Innovative Medicines Initiative

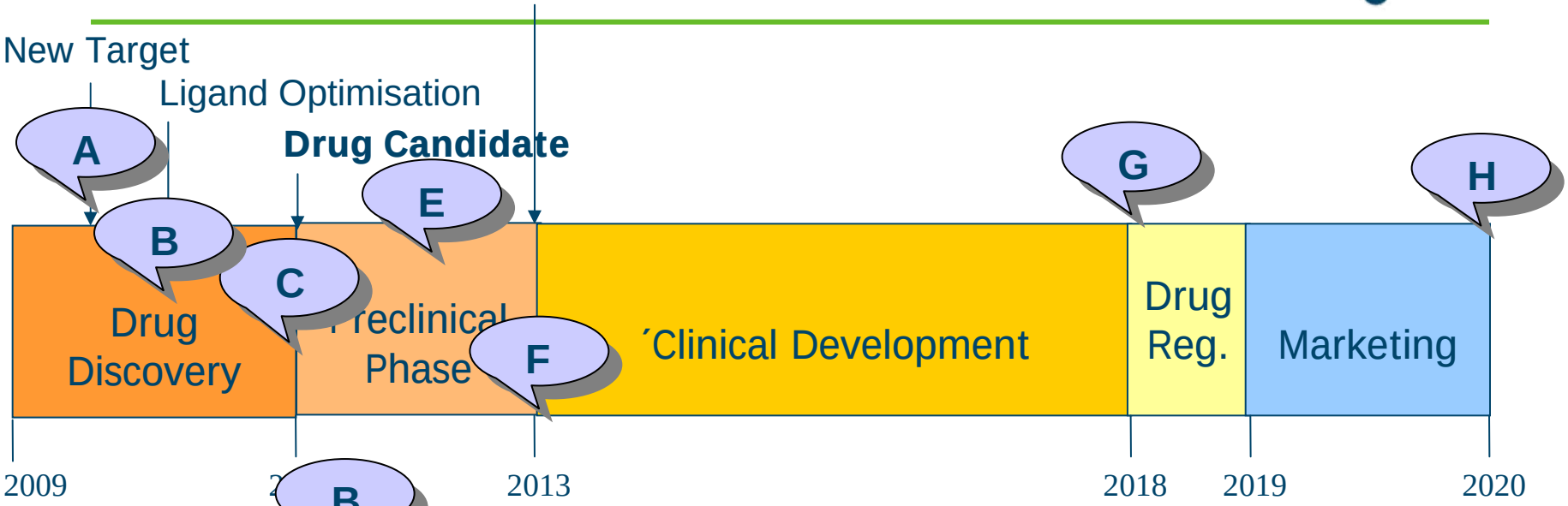
Revision of the IMI scientific strategy: Towards a new Research Agenda

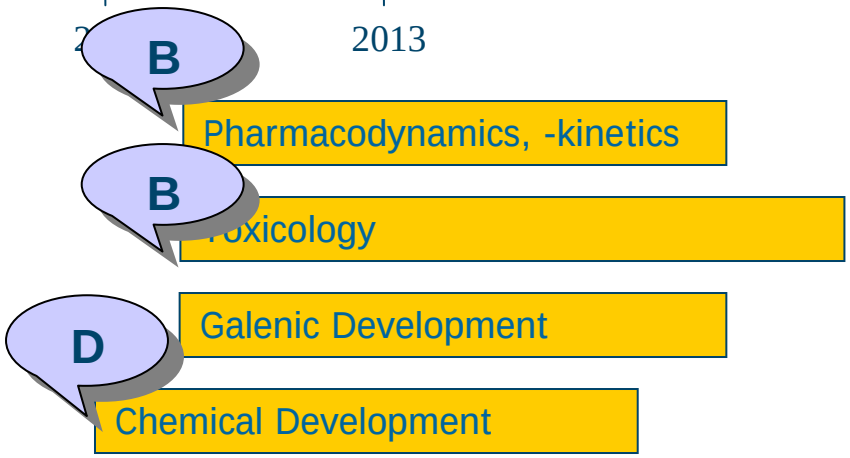
Christian Noe, Adam Smith and Elisabetta Vaudano

Brussels, June 15th, 2010

efpia

„Cultures“ and Co-operation in R&D





A Biologist - Designer T.
B Pharmacologist - Designer T.
C Academia - Industry T.
D Lab – Plant T.
E Industry – Regulatory T.
F Bench – Bed T.
G Industry – Health System T.
H Doctor – Patient T.

