The Innovative Medicines Initiative: Implications for the Development of 3R-Alternatives

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7th Annual ecopa Workshop
REACH for help: science backup?
Brussels November 25th – 26th 2006

Answers That Matter.

The Innovative Medicines Initiative
What is it?

- Clear, practical paths to accelerate the discovery and development of more effective innovative medicines with fewer side-effects.
- Innovative projects that address the causes of delay or bottlenecks in the R&D process.
- Unique pan-European public and private sector collaboration in biopharmaceutical research.
- First pre-competitive collaboration of this amplitude: €460 million per annum over 7 years (50% EU; 50% Industry)

The Innovative Medicines Initiative
History and Future

- Joint initiative between EFPIA and European Commission in 2004 – consultation with stakeholders throughout 04/05.
- Pilot proposal generated and now funded under Framework Programme 6, InnoMed
- Strategic Research Agenda:

  www.efpia.org/4_pos/SRA.pdf

  www.imi-europe.org
- IMI to be proposed as a Joint Technology Initiative under Framework Programme 7

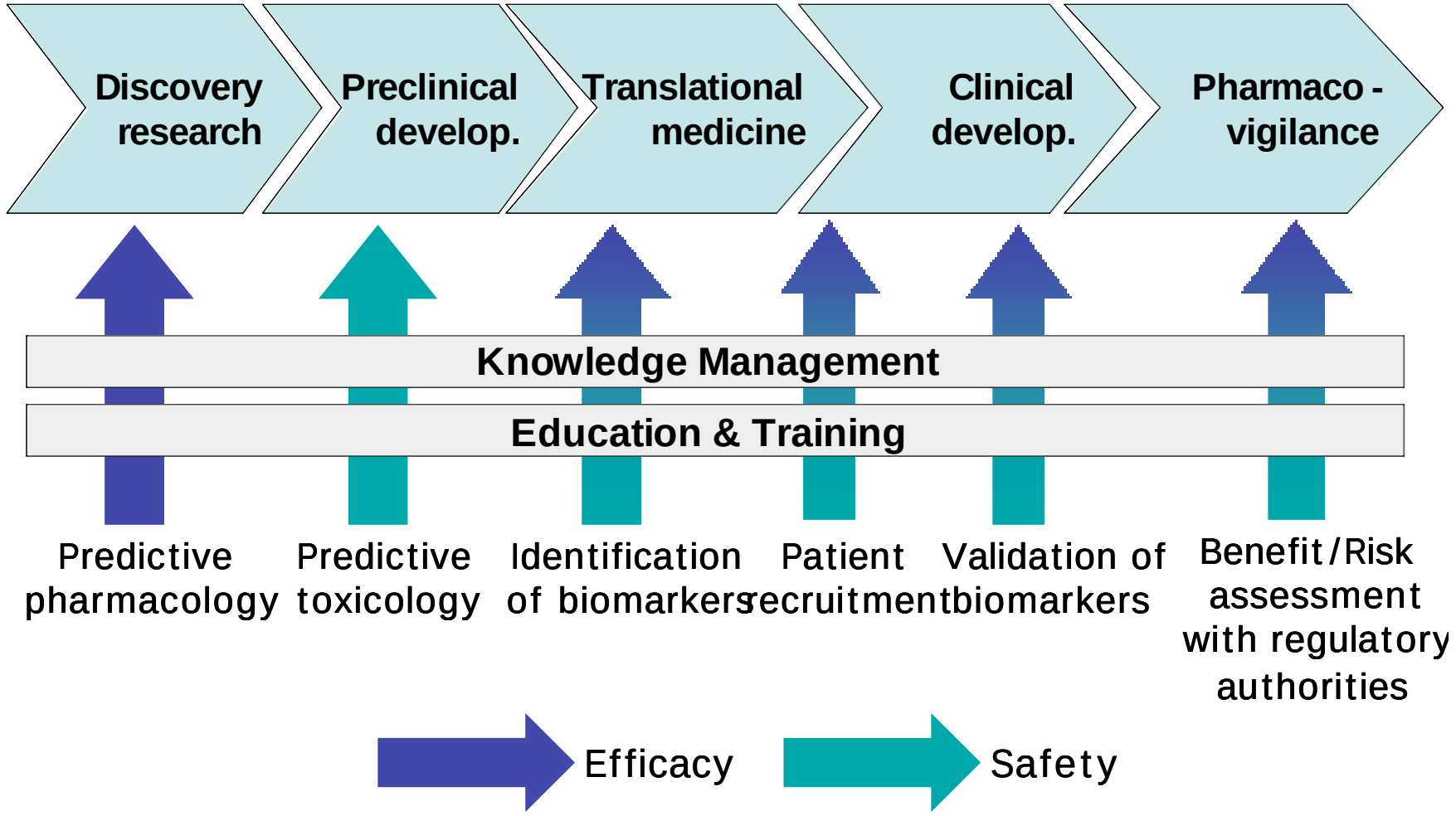

The Innovative Medicines Initiative (IMI)
Strategic Research Agenda

Creating Biomedical R&D Leadership for Europe to Benefit Patients and Society

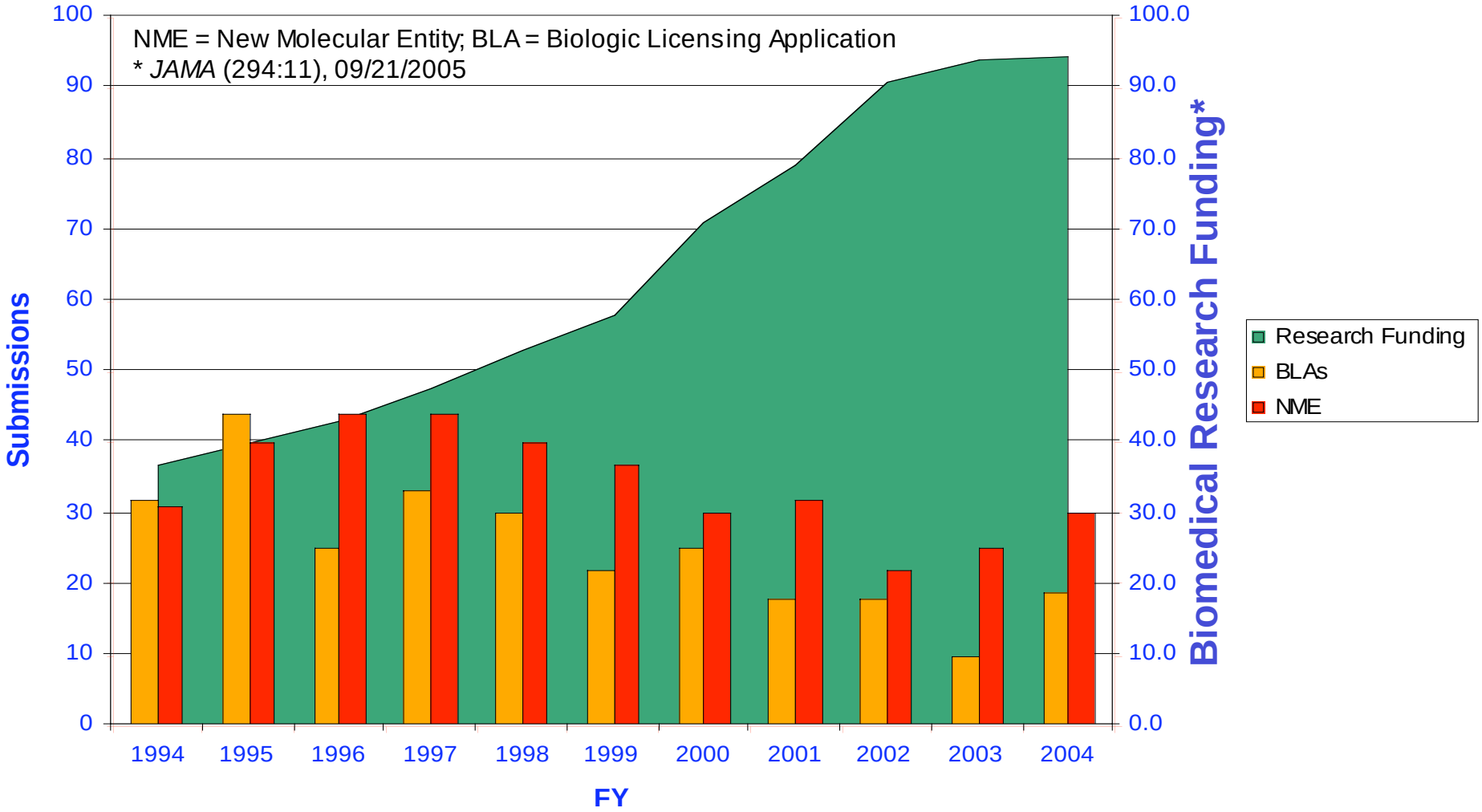
DATE OF PREPARATION: 15 September 2006 (Version 2.0)

