



Innovative Medicines Initiative

IMI: opportunities and challenges for immunologists

Michel Goldman, *Executive Director*

Public-Private Partnerships: Why ?

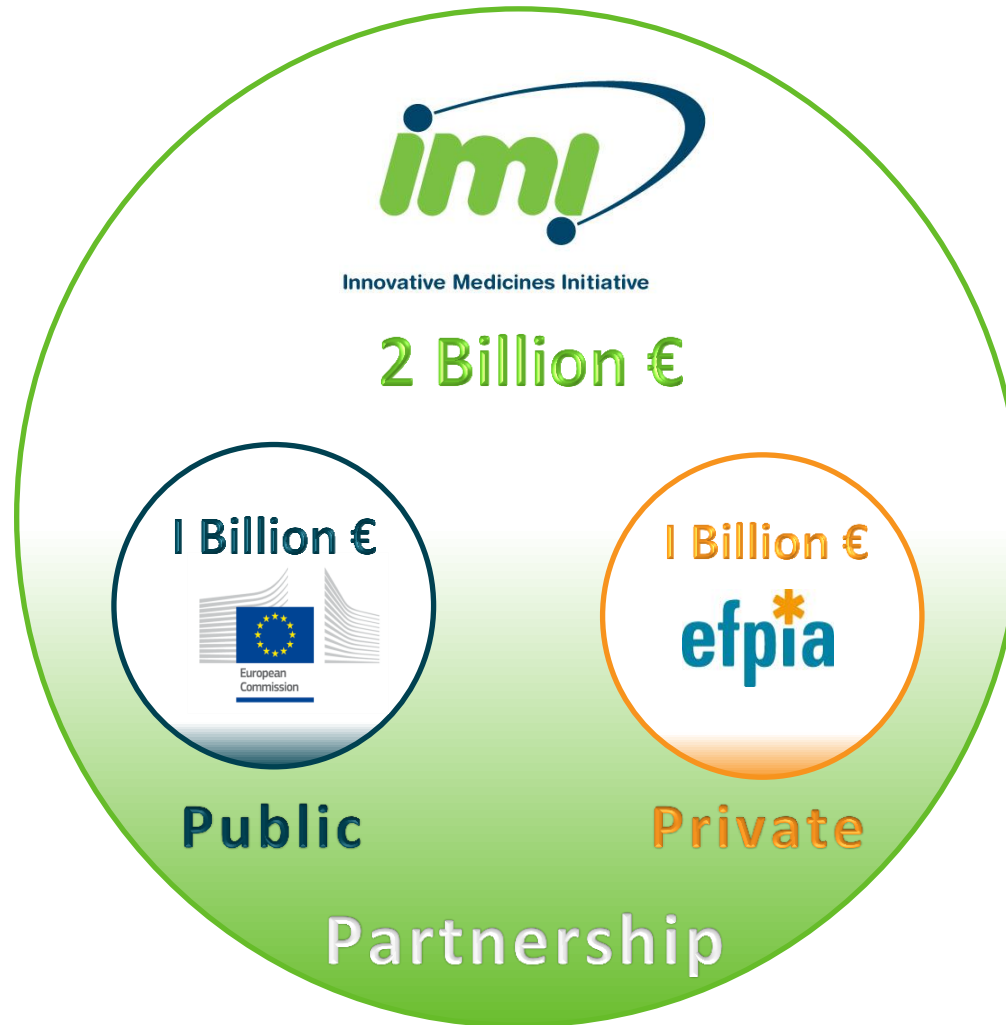


- ❑ Developing incentives to address major unmet medical needs
- ❑ Pooling expertise, knowledge and resources
- ❑ Providing a neutral trusted platform to align public and private interests