Lack of co-operation is an issue in the „translational crisis“

Background Trends

The evolution of co-operation in a globalised world

The role of innovation in a „finance driven“ economy

The evolution of logics and intelligent systems

A unique tool to promote innovation and co-operation:

IMI is a novel approach of co-operation in pharmaceutical sciences, in which the European Commission, industry, academia and regulatory are connected.

The main goal of IMI is to promote innovation.

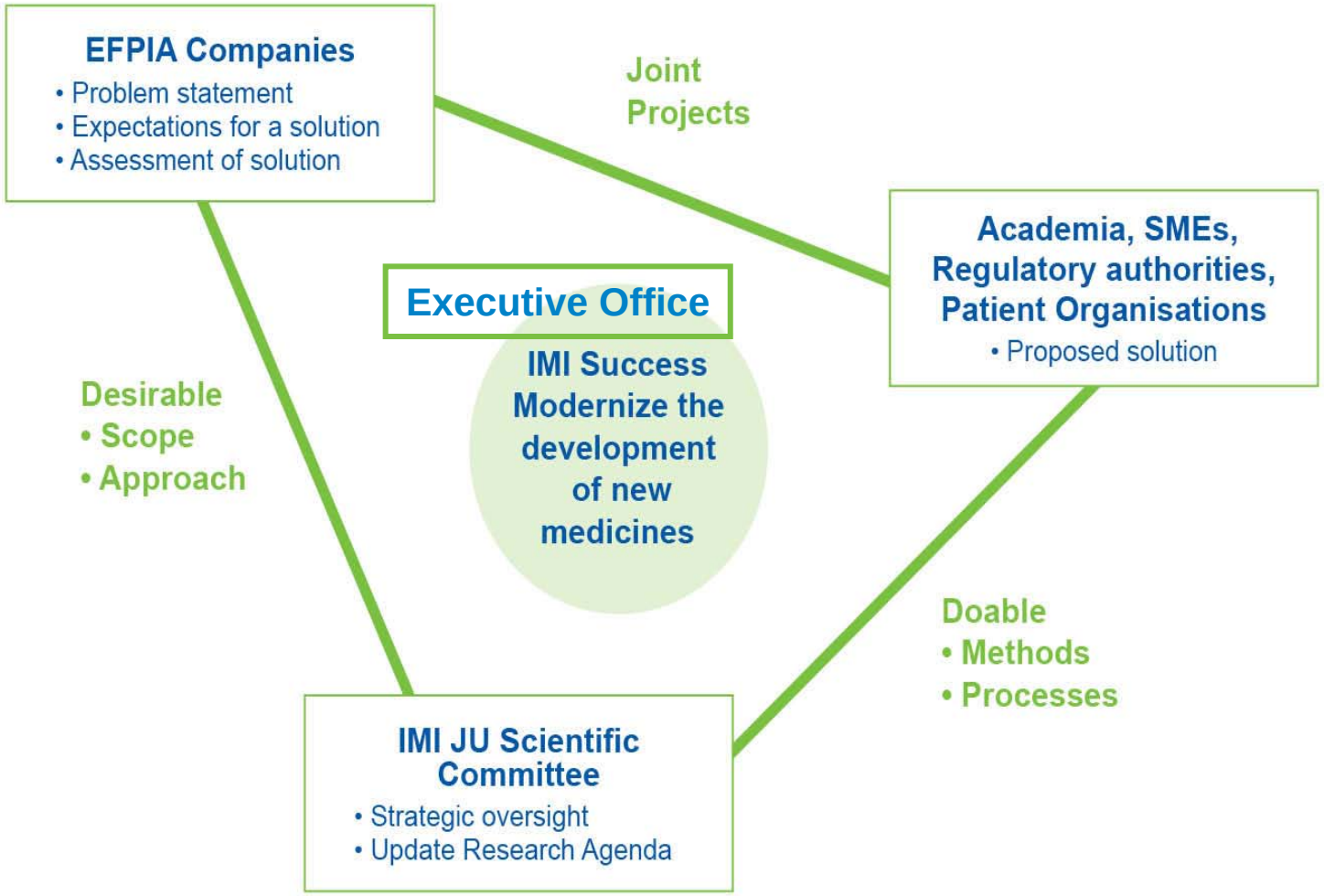
The Scientific Committee

- Composed by 15 members selected to ensure **a balanced representation of expertise from academia, patient organisations, industry and regulatory bodies.**

- Members appointed based on list proposed by the IMI States Representatives Group: **C. AVENDANO, M. BAKER, J. BELL, D. D. CROMMELIN (Vice-chair), J. DULAK, G. GAVIRAGHI, G. GEISSLINGER, L. HØJGAARD, T. JONES, A. MAGGI, C. NOE (Chair), F. SANZ, P. SOKOLOFF, A. VAS, I. XENARIOS**

- **« Ambassadors » of IMI**

IMI Stakeholder Partnerships translated into Operations



Terms of Reference of the SC

To advise on the Research Agenda and recommend amendments;

To advise on the scientific priorities for the continued relevance of the annual implementation plan proposal;

To advise on the scientific achievements described in the annual activity report;

To advise on the composition of the peer review committees.

The Research Agenda

- The IMI Research Agenda is a multiannual plan.
- It identifies principal research bottlenecks in the biopharmaceutical R&D process.
- It describes recommendations to overcome these bottlenecks and a plan to guide their implementation.
- It focuses on four areas: predicting safety, predicting efficacy, knowledge management, education and training.
- It is a tool to communicate the IMI mission.

Revision of the SRA: why now?