The Innovative Medicines Initiative

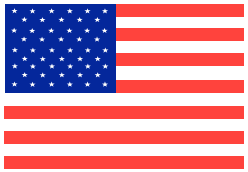
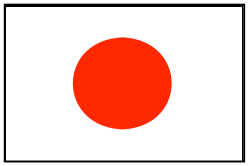
Strategic Research Agenda focus on the "pre-competitive" bottlenecks in the R&D Process



Trends in Biomedical Research Spending



Global recognition of the problem

	Innovative Medicines Initiative (EU)
	Medicamentos Innovadores (Spain)
	Top Institute Pharma (Netherlands)
	ECRIN (France)
	Safety Biomarkers (UK)
	FDA Critical Path Initiative (NIH)
	Safe and Innovative Medicines (PhRMA)
	Biomarker Initiative (PhRMA)
	Critical Path Institute (University of Arizona)
	Center for Biomedical Innovation (MIT)
	Toxicogenomics Project (JPMA)
	Proteome Factory Consortium (JPMA)
	Large-scale Clinical Trial Network

The drivers for a new R&D model of public-private partnership

- Cost and timelines of drug development
  - Change the paradigm of drug discovery to decrease attrition and improve effectiveness
- Wealth of novel opportunities from genomics
  - How to pick the right molecules and bring them to the right patients
- The potential of increased cooperation with stakeholders
  - Greater academic collaboration, increased patient involvement and better dialogue with regulators
- The need for increased openness
  - Transparency of operation e.g. publication of Clinical Trial data, sharing toxicology data