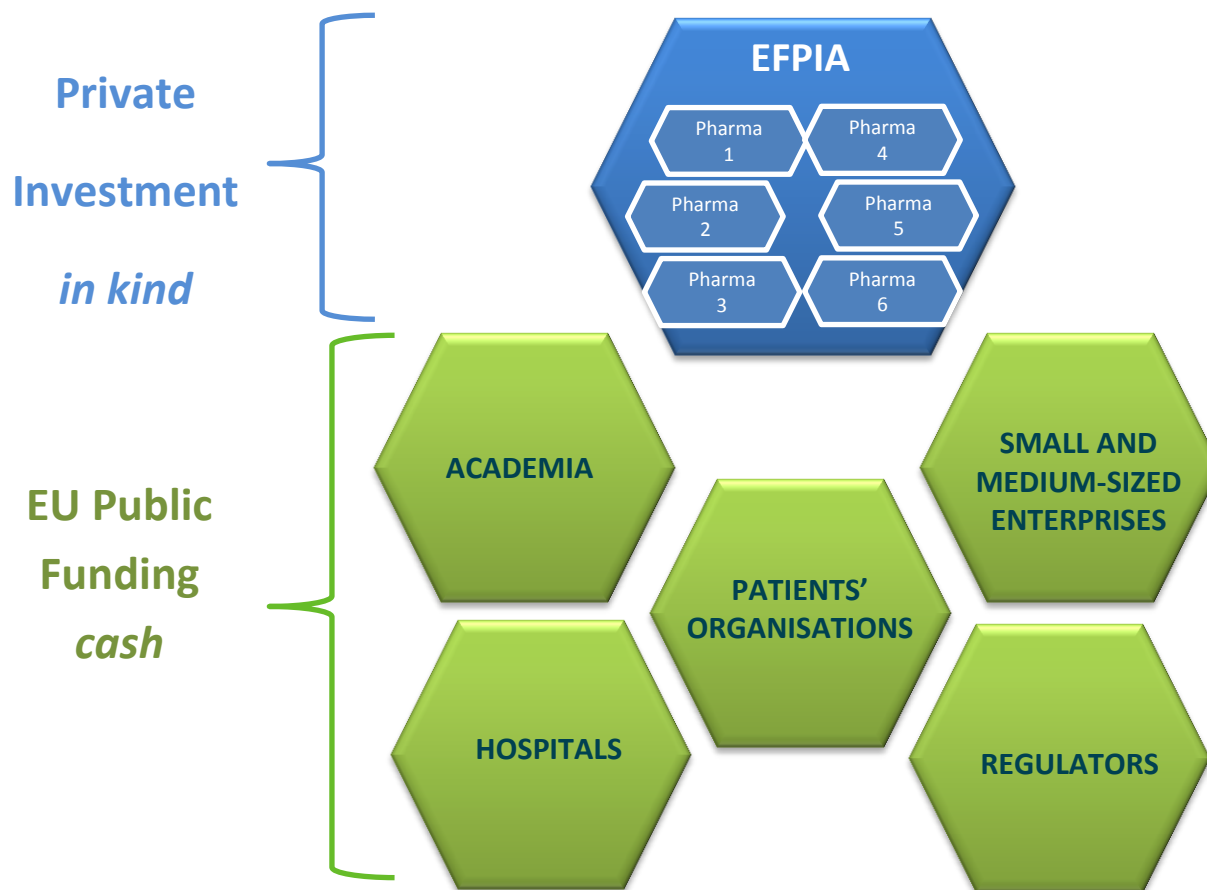


Innovative Medicines Initiative:

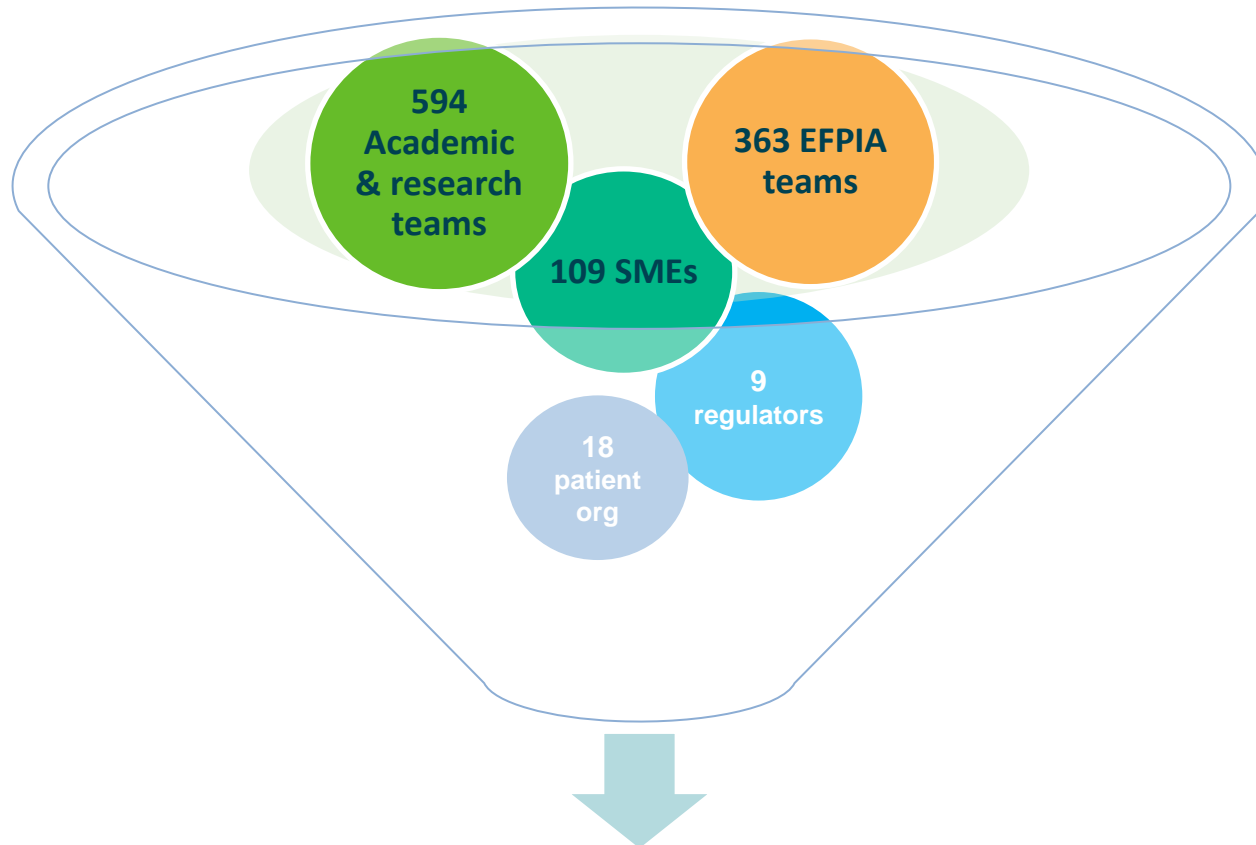
Joining forces in the healthcare sector



A Typical IMI Consortium



Key figures of 42 on-going projects



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

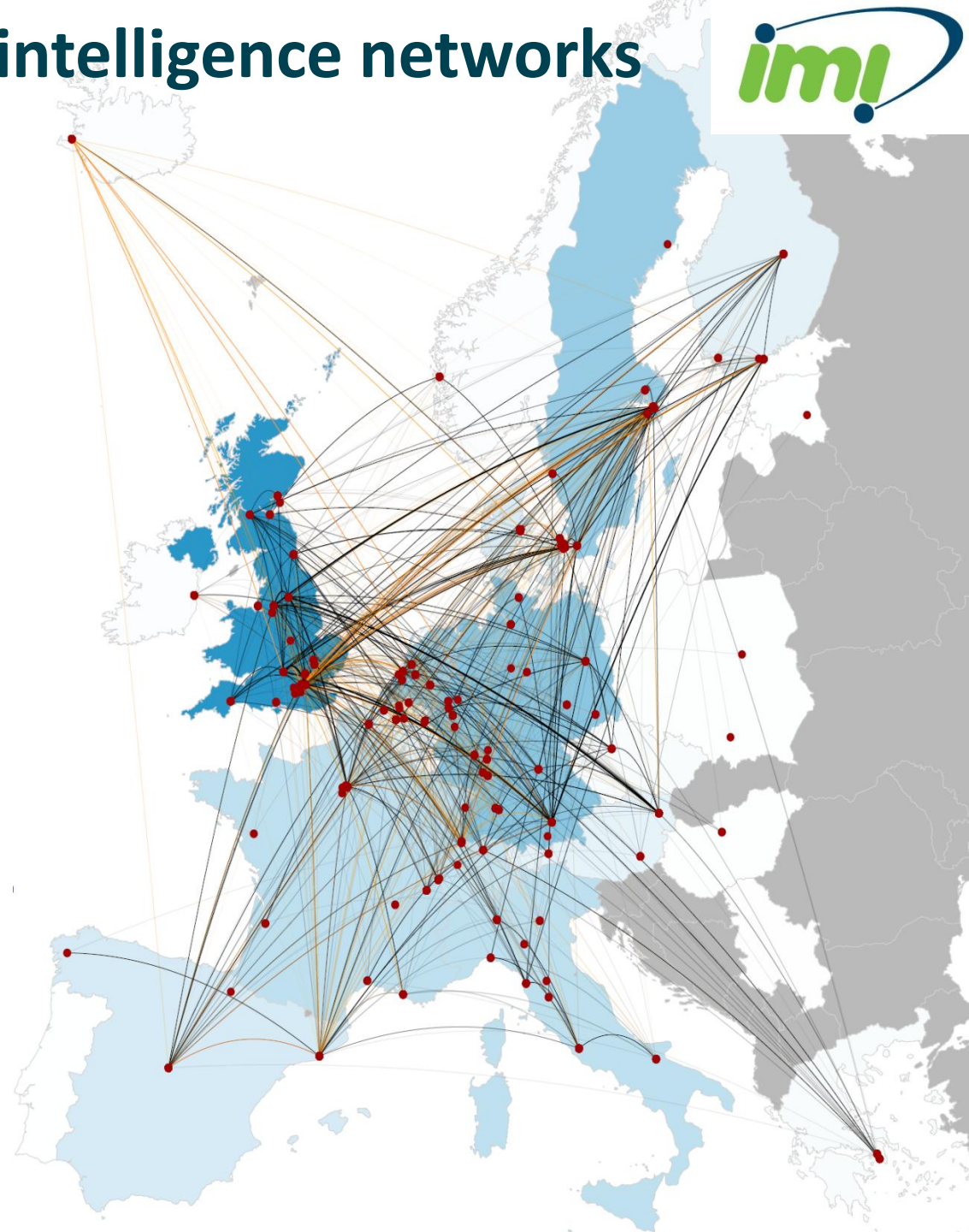


IMI creates collective intelligence networks

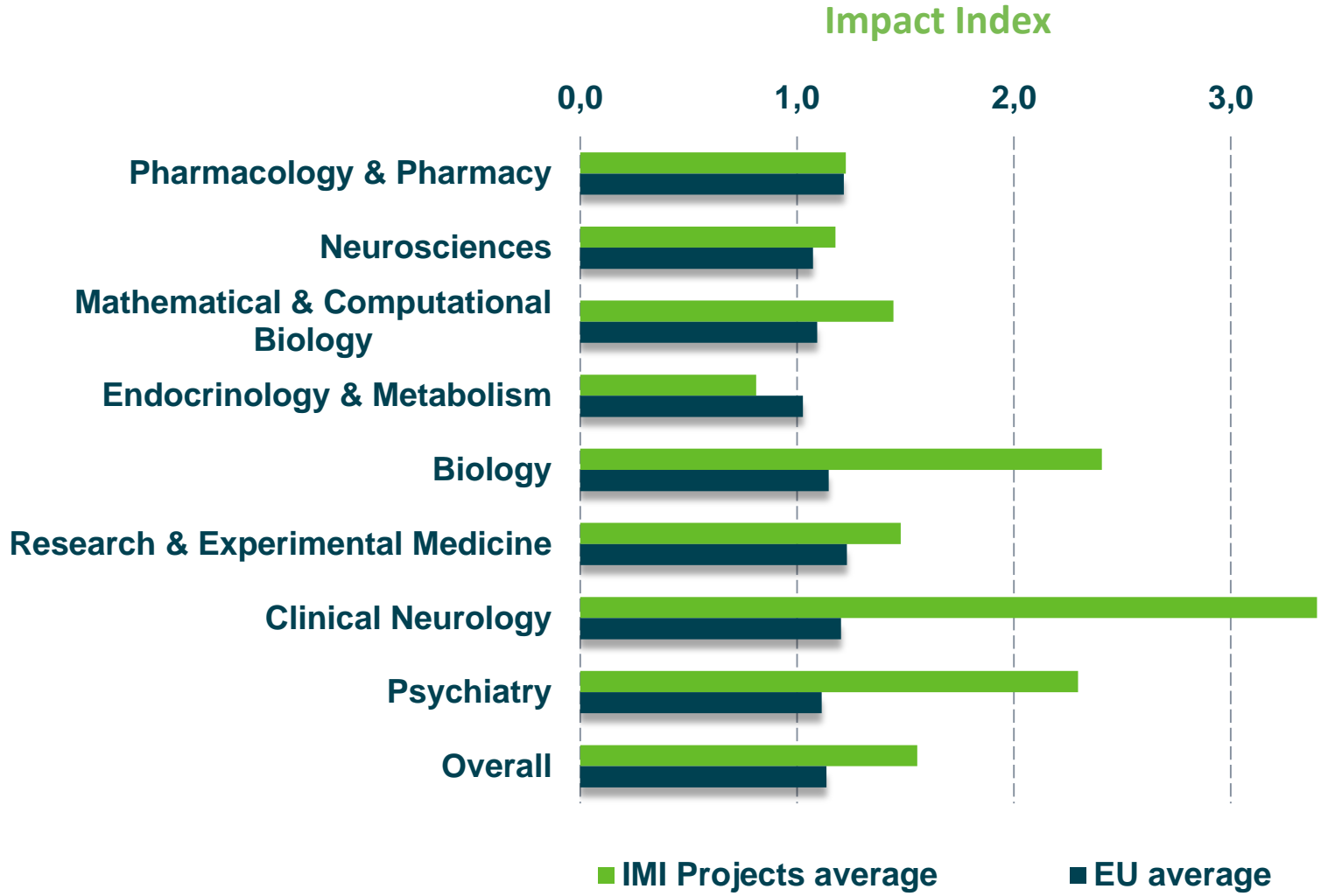
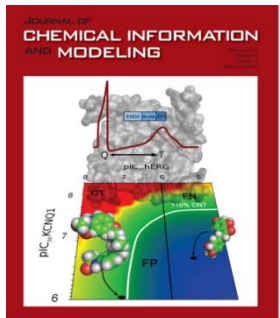
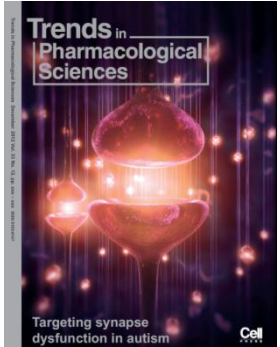
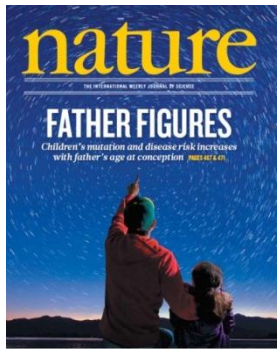


*Collaborative publications
among IMI researchers - Calls 1-3*

Data & analysis: Thomson Reuters
