



# The Innovative Medicines Initiative (IMI)

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## Introducing the IMI Call Process

February 8<sup>th</sup>, 2008



# Agenda



- 
- Participation & Funding
  - Call Process

# IMI Call Process is Different from the 7<sup>th</sup> Framework Programme Process

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1. Research Topics are approved by the IMI Governing Board (EFPIA and European Commission) based on a proposal from EFPIA Research Directors Group.
2. The private consortium is established by the EFPIA Research Directors Group
3. The public consortium submits an Expression of Interest without involving the private consortium
4. The public-private consortium is established at the stage 1 of the peer review process.

# Rules for Participation in IMI Consortium



- Independent legal entities
- Capacities to carry out work themselves
- Research performed in Europe or country associated with the 7th framework programme
- At least 2 EFPIA legal entities and 2 non-EFPIA legal entities per project

# Eligibility for IMI funding



<b>Eligible for funding</b>	<b>Non-eligible for funding</b>
<ul style="list-style-type: none"><li>– Academia</li><li>– SMEs (EU definition)</li><li>– Patient Organisations</li><li>– Other non-for-profit legal entities</li></ul>	<ul style="list-style-type: none"><li>– EFPIA companies</li><li>– Other companies not falling within the EU definition of SMEs</li></ul>

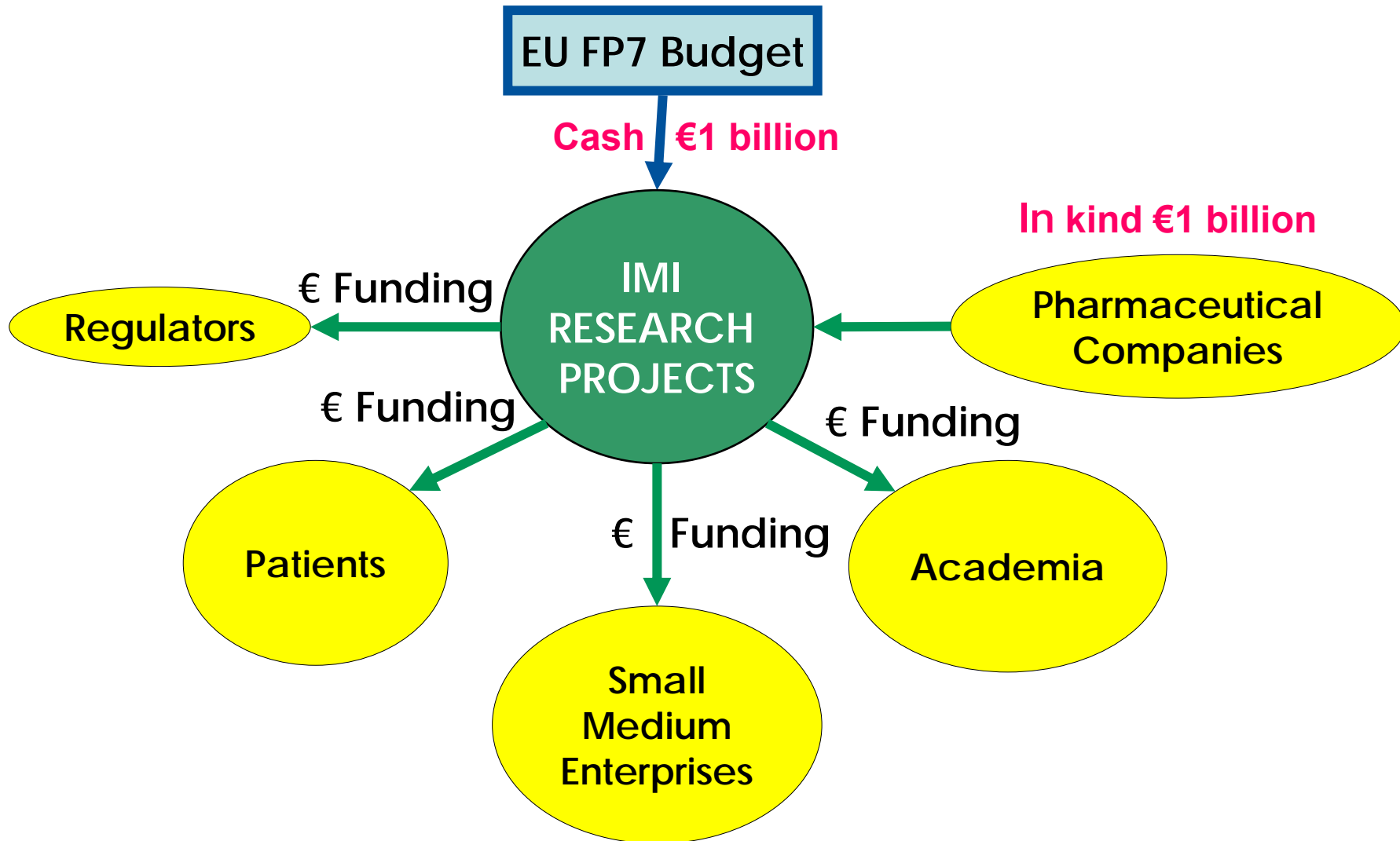
# Funding is according to EU State Aid Rules