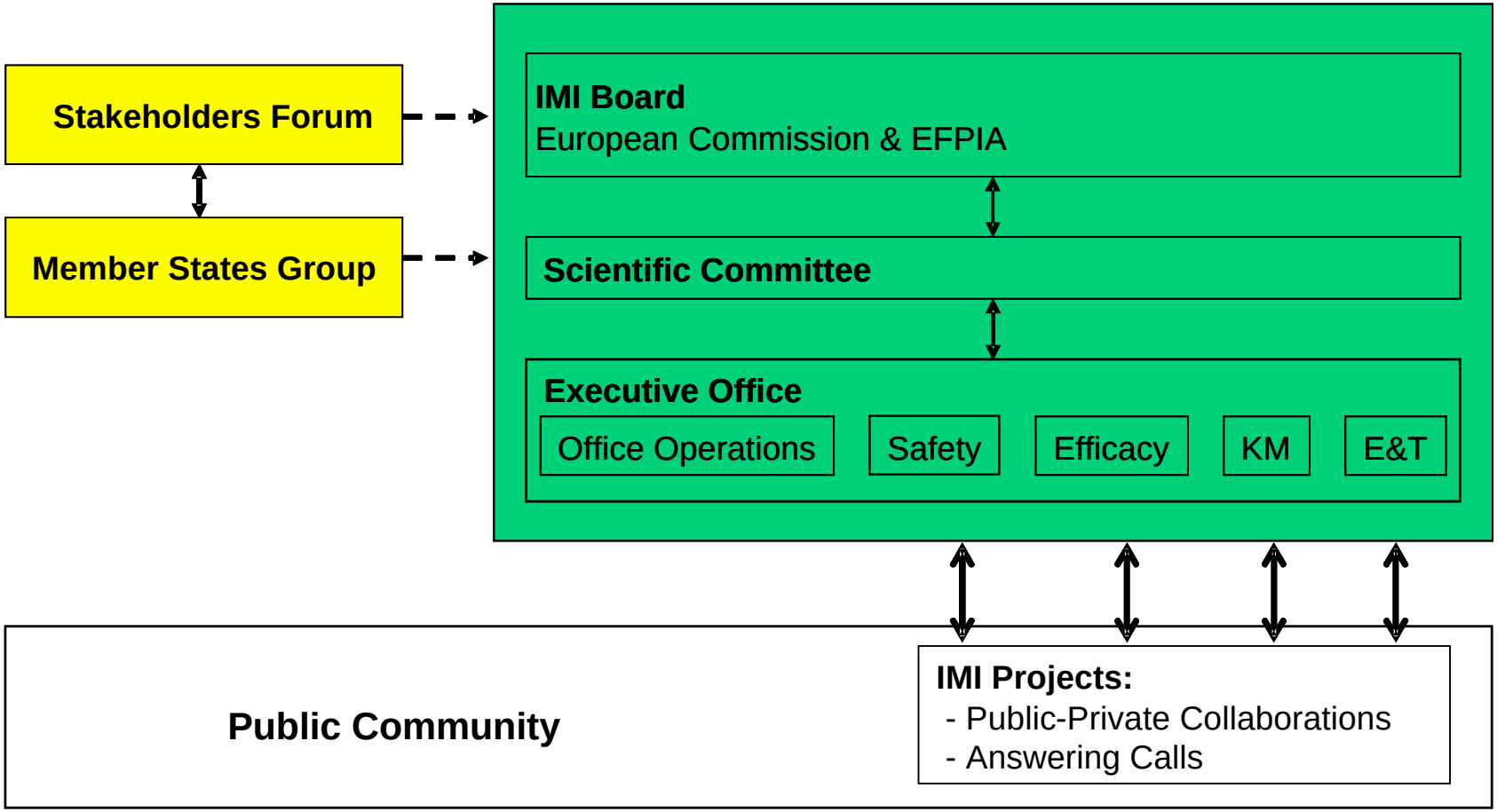
SAFETY: Making Medicines Safer

- Goal: improve the predictability of toxicological observations
- Main recommendations:
  - Create a European Centre for Drug Safety Research
  - Establish a framework for biomarker development to study human relevance and regulatory utility
  - Develop computational methods for predicting toxicity
  - Pharmacovigilance: Develop novel methods of risk prediction and benefit-risk assessment

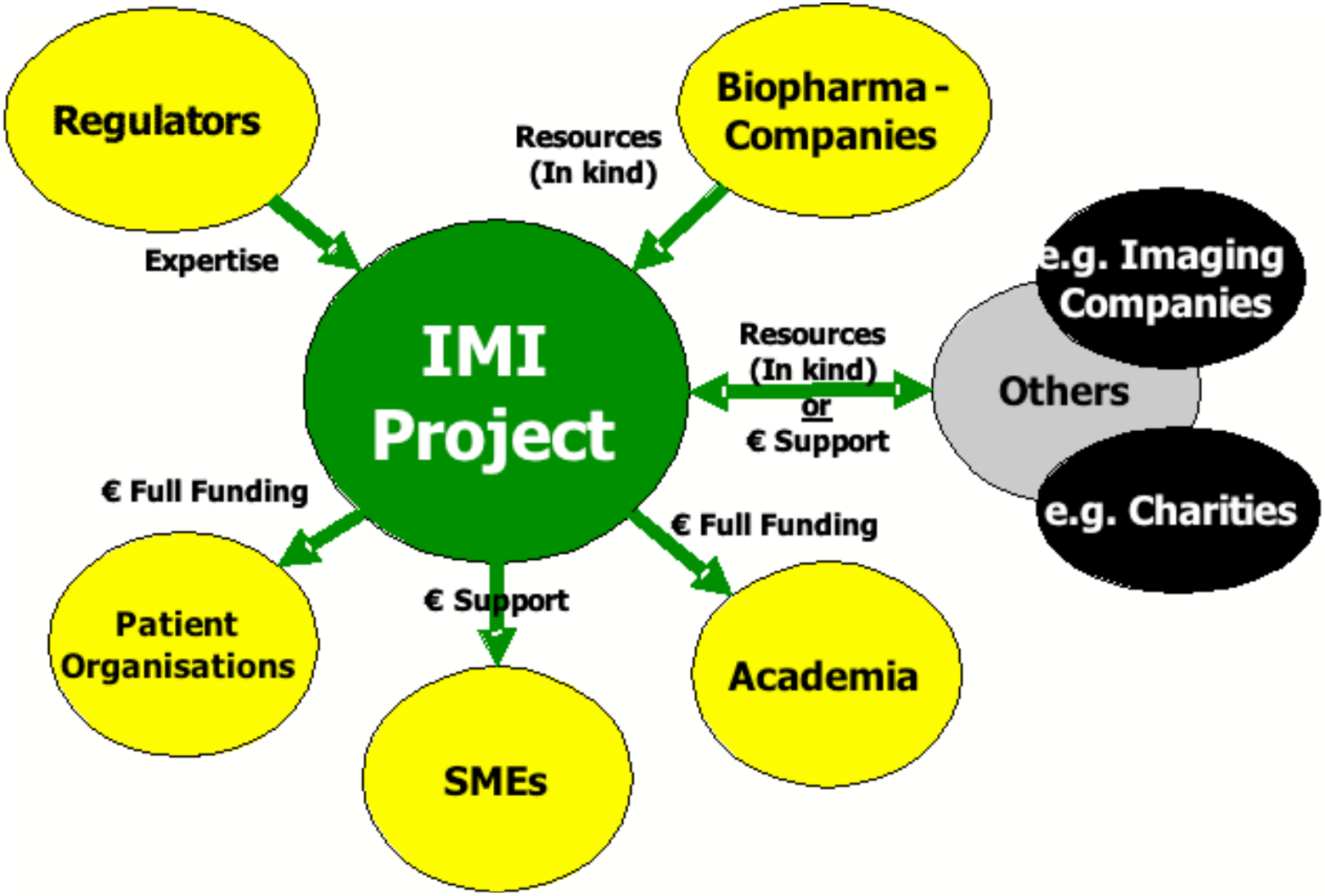
EFFICACY: Making Medicines More Effective

- Goal: improve clinical performance and early access to innovative medicine
- Main recommendations:
  - Focus on areas of high scientific challenge
    - cancer, inflammatory disease, brain disorders, metabolic disease, infectious disease
  - Stimulate translational medicine in an integrated fashion
  - Create disease-specific imaging networks
  - Develop partnership with regulators for innovative clinical trial design and acceptance of biomarkers

IMI structure and governance



Project Participants & their Contribution

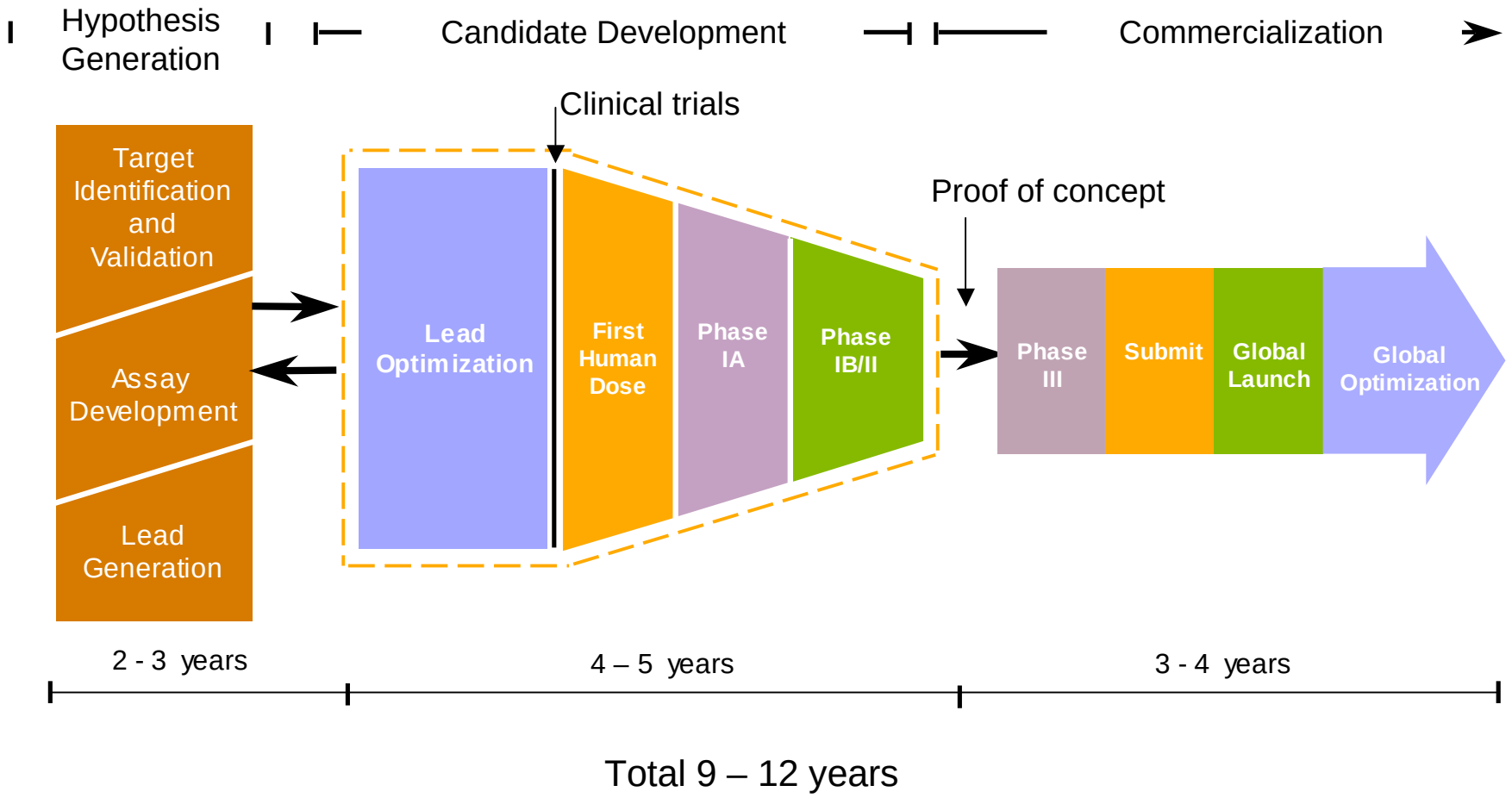


Benefits of IMI for Europe

- Synergy with national research funding
- Stimulus for large and small companies – more jobs
- More education and training in the biomedical arena
- Decreasing the brain drain by strengthening the European science base
- More effective healthcare

- New predictive science will lead to development and acceptance of animal alternatives and further implementation of the 3Rs

Discovery and Development Drug Process

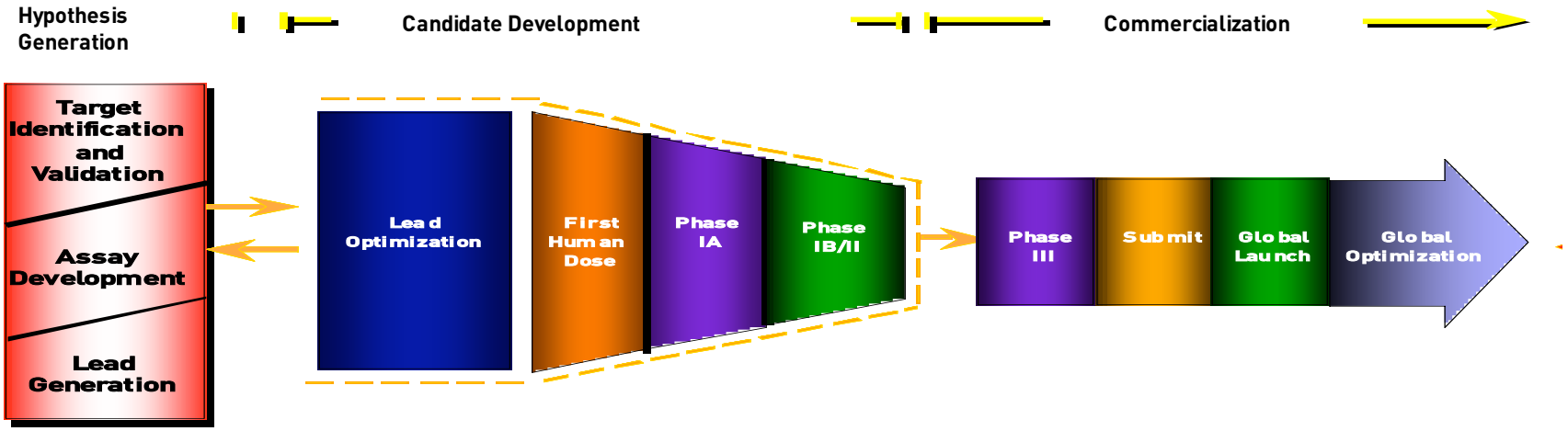


Total 9 – 12 years

Implications of the IMI for animal use

Reduction of attrition in preclinical drug discovery

- *In vivo* work is primarily for selecting molecules on the basis of ADME and toxicology



- **Increased *in silico* and *in vitro* methods** could
  - replace some *in vivo* tests
  - reduce use of animals by eliminating drugs with undesirable properties prior to *in vivo* testing

Implications of the IMI for animal use

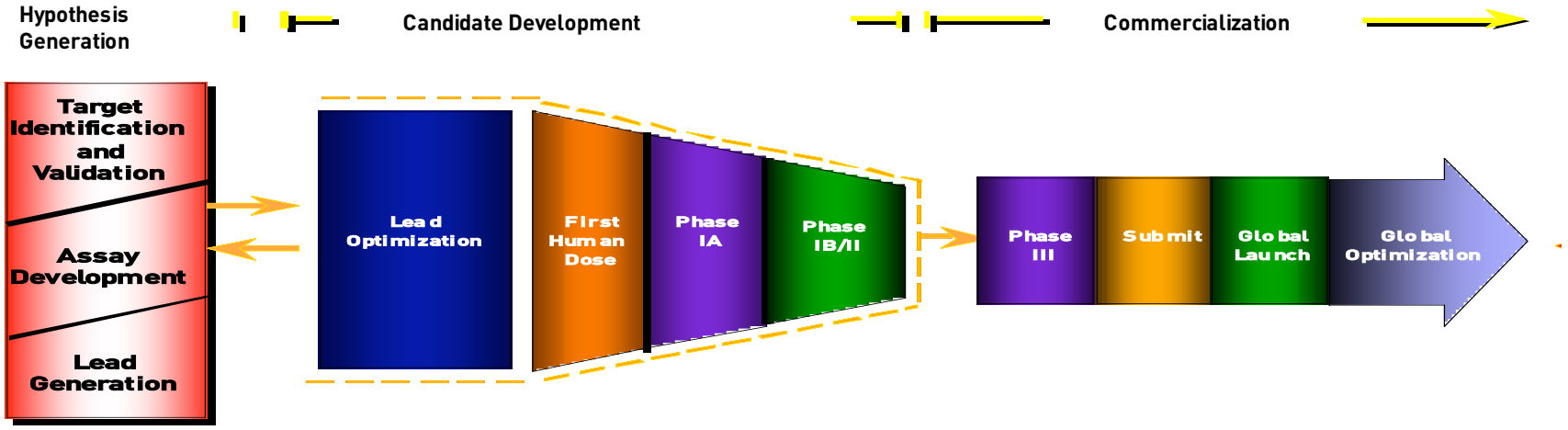
Reduction of attrition in preclinical drug discovery

- **Development of predictive biomarkers for safety or efficacy** could promote
  - reduction through early elimination of unsuitable molecules
  - reduction through animal tests with better predictive value
  - refinement through biomarkers predicting serious toxicity
- **Understanding of human relevance of animal toxicology findings** could
  - replace current tests with *in vitro* or acute *in vivo* studies
  - eliminate use of irrelevant *in vivo* tests

Implications of the IMI for animal use

Reduction of attrition in clinical development or post-marketing

- Attrition due to safety issues caused by failure of animal studies to predict toxicity in man

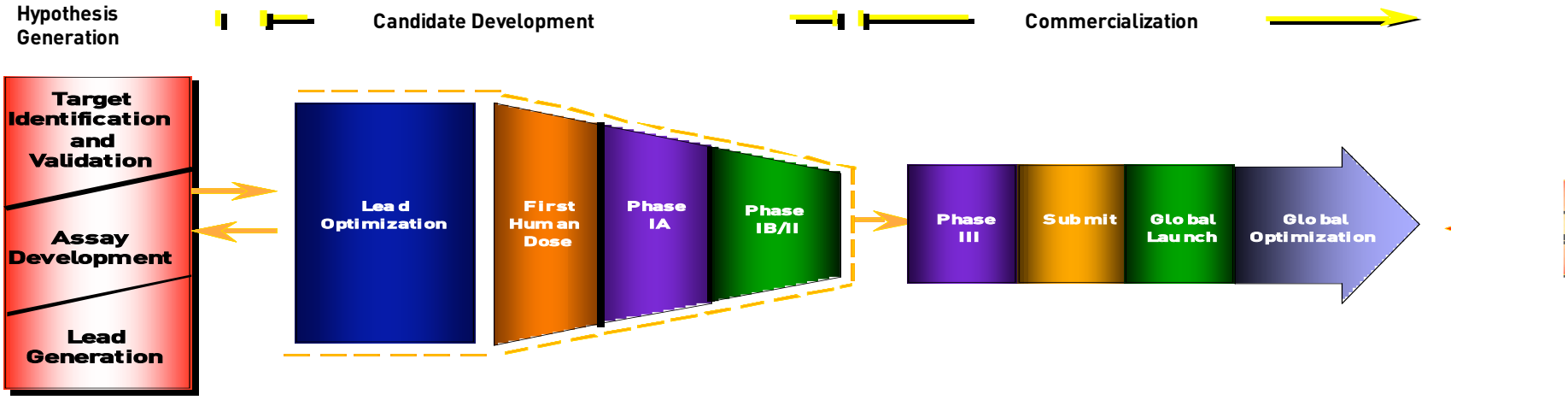


- **Better *in silico*, *in vitro* and *in vivo* tests** could
  - reduce use of animals by eliminating GLP tox studies on unsuitable molecules

Implications of the IMI for animal use

Reduction of attrition in clinical development or post-marketing

- Attrition due to lack of efficacy caused by failure of animal studies to predict effects in man



- **Better animal models of disease** could
  - increase use of animals initially BUT
  - reduce use of animals by eliminating preclinical and GLP tox and ADME studies on unsuitable molecules
  - reduce reliance on multiple disease models

Implications of the IMI for animal use

Data sharing

- Sharing of animal data eg toxicology, metabolism
- Sharing of clinical data eg toxicology, metabolism, results from placebo arms of clinical trials
  - could lead to reduction of animal use through
    - lower attrition
    - elimination of duplication resulting from concerns about confidentiality

Better basic science and clinical development, and greater cooperation and transparency will lead to 3Rs benefits

Next Steps

1Q2007	European Commission finalises package for submission to the Member States (European Competitiveness Council)
1-2Q2007	European Commission submits package to the European Competitiveness Council
3-4Q2007	Competitiveness Council approves IMI
3-4Q2007	Executive Office set up
4Q2007	IMI publishes first calls for proposals

It is Possible…. InnoMed

16 Companies – 14 Universities – 7 SMEs from across EU

- 18 mio euros including European Commission funding
- Biomarkers in Alzheimer's Disease:
  - Better and earlier diagnosis of onset of disease
- Predictive Toxicology:
  - New approaches to measure earlier potential medicine side effects

The Innovative Medicines Initiative
IPR Policy "Research Use"

Research Use after Completion of the Project

The right to make and use products or processes which are protected by licensed IP for all purposes relating to research, discovery, development, approval and commercialisation of diagnostic or pharmaceutical products.

Licensee	Foreground IP	Background IP necessary to use Foreground IP
Project Participants	Made available for Research Use on a royalty free non-exclusive basis	Made available for Research Use on a non-exclusive basis on fair and reasonable terms or royalty free
Third Parties	Made available for Research Use on a non-exclusive basis on fair and reasonable terms, which may include free use.	Made available for Research Use on a non-exclusive basis on fair and reasonable terms

The Innovative Medicines Initiative
IPR Policy "Direct Exploitation"

Direct Exploitation after Completion of the Project:

- The right to develop, sell or otherwise commercialise products or processes which are the subject of the IPR itself.
- Participants may exploit their intellectual property rights as they see fit beyond the Research Use rights described in the IP Policy.
  Participants may agree such use rights in the Project Agreement.