(*Custom Analytics & IP Solutions*)



Delivering high quality research



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



U-BIOPRED

Total Budget: 20.6 Mi €



PHILIPS



Aerocrine



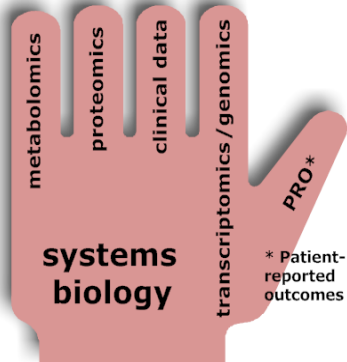
Imperial College London





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 €



Janssen



ALEXANDER FLEMING
Biomedical Sciences Research Center





Autoantibodies recognizing carbamylated proteins are present in sera of patients with rheumatoid arthritis and predict joint damage

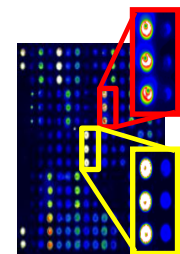
Jing Shi^{a,1}, Rachel Knevel^a, Parawee Suwannalai^a, Michael P. van der Linden^a, George M. C. Janssen^b, Peter A. van Veelen^b, Nivine E. W. Levarht^a, Annette H. M. van der Helm-van Mil^a, Anthony Cerami^{c,1}, Tom W. J. Huizinga^a, Rene E. M. Toes^a, and Leendert A. Trouw^{a,1}

^aDepartment of Rheumatology, ^bDepartment of Immunohematology and Blood Transfusion, and ^cDepartment of Nephrology, Leiden University Medical Center, 2300 RC, Leiden, The Netherlands

Arthritis Rheum. 2013 Apr;65(4):899-910. doi: 10.1002/art.37835.

