

The Innovative Medicines Initiative (IMI)



Innovative Medicines Initiative

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Objective of the presentation



-
- To present an overview of the Innovative Medicines Initiative
 - What it is
 - How it will function
 - Where it is at

The IMI- What is it? What does it do?



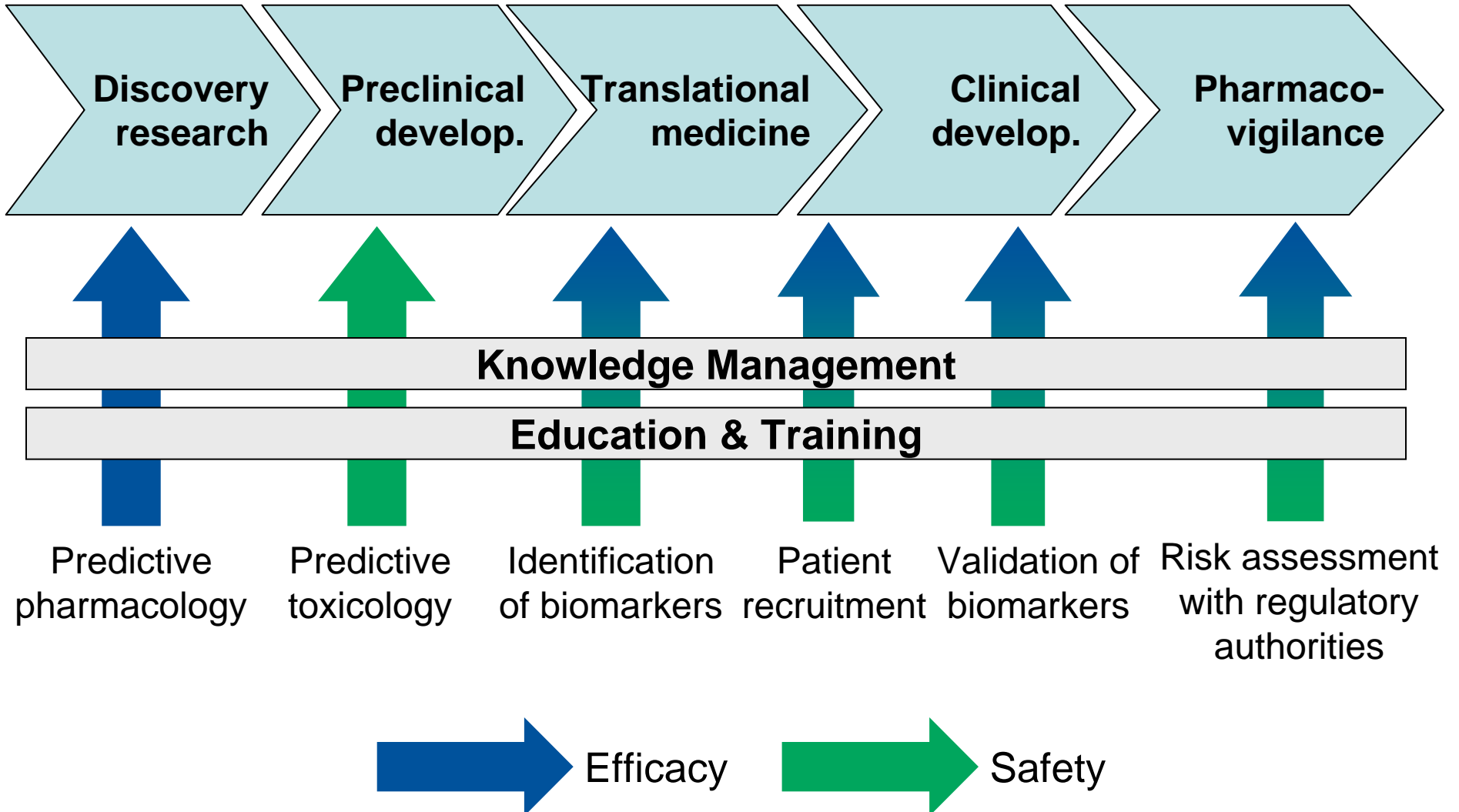
-
- Public Private Partnership between EFPIA and the EU
 - Will fund collaboration pre-competitive to drug development
 - Address causes of delay or bottlenecks in the R&D process
 - Accelerate discovery and development of more effective innovative medicines with fewer side-effects

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

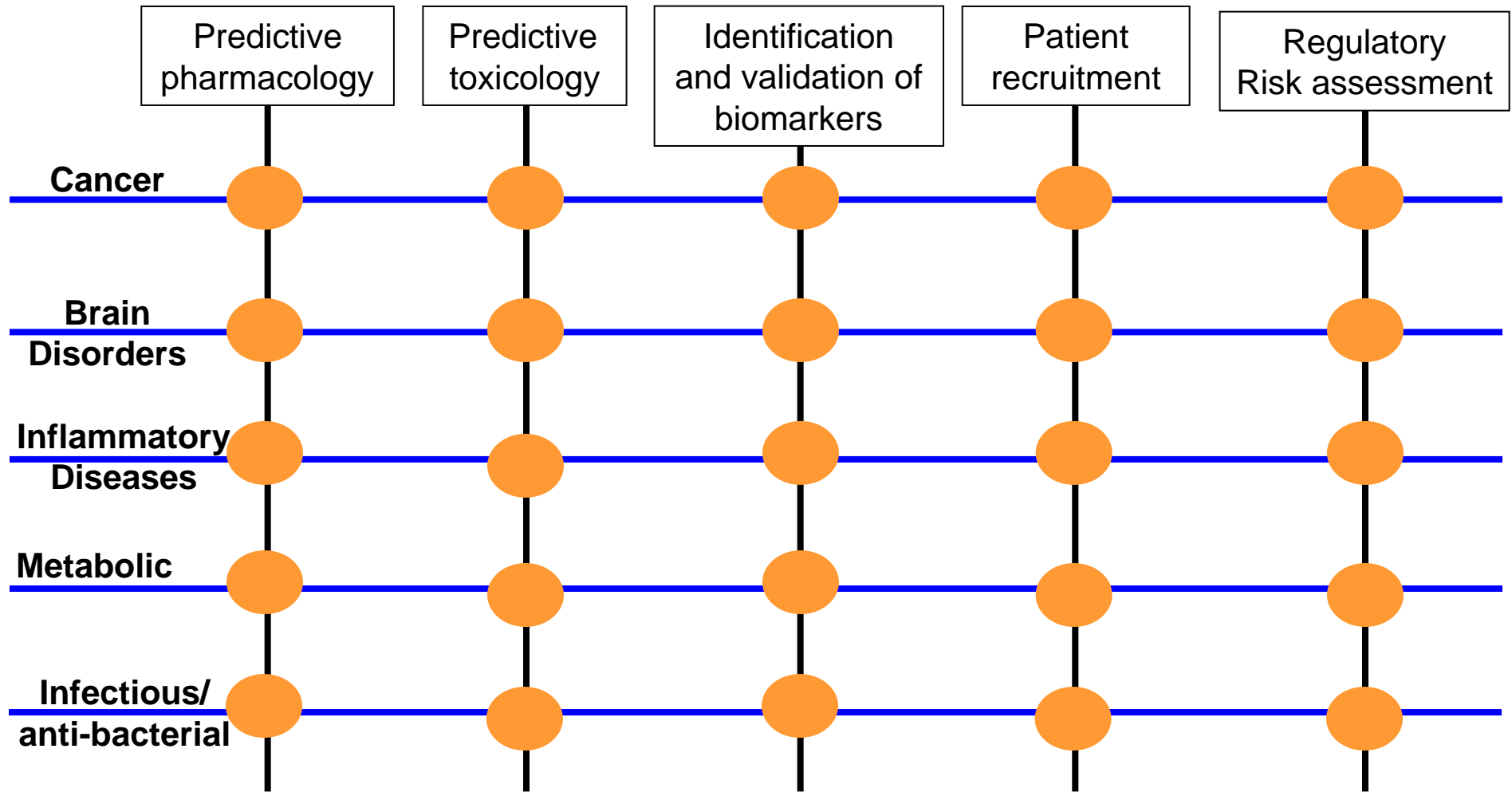


- Wealth of novel opportunities from genomics
 - How to pick the right molecules and bring them to the right patients
- Cost and timelines of drug development
 - Need a change the paradigm of drug discovery to decrease attrition and improve effectiveness
- The potential of increased cooperation with stakeholders
 - Greater public understanding, increased patient involvement and greater dialogue with regulators
- The need for increased openness
 - transparency of operation eg publication of CT data, sharing toxicology data,

IMI focuses on bottlenecks in biomedical R&D



Efficacy and Safety are often disease specific

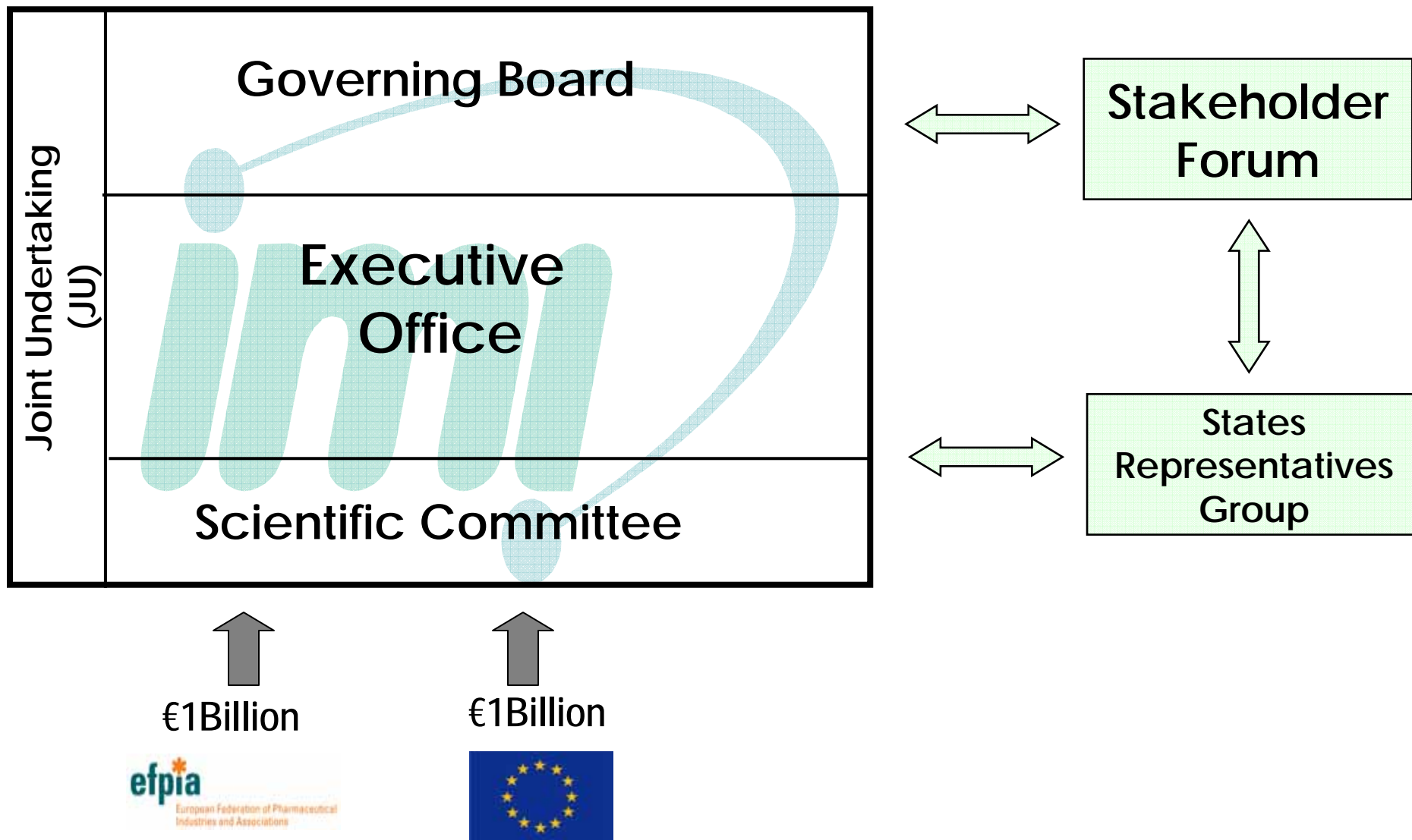


IMI First Year Expected Topics



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- 5 in Safety
 - 1 in Pharmacovigilance
 - 2 in Diabetes
 - 3 in Brain Disorders
 - 2 in COPD & Asthma
 - 1+ in Education & Training

Structure and funds



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dlf2

inhaltliche änderung:

die überschrift verweist jetzt auf die struktur der initiative

im bild erfolgte die kennzeichnung der legal struktur mit dem word Undertalking

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How to be involved in IMI



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- Provide input and feedback on IMI progress and way forward, via the IMI Stakeholder Forum
 - Participate in the actual implementation, via IMI Projects

Rules for participation



- Independent legal entities
- Capacity to carry out work themselves
- Research performed in Europe or country related to FP7
- 2 EFPIA legal entities and 2 non-EFPIA legal entities per project

Eligible for IMI funding	Non-eligible for IMI funding
<ul style="list-style-type: none">– SMEs– Academia– Patient Organisations– Other non-profit public entities	<ul style="list-style-type: none">– EFPIA companies– Other pharmaceutical companies not falling within definition of SMEs

Call and Evaluation Process



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keine änderung des textes

farbliche änderung für eine bessere lesbarkeit

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Information provided on the topics



1	Topic Title	<i>Provide with a clear topic title</i>
2	Project Description	<i>Describe the envisaged research program What approaches are envisioned (Maximum 2 pages)</i>
3	Key Deliverables of the project	<i>What the project aims to achieve after completion (Maximum 1 page)</i>
4	EFPIA Participants in the project	<i>Name EFPIA companies which plan to participate in the project</i>
5	Role of EFPIA Participants in the project	<i>EFPIA Participants in the project will contribute (Maximum 2 pages)</i>
6	Indicative duration of the project	<i>X years</i>
7	Indicative total in kind contribution from the EFPIA companies	<i>€ X mio</i>
8	Indicative expectations from the Public Consortium	<i>What are the deliverables expected from the Public Consortium (Maximum 1 page)</i>

Expressions of Interest



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- Short – few pages only (5-10)
 - Describes how the Public Consortium will address the topic
 - outline Work Packages and Budget
 - Identifies the members of the Public Consortium and the Public Coordinator
 - Identifies Knowledge Management and Education and Training needs
 - Reviewed by Peer Review, ad hoc experts including representatives of the EFPIA Consortium

Competition between the Expressions of Interest from the public consortia

Project Proposal



- Written jointly by the EFPIA Consortium and Public Consortium members
- Full description of research activities
 - Who, when, and how much
- Will need a draft Project Agreement before submission
 - IPR sharing agreed between all partners
- Peer Reviewed independently of EFPIA involvement
 - Judged against absolute standard
 - Expectation of high success rate

Minimize competition at this stage in order not to waste effort

Peer Review



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- Peer Review Committees
 - One Standing Peer Review Committee per Pillar of the Strategic Research Agenda
 - Assisted by ad hoc experts relevant to the call topics
 - EFPIA Consortia members participate only in evaluation of Expressions of Interest
 - Responsibility
 - To evaluate science of Expressions of Interest
 - To evaluate Full Proposals based on science and feasibility
 - Composition
 - Members reflecting a balance of public-private research expertise
 - Decision Making
 - By consensus between all experts

Research Project Funding



Research performed by pharmaceutical industry funded by own resources (= in kind contribution)

Research performed by public sector and SMEs funded by European Community (= cash contribution)

Benefits of Increased Collaboration for All Stakeholders



- Access to pre-competitive knowledge that was previously out of reach
 - Stimulation of creativity
 - Achievement of critical mass
 - Shared risk of failure
 - Enhanced learning experience
- ➔ Generation of More Innovative Solutions**

Benefits of IMI for Academia



- Source of funding for research
- Improved infrastructure with state-of-the-art technological equipment
- Opportunity to establish infrastructure for GLP/GCP compliant drug development
- Access to pre-competitive knowledge that was previously out of reach
- Increased mobility between the public and private sectors
- Increase co-ordination internationally on medical research topics
- Faster application of research results
- Increased collaboration with all relevant stakeholders

→ More funding for research

Benefits of IMI for Small & Medium-sized Enterprises (SMEs)



- Lower risk of technology development as shared with end-users
- Lower costs of technology development through IMI funding
- Easier access to Venture Capital funds for SMEs involved in IMI
- Easier access to relevant experts in the pharmaceutical companies
- Easier development of given technology for new application
- Clear Intellectual Property Rights policy from the onset
- Increased collaboration with all relevant stakeholders

➔ Better Investment Environment

IMI - Expected timelines



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- December 2007/January 2008
 - Communication of First Call Topics
 - February 2008
 - Official Launch of IMI Joint Undertaking
 - Publication of First Call Topics
 - April 2008
 - Deadline for Expression of Interest
 - June 2008
 - Invitation of full project proposal
 - End 2008
 - Signing of Grant Agreements and Start of Research Projects
 - January 2009
 - Publication of Call Topics for Second Year

Links and Material available



<http://www.imi-europe.org/Publications.asp>

- Strategic Research Agenda
- IMI Intellectual Property Policy
- IMI Frequently Asked Questions
- IMI Keys for Success – Industry input
- IMI Two-pager
- IMI Key Messages for Member States
- IMI Flyer
- IMI Glossary

http://ec.europa.eu/research/health/imi/index_en.html

http://cordis.europa.eu/fp7/cooperation/health_en.html

http://ec.europa.eu/research/health/imi/member-states-group_en.html

- Proposal for a COUNCIL REGULATION setting up the Innovative Medicines Initiative Joint Undertaking
- Assessment of Economical and Societal Effects of IMI
- FP7 Health brochure
- Health Research in FP7 Flyer
- Innovative Medicines Initiative Flyer
- Joint Technology Initiatives Brochure

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hier war die einfügung des links zur memberstate contact group unbedingt gewünscht worden daher musste ich auch die überschrift ändern

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The Innovative Medicines Initiative (IMI)



The End

Questions?

efpia



Benefits of IMI for the Biopharmaceutical Industry



- Validation of new assessment methods such as biomarkers
- Faster interpretation of safety findings through sharing pre-competitive toxicology data
- Reduced attrition rate in late-stage development
- Reduction of animal use in safety evaluation
- Fewer patients needed in pivotal trials
- Faster approvals through better collaboration with EMEA
- Fewer post-marketing withdrawals
- More skilled professionals
- Increased collaboration with all relevant stakeholders

→ More cost-efficient R&D