- Several priorities of the original SRA have already been addressed by the first 3 IMI calls.
- Science and technology have moved fast in the last five years.
- The industry is also constantly changing.
- Taking advantage of lessons learnt from the previous activities.
- A revised agenda can be a tool to boost engagement in Calls 4 and 5.

The parties involved and their role

- **Industry:** the principal party, since the mission of IMI is to generate efficient tools for addressing industry bottlenecks. Industry has to identify the bottlenecks on which the IMI activities should focus.
- **The Commission:** provides input to ensure synergy with other European initiatives.
- **The Executive Office:** organises and co-ordinates all IMI activites.
- **The Scientific Committee:** has the role of advising on current trends and opportunities.
- **Regulatory authorities, HTA and patients organizations:** are key stakeholders which provide input to guarantee the value of the IMI activities.
- **The Stakeholder Forum:** providing input from behalf of the scientific communities and other participants.
- **Anyone:** is welcome to add the voice via the IMI website.

The revision process: Procedure and Timelines - Phase 1

- **Subgroup of SC starting discussions on review during summer 2009;**
- **Agreement on start of procedure in meeting with EFPIA-RDG Group on October 8th, 2009 in Brussels;**
- **Brain storming meeting of SC on December 4th, and 5th, 2009;**
- **Preparation of the Status Report,** providing an overview of what the SC sees as potentially new, exciting research opportunities from the viewpoint of the Academic/SME world.

The Status Report 2010

Trends, Challenges and Opportunities in Drug Research

IMI - An Initiative for Innovative Medicines

IMI - An Innovative Initiative

Optimisation of Administrative Modalities

The status report is a living document. Contributions are still welcome. The final version will be placed on the IMI website.