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

Brink M, Hansson M, Mathsson L, Jakobsson PJ, Holmdahl R, Hallmans G, Stenlund H, Rönnelid J, Klareskog L, Rantapää-Dahlqvist S.



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



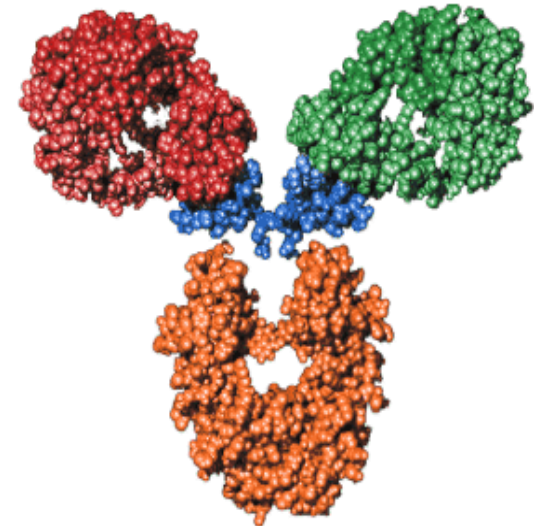
The Objective

9 EFPIA companies; 24 Public organizations; 2 SME
Total Budget: 34.9 M €

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

PROTECT



EUROPEAN MEDICINES AGENCY

+

4 other regulatory agencies

12 EFPIA companies

11 Academic institutions

1 Patient coalition

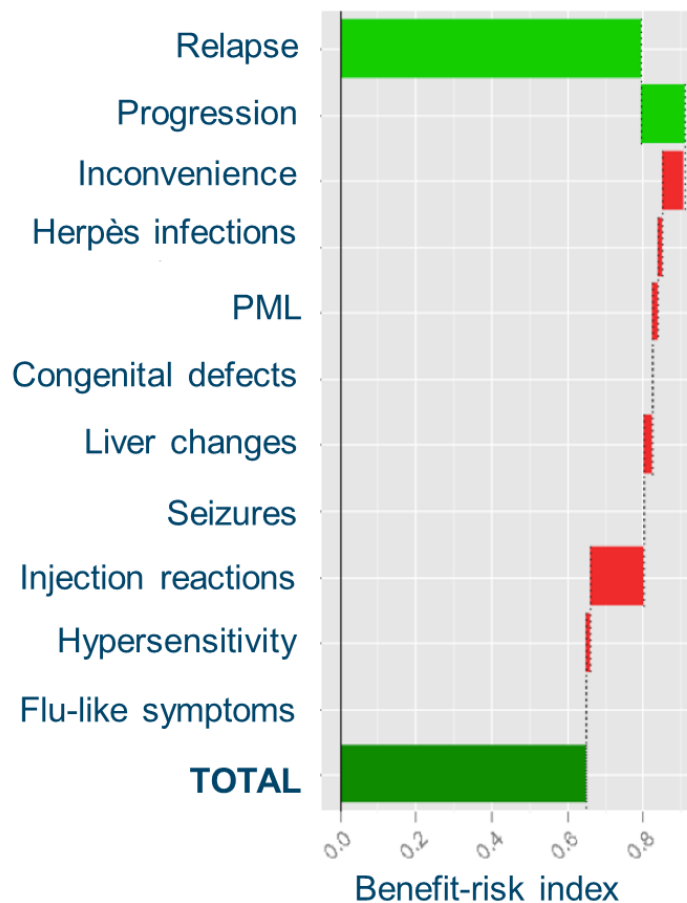
2 SMEs

Budget: 29.8 Mi €

Advancing benefit-risk assessment methods



Case study: **Natalizumab**



efpia

What's next for IMI ?

- ❑ 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

Draft available at

<http://bit.ly/1axl076>

Comments and suggestions are welcome:

SRAconsultation@efpia.eu





Innovative Medicines Initiative

Thank you
www.imi.europa.eu



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#IMlatICI



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