



Breakthrough Designation & Medicine Adaptive Pathways to Patients – What does it all Mean?

12 May 2014

Nathalie Seigneuret
Senior Scientific Project Manager
Nathalie.seigneuret@imi.europa.eu

IMI: Driving force for therapeutic innovation

Changing in Pharma landscape

Decline in R&D

Healthcare costs pressure

Increasing R&D costs

Increasing regulatory demands

Changing markets

Multi-stakeholder

Public expectation

IMI neutral honest broker

Non-competitive collaborative research

(Pooling expertise, knowledge and resources)

Incentives to address major unmet medical needs

Unique environment in Europe for a continuous dialogue between all stakeholders

Align public & private interests

Open innovation & collaboration
(data sharing, dissemination of results)

Address key scientific challenges

Disease heterogeneity

New standards for drug development

Biomarkers predictive for efficacy, safety

Innovative clinical designs, data analysis, modeling & simulations

Adapt regulatory processes

Healthcare delivery system

Mindset shift in stakeholder communities

Education & training

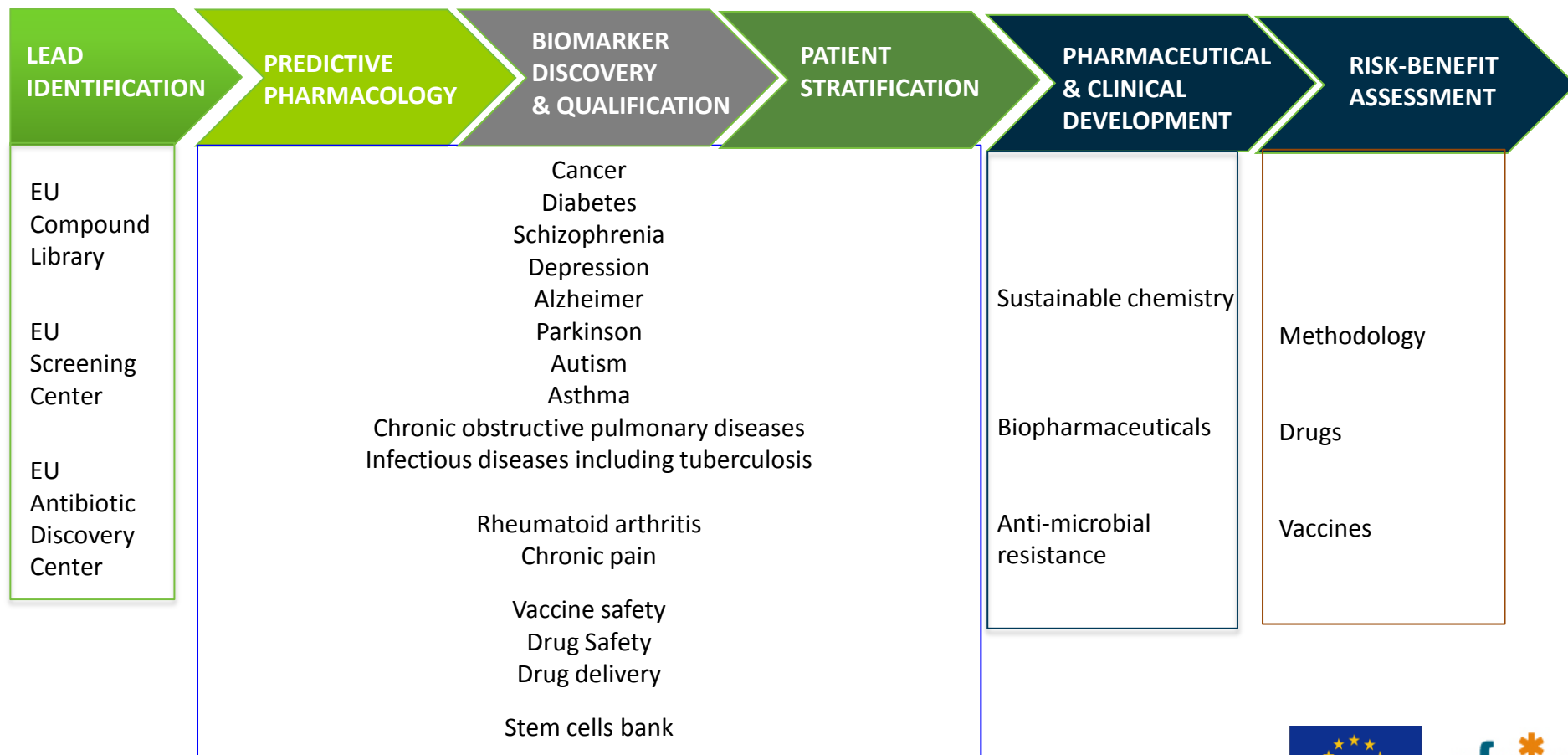


Overview of IMI projects

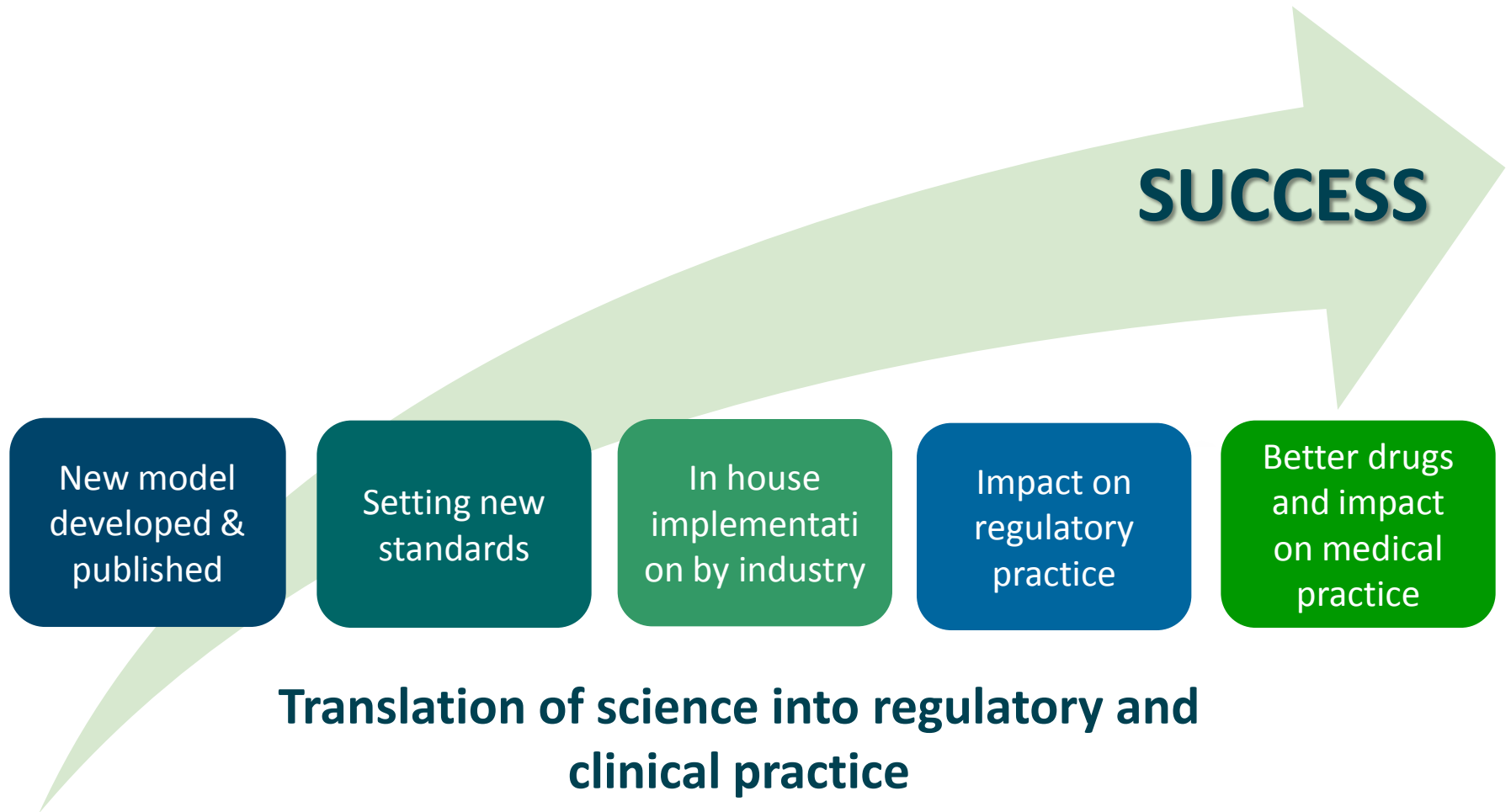


11 Calls: 46 ongoing projects + 13 upcoming

> 6000 researchers (e.g Pharma, SMEs, academia, patients, regulators)



Measures of success