Research Activities Maximum 75%	Management Activities Maximum 100%
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Indirect Costs max 20% of Direct Costs

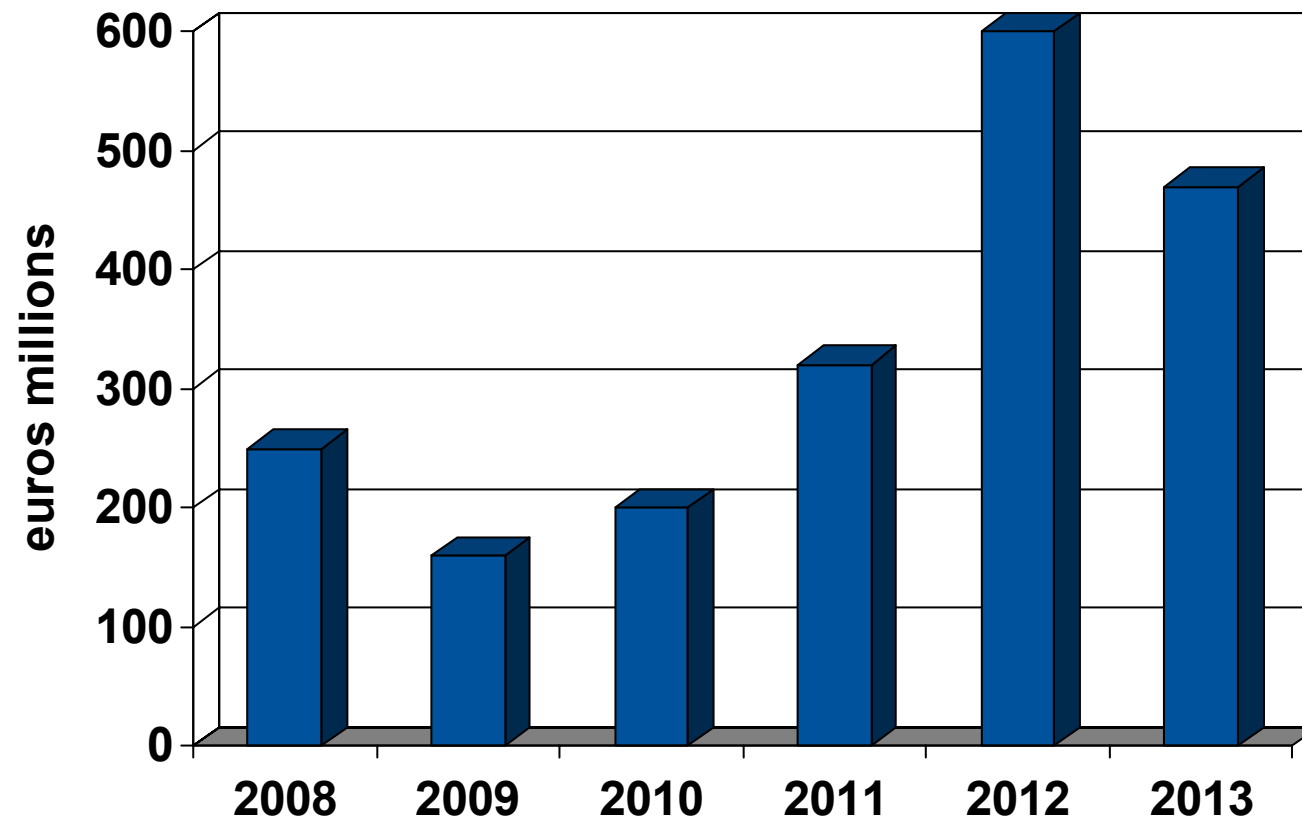
# Funding of Research Projects



Funding will be allocated to IMI projects until 2013 but research will be supported until 2017