The IMI Commitment

To meet the medical need

To support breakthrough of novel therapies

To harmonise reductionist and systemic approaches in drug research

To optimise the Drug R&D Process

To implement new techniques and technologies

The Disease Areas

“Medical need” in the selected major disease areas

Socio-economic Criteria

Rare diseases
Tropical diseases
Neglected Diseases

Patient Stratification

Female health
Male Health
Age related diseases
Medicines for children

Novel Therapies

“Autologous” Therapies – Regenerative Medicine

Health Technologies (The Three Ds)

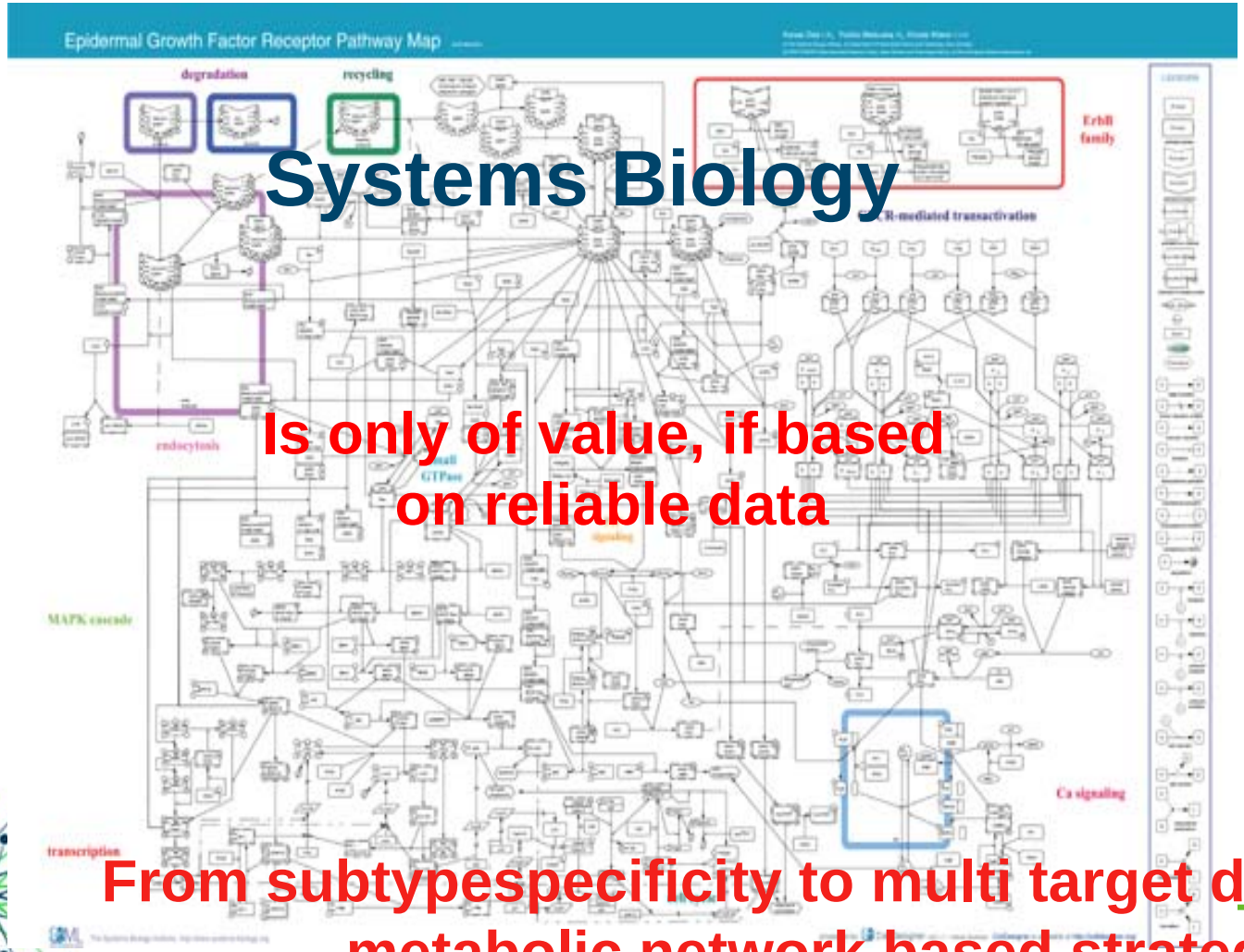
Immunotherapies - Vaccines

Nucleic Acid Therapies

Nuclear Medicine and Imaging Based Approaches

Production Technologies of Biologicals

Harmonisation of reductionist and systemic approaches in drug research



Systems Biology

Is only of value, if based on reliable data

The EGFR Pathway Map

Contains a total of 219 reactions and 322 species.

Established by help of CellDesigner ver. 2.0
http://www.systems-biology.org/002/

***Oda et al., Molecular Systems Biology* 1 doi:10.1038/msb4100014 published online: 25 May 2005**

From subtypespecificity to multi target design and to metabolic network based strategies

Optimising the Drug R&D Process

Correlation of scales and phases in drug research - Widening the “translational task”

Humans – animals – cells: Veterinary Drugs etc.

Pharmacoinformatics - Correlating *in vivo, in vitro* and *in silico* research

Pharmacogenetics-Pharmacogenomics (Pgx)

Implemention of new techniques and technologies

Novel approaches in target search

Laying foundations for better APIs

Novel pharmacological tools in drug discovery

Advanced Formulations

Imaging

Practicability of biomarkers and biobanks

The revision process: Procedure and Timelines – Phase 2

- **Following-on from the Status Report, the IMI Executive Office is organizing workshops to solicit ideas and feedback from stakeholders including the industry, academia, regulatory authorities and patient organizations.**

- **Presentation of the Status Reports to industrial EFPIA-RDG partners in a Workshop on June 1st, and 2nd, 2010.**

Key Areas that the SRA Revision will Cover

- Status of play
- Updates on the disease areas covered already in the original SRA
- Newly available tools and technologies
- New areas of focus
- Possible modifications of the funding instruments

Examples of Possible Updates to the Disease Areas Covered in the Original SRA:

Respiratory diseases:

Highest areas of interest **COPD>asthma>allergic rhinitis**.

Key Activities to address bottlenecks include: linkage of pre-clinical to clinical, biomarker development, **advancing disease understanding**, developing and validating relevant and novel end-points for clinical studies.

CNS disorders:

High unmet need, highly challenging area,
most expensive/lengthiest area of R&D.

Potential priorities: platforms to measure **translational fingerprints** of drug efficacy, **novel and more holistic models for CNS R&D**

Examples of New/enhanced Areas of Focus with examples of possible IMI contributions

Development of Risk-Benefit Assessment Tools:

Study designs that enable demonstration of clinical added value (Patient reported) outcomes that demonstrate value in the eyes of patients

Improve R&D Decision Making by Incorporating New Tools and Methods

Molecular imaging to promote preclinical to clinical translation and integration, identification, validation and strategy for new biomarkers, new surrogate markers and clinical endpoints.

Examples of New/enhanced Areas of Focus with examples of possible IMI contributions

Precompetitive Research in Stem Cell Science

Molecular imaging to track biodistribution, cell migration & persistence and in stem cell safety

Developing **Standardized Quality Control**

Areas where IMI could add value by creating synergy with other European initiatives:

Nanotechnologies and nanomedicine with focus on nanosafety

Immunogenicity: in synergy with planned high impact activities of FP7 Health for 2011

The Nanoscalar Challenge !

A Gap in Methods, Tools and Understanding

more than just

Nanotechnology

The revision process: Procedure and Timelines – Phase 3

- **Discussions during the Stakeholder Forum on June 14th and 15th, 2010 expand the input into the process and support the revision process.**
- **Open consultation with the public will also be encouraged via the IMI website.**
- **The Commission will also provide feedback to promote synergy with other activities supported by the framework programme and help avoid duplication of efforts.**
- **In conjunction with these various levels of consultation, the IMI Executive Office will define and communicate the detailed process for updating the SRA.**
- **The process should be concluded by end of year 2010/January 2011.**

IMI - An Innovative Initiative

Knowledge

Science Communication

Co-operation

Innovation

Science Communication

Education – Communication between generations

Fundamental Reorganisation of Education
Promotion of specific professional profiles
e-Learning and blended learning

Training

Connecting courses and curricula
Education about novel therapies

Science communication to patients and the public

Co-operation

Promoting regulatory-industrial-academic co-operation

Organising thematic networks – Increasing European competence

Promoting work and co-operation of European scientific organisations

Innovation means value generation

Reducing cost of clinical development

Funding of drug discovery and early development

New business models for new therapies

Sustainable SMEs

PPP-Systems

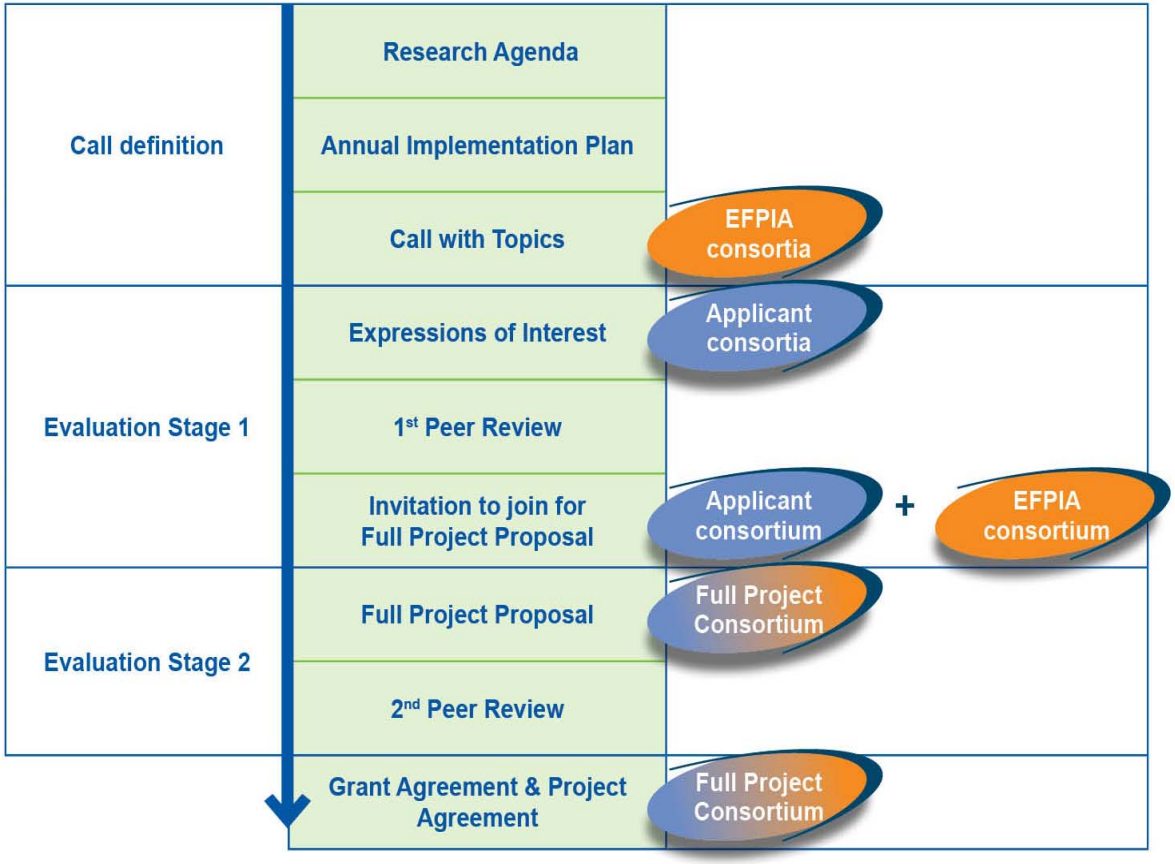
Translating projects into enterprises

Finding alternatives for “generics” regulations

IMI is – based on PPP - a spearhead of innovative structural concepts in pharma R&D.

Administrative Proposals

The IMI call process – Room for optimisation?



Thank you!

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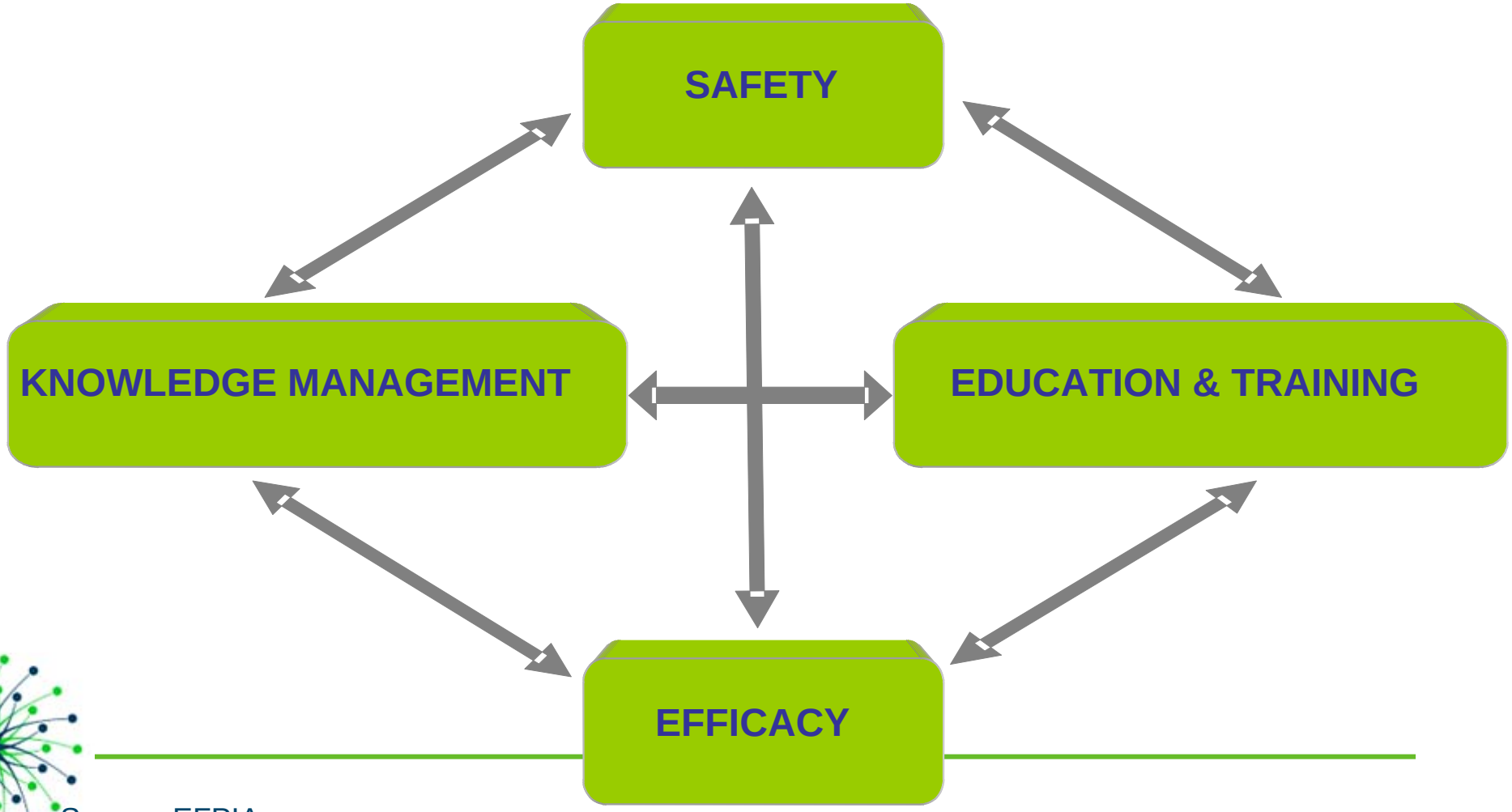
IMI Research Agenda - Pillars



Source: EFPIA

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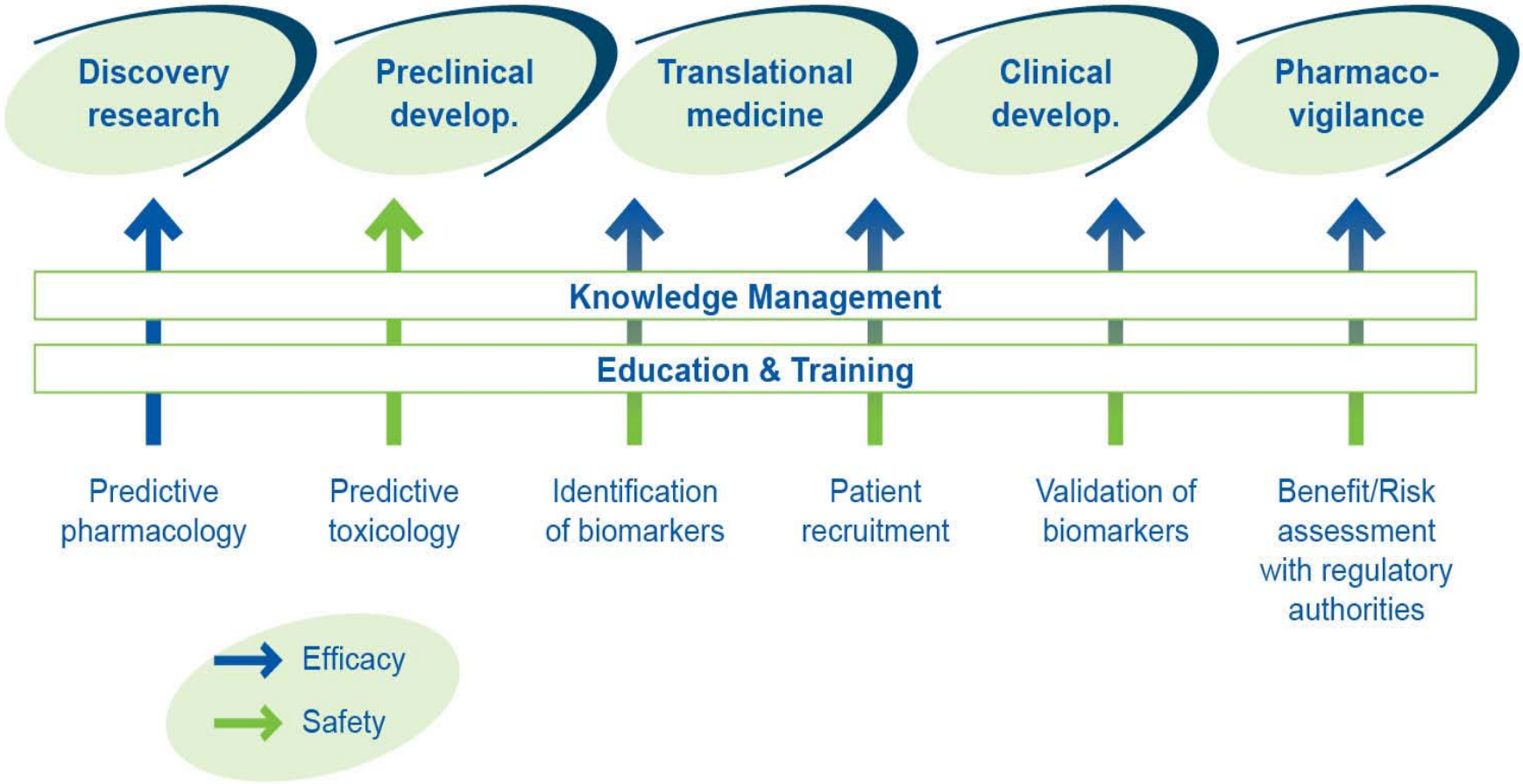
IMI Research Agenda



The Matrix of Diseases