BETTER SCIENCE = BETTER DECISION MAKING



Maximise value of IMI projects results

Approaches to help evidence generation and decision made throughout product life cycle

Biomarkers
Patients selection/stratification
New study design

➔ “Platform for Stakeholder Involvement to Optimise Project Outcomes”:

- Review IMI portfolio
- Identify key barriers and enablers
- Engage stakeholders
- Identify key gaps in future IMI project portfolio



Strategic Research Agenda for IMI2
The right prevention and treatment
for the right patient at the right time

[http://www.efpia.eu/uploads/Modules/MCMedias/1373296554546/IMI2%20Strategic Research Agenda v%208%20July%202013.pdf](http://www.efpia.eu/uploads/Modules/MCMedias/1373296554546/IMI2%20Strategic%20Research%20Agenda%20v%208%20July%202013.pdf)

<http://www.imi.europa.eu/content/imi-2>

Priority Themes

1. Neuro-degeneration
2. Immuno-inflammation
3. Metabolic disorders
4. Infection control
5. Translational Safety

Support Technologies

1. Imaging
2. ICT
3. Medical devices....

Enablers

Patient access to innovative solutions (MAPPs):

- Target validation
- Stratified medicine, precision medicine
- Innovative trials
- Data generation and interpretation
- Prevention, disease interception
- Patient adherence
- Health disease management
- Regulatory framework
- Reimbursement/patient access