet medical needs
- Pooling expertise, knowledge and resources
- Providing a neutral trusted platform to align public and private interests
Innovative Medicines Initiative: Joining forces in the healthcare sector
How IMI works

A Typical IMI Consortium

Private Investment in kind

EU Public Funding cash

EFPIA

Pharma 1
Pharma 2
Pharma 3
Pharma 4
Pharma 5
Pharma 6

ACADEMIA
HOSPITALS
PATIENTS’ ORGANISATIONS
SMALL AND MEDIUM-SIZED ENTERPRISES
REGULATORS
Key figures of 42 on-going projects

Collective intelligence networks
Improved R&D productivity of pharma industries
Innovative approaches for unmet public health needs
IMI creates collective intelligence networks

Collaborative publications among IMI researchers - Calls 1-3

Data & analysis: Thomson Reuters (Custom Analytics & IP Solutions)
Delivering high quality research

Impact Index

- Pharmacology & Pharmacy
- Neurosciences
- Mathematical & Computational Biology
- Endocrinology & Metabolism
- Biology
- Research & Experimental Medicine
- Clinical Neurology
- Psychiatry
- Overall

IMI Projects average

EU average

Data & analysis: Thomson Reuters (Custom Analytics & IP Solutions)
Towards precision medicine:

*New taxonomy of diseases*

*Validated biomarkers*
Systems biology for stratification of patients with severe asthma

Total Budget: 20.6 Mi €
Biomarkers for predicting severe asthma outcome

Progress

✓ Established diagnostic criteria on severe asthma
✓ Developed various “omics” platforms based on genetic, proteomic, metabolomic, breathomic biomarkers
✓ Generated a preliminary phenotype ‘handprint’ by combining molecular, histological, clinical and patient-reported data
✓ Patient cohort - 14 centres across Europe targeting 1025 subjects, to validate the handprints for their predictive efficacy in gold standard and experimental therapeutic intervention

THORAX
An International Journal Of Respiratory Medicine
Diagnosis and definition of severe asthma: an international consensus; Bel et al., 2011

CHEST
An integrative system biology approach to understanding pulmonary diseases; Auffray et al., 2010
Targeting Rheumatoid Arthritis

Total Budget: 38.1 Mi €
Autoantibodies recognizing carbamylated proteins are present in sera of patients with rheumatoid arthritis and predict joint damage

Jing Shi, Rachel Knevel, Parawee Suwannalai, Michael P. van der Linden, George M. C. Janssen, Peter A. van Veelen, Nivine E. W. Levarht, Annette H. M. van der Helm-van Mil, Anthony Cerami, Tom W. J. Huizinga, Rene E. M. Toes, and Leendert A. Trouw

Department of Rheumatology, Department of Immunohematology and Blood Transfusion, and Department of Nephrology, Leiden University Medical Center, 2300 RC, Leiden, The Netherlands


Multiplex analyses of antibodies against citrullinated peptides in individuals prior to development of rheumatoid arthritis.

Risk-benefit assessment of biopharmaceuticals and vaccines
Immunosafety of vaccines – New biomarkers associated with adverse events

3 EFPIA companies; 13 Public organizations; 3 SME
Total Budget: 30.2 Mi €

Objectives

✓ Development of cutting edge tools to speed up and improve the testing and monitoring of vaccine safety, both before and after release to the market
✓ Characterization of early inflammation induced by vaccines
✓ Identification and validation of biomarkers of early inflammation, allergic response and autoimmunity
✓ Analysis of the incidence and epidemiology of autoimmune disease in the general population
Antibodies to biopharmaceuticals: prediction and risk analysis

The Objective

Investigate the factors behind the immune response to biopharmaceuticals and the mechanisms involved. Develop new validated assays for ADA, animal models and tools to predict individual patients response

Potential Impact

✓ Improved biopharmaceutical drug development
✓ More science based regulatory guidelines
✓ Better specification of biopharmaceuticals
✓ Standardization of immunoassays

First achievement:

✓ Drafted guidelines for immunogenicity assessment

9 EFPIA companies; 24 Public organizations; 2 SME
Total Budget: 34.9 M €
Advancing benefit-risk assessment methods

**Case study: Natalizumab**

<table>
<thead>
<tr>
<th>Event</th>
<th>Benefit-risk index</th>
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<tbody>
<tr>
<td>Relapse</td>
<td>0.3</td>
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<tr>
<td>Progression</td>
<td>0.3</td>
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<tr>
<td>Inconvenience</td>
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</tr>
<tr>
<td>Herpès infections</td>
<td>0.3</td>
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<tr>
<td>PML</td>
<td>0.2</td>
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<tr>
<td>Congenital defects</td>
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<tr>
<td>Liver changes</td>
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<tr>
<td>Seizures</td>
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<tr>
<td>Injection reactions</td>
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<tr>
<td>Hypersensitivity</td>
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<tr>
<td>Flu-like symptoms</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td><strong>0.8</strong></td>
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</tbody>
</table>

Budget: 29.8 Mi €

+ 4 other regulatory agencies

12 EFPIA companies

11 Academic institutions

1 Patient coalition

2 SMEs
What’s next for IMI?
In the pipeline for Q4 2013

- Project to be launched: 
  *Towards a new taxonomy of SLE*

- Call for Proposals to be launched:
  *Correlates of protection for flu vaccines*
Strategic Research Agenda for IMI2:
The right prevention and treatment for the right patient at the right time


Comments and suggestions are welcome: SRAconsultation@efpia.eu
Thank you

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