**Total Annual Budget**

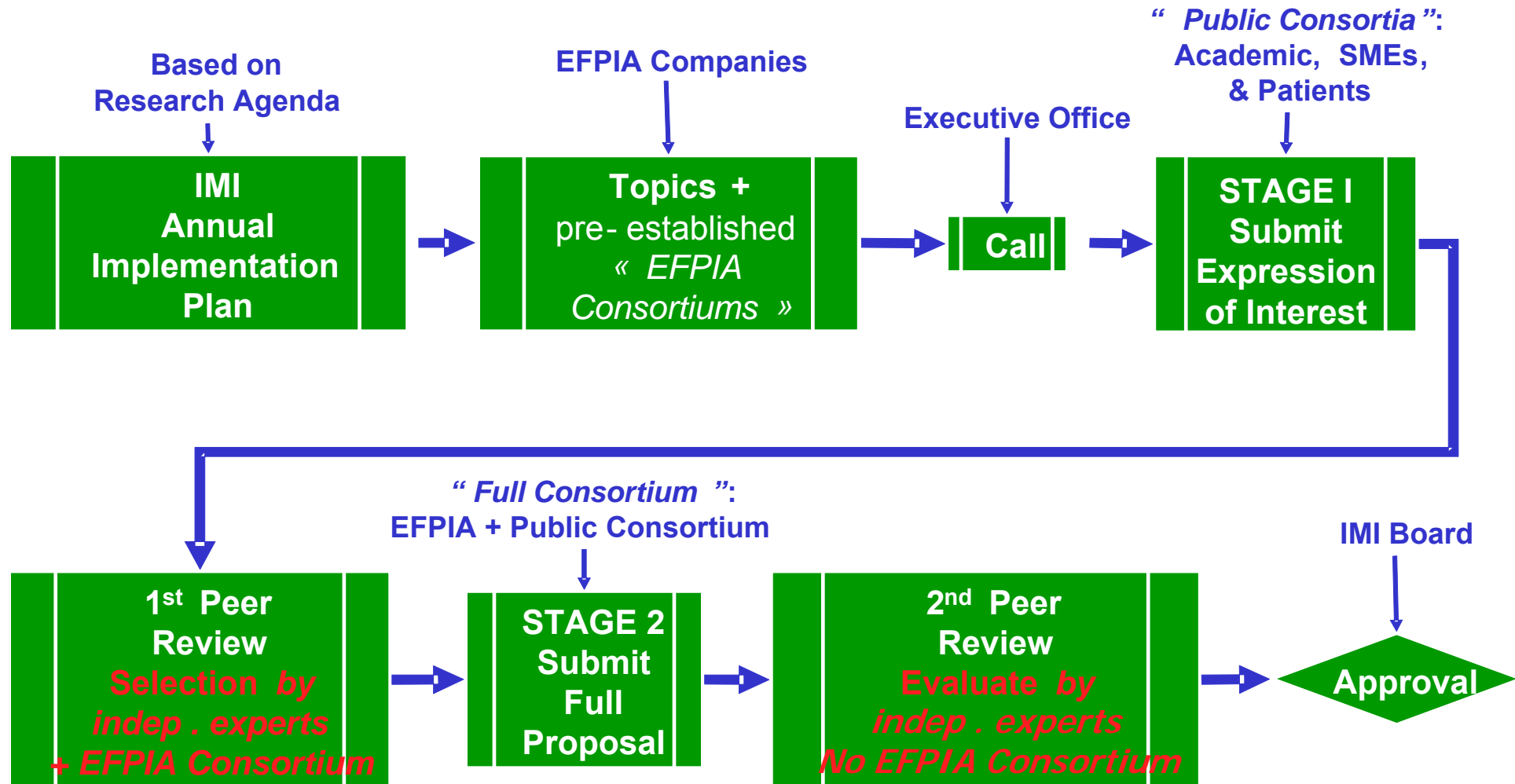


# Agenda



- 
- Participation & Funding
  - Call Process

# Call & Evaluation Process Overview



# Call & Evaluation Process

## Call definition

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Call definition

# Description of the Call Topics

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1. Title
2. Project description
3. Key deliverables of the project
4. EFPIA participants in the projects
5. Role of EFPIA participants in the projects
6. Duration of the project
7. Total in kind contribution from the EFPIA companies
8. Expectations from the public consortium

# Call & Evaluation Process

## Stage 1



**Research Agenda**

**Annual Implementation Plan**

**Call Topics**

**Call**

Call definition

**Expression of Interest**

**1<sup>st</sup> Peer Review**

**Invitation to Submit Full  
Project Proposal**

Stage 1: Scientific excellence

≈ 3 months



# Description of the Expression of Interest



1. Composition of the public consortium
2. Abstract (1/2 pages)
3. Science (3 pages)
4. Knowledge Management (1/2 page)
5. Training and Education (1/2 page)
6. Outstanding issues (1/2 page)
7. Budget plan (1/2 page)

**Written by the Public Consortium:  
i.e. academia, SMEs, regulators, patients organisations (without EFPIA)**

# Peer Review Stage 1



- **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 in evaluation of Expressions of Interest
- **Responsibility**
  - To evaluate science of Expressions of Interest
- **Composition**
  - Members reflecting a balance of public-private research expertise
- **Decision Making**
  - By consensus between all experts

# Call & Evaluation Process

## Stage 2



# Description of the Full 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

**Written by the Public Private Consortium:  
i.e. academia, SMEs, regulators, patients organisations with EFPIA**

# Peer Review Stage 2



- **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
  - No EFPIA Consortia members
- **Responsibility**
  - 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

# Call & Evaluation Process



# Starting Research Projects...



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March 3 <sup>rd</sup> , 2008:	Approval by IMI Board
March 4 <sup>th</sup> , 2008:	Call text available on the IMI Website
April 2008:	Publication of the IMI Call
July 2008:	Deadline for Expression of Interest
October 2008:	Deadline for Full Project Proposal
December 2008	Signature of Project/Grant Agreements
January 2009:	Start of research projects
February 2009:	Publication of the second IMI Call



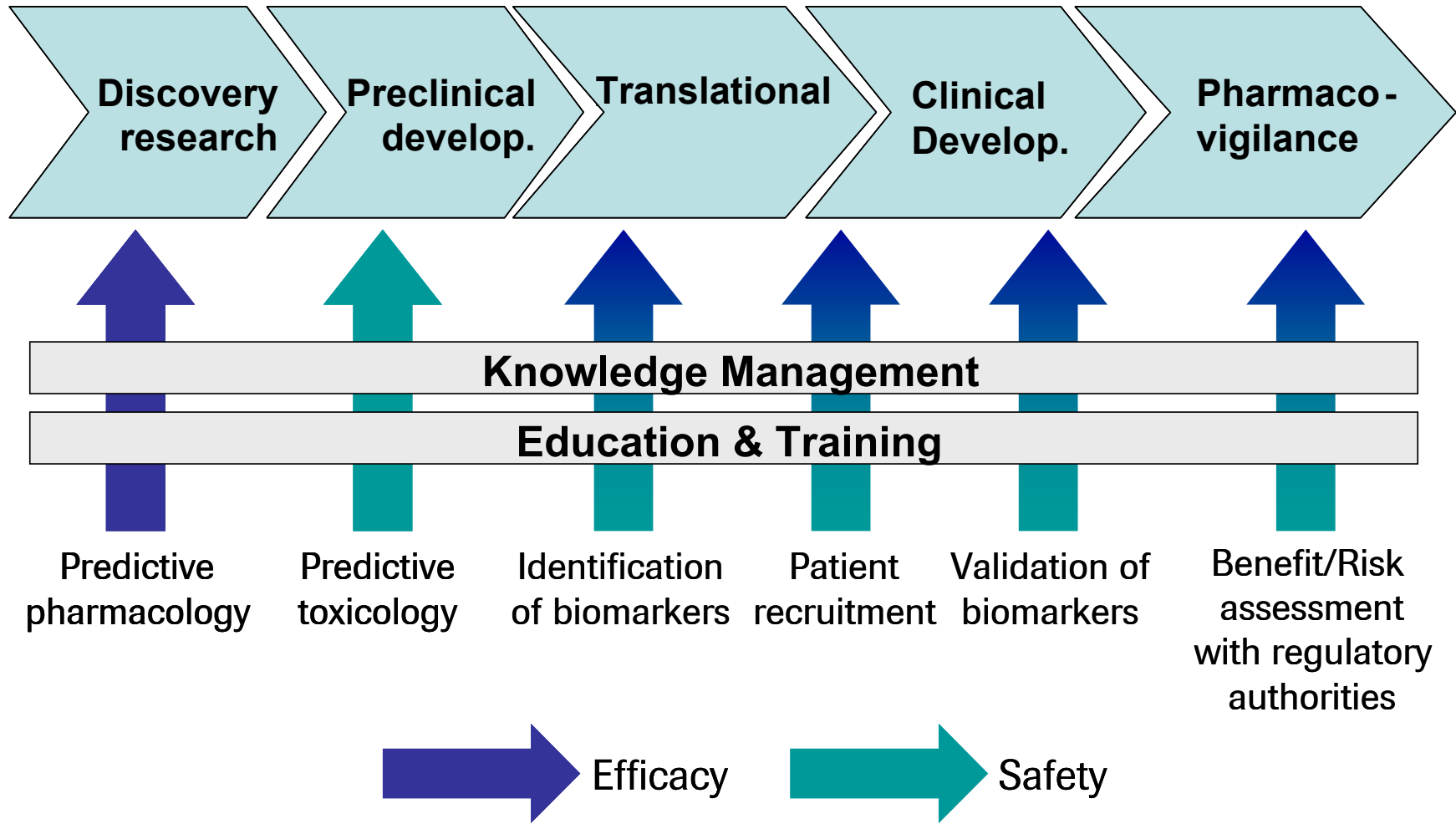
# The Innovative Medicines Initiative (IMI)

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## IMI Scientific Priorities

February 8<sup>th</sup>, 2008

# Pre-Competitive Bottlenecks in the R&D Process



## Criteria for Selection of the Scientific Priorities



- Addressing bottlenecks in the R&D process
- Need for public private collaboration
- High interest from numerous EFPIA companies
- Clarity concerning “role of EFPIA participants”

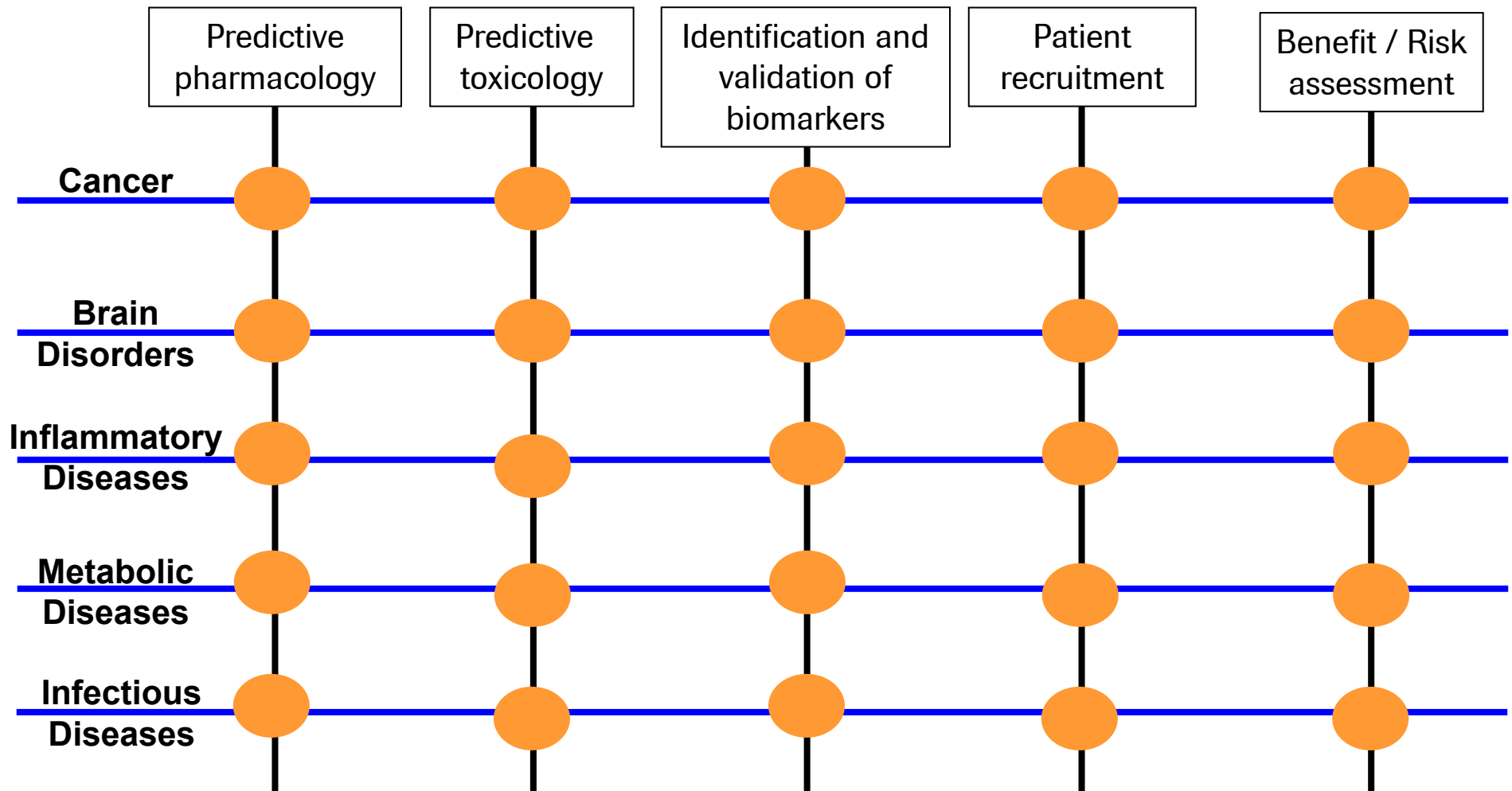
# Research Priorities for 2008



- ✓ 5 safety prediction
- ✓ 1 pharmacovigilance
- ✓ 2 diabetes
- ✓ 3 brain disorders
- ✓ 2 respiratory diseases
- ✓ 5 education & training

A 100-page document prepared by over 150 scientists from 24 companies. To be approved by the IMI Governing Board

# Focusing on 5 Disease Areas



# Potential Scientific Priorities for 2009



- More topics on?
  - Benefit/risk prediction
  - Severe asthma, COPD
- Introducing topics on?
  - Cancer
  - Infectious diseases
  - Knowledge Management

# Overview of the topics for 2008

(®: number of companies per call topic)



Translational safety biomarkers	€ 21.0	5 years	® 11
Immunogenicity	€ 13.0	5 years	® 11
Non-genotoxic carcinogenesis	€ 2.5	2 years	® 8
Expert systems for in silico toxicity prediction	€ 5.0	5 years	® 9
Non-clinical safety evaluation	€ 10.0	3 years	® 11
Pharmacovigilance	€ 15.0	5 years	® 14
Islet cell research	€ 10.0	5 years	® 10
Surrogate markers for vascular endpoints	€ 20.0	5 years	® 8
Pain	€ 7.5	5 years	® 13
Psychiatry	€ 10.0	5 years	® 12
Neurodegeneration	€ 7.5	5 years	® 14
Severe asthma	€ 1.0	1 year	® 8
COPD	€ 1.0	1 year	® 9
Education & Training	€ 16.5	4-7 years	® 24

- Qualification of translational safety biomarkers
- Immunogenicity of biotherapeutics in man
- Non-genotoxic carcinogenesis
- Expert systems for *in silico* toxicity prediction
- Improved predictivity of non-clinical safety evaluation
- Strengthening the monitoring of benefit/risk assessment

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- Islet cell research
  - Surrogate markers for vascular endpoints
  
  - Pain research
  - Psychiatric disorders
  - Neurodegenerative disorders
  
  - Severe asthma
  - COPD

## Education & Training

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- European Medicines Research Academy (EMRA) Hub
- Safety sciences training programme
- Pharmaceutical medicine training programme
- Integrated medicines development training programme
- Pharmacovigilance training programme



# The Innovative Medicines Initiative (IMI)

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EFPIA RDG Scientific Priorities for 2008

February 8<sup>th</sup> , 2008



- 
- Qualification of translational safety biomarkers
  - Immunogenicity of biotherapeutics in man
  - Non-genotoxic carcinogenesis
  - Expert systems for *in silico* toxicity prediction
  - Improved predictivity of non-clinical safety evaluation
  - Strengthening the monitoring of benefit/risk assessment

# Translational Safety Biomarkers Qualification

## Deliverables



- Define clinical qualification process(-es) for translational safety biomarkers
- Define the needs for new clinical biomarkers for DILI, DIKI, DIVI compared to current standards and features/criteria to be met
- Select mechanistic biomarkers panels from different discovery exercises (e.g. PredTox I, PSTC,...) based on their potential for translational use and secure assays for human use
- Establish baseline values and their variability ranges in healthy subjects (as well as in most common pathologies which could interfere based on mechanistic understanding)
- Define and run protocols to measure the performances of these biomarkers related to sensitivity and specificity (ROC analysis) against current standard markers (Involve HAs at this point)
- Establish a common database to be able to build up on any new data set upcoming in the future

# Translational Safety Biomarkers Qualification

## Expectations from a Public Consortium



- Options for qualification processes
- Markers or marker panels having high probability of being “validatable”
- Clinical trials and sample analysis esp. on specificity (e.g. diseased populations)
- Biomarker assays (methods/reagents, sensitivity/specificity, dynamic range,...)
- Biological and mechanistic understanding (potential limitations and other applications)
- Data management and marker performances
- Submission of full package to Health Authorities

# Immunogenicity Deliverables



- Find ways to make immunogenicity analysis comparable between compounds and companies
- Generate database of immunogenicity-relevant data of consortium compounds
  - Identify factors or patterns favouring immunogenicity
  - Evaluate value of existing predictive tools
- Investigate predictive value of most advanced in-silico and in-vitro tools (compare, verify, improve, validate, understand limitations)  
*[assays from SMEs like Algonomics, Antitope,...]*
- Explore potential utility of animal models to predict immunogenicity incidence and/or clinical consequences in man (compare, verify, improve, validate, understand limitations)
- Publish recommendations

# Immunogenicity

## Expectations from a Public Consortium

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- Standardization: Partner for elaboration and validation of standardization approach
- Database: Set up of database and data mining (CRO)
- In-silico/in-vitro: Share existing assays. Intellectual input from public centres of expertise to compare and improve the predictive value of currently existing algorithms and in-vitro assays.
- Animal models: Share existing animal models. Investigate the potential of animal models to predict immunogenicity and/or clinical consequences. Share novel insights into relevant areas of science (e.g. comparability of immune systems between species)
- Contribute to publications

# Non-genotoxic Carcinogenesis

## Deliverables

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- Identify industry-relevant model systems for mechanistic studies of epigenetic and/or receptor-mediated non-genotoxic carcinogenic effects
- Investigate predictive value of novel early mechanism-based biomarkers across diverse classes of non-genotoxic carcinogens in preclinical animal models
- Explore utility of circulating tumour cells and nucleic acids (*e.g. methylated DNA*) as blood-based surrogate biomarkers for NGC
- Compare biomarker findings between preclinical animal models and humans
- Generate unique database of molecular profiles of spontaneous and drug-induced rodent tumours

# Non-genotoxic Carcinogenesis

## Expectations from a Public Consortium

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- Establish industry-relevant models for mechanistic studies of epigenetic and/or receptor-mediated carcinogenesis + biomarker identification
- Define the causal relationship (*MoA*) between candidate early biomarkers and cancer using established models
- Focus on models and tools for investigating emerging/novel areas of science relevant to non-genotoxic carcinogenesis (e.g., Epigenetics, Transgenic mouse models for nuclear receptor function, Cell-type specific effects, Phosphoproteome, Circulating tumour cells and nucleic acids as surrogate biomarkers)

# Expert Systems for in Silico Toxicity Prediction

## Deliverables

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- Enabling of broad-based data sharing between participating companies for their collective advantage
- Improved selection/exclusion of candidate compounds
- Better tox characterisation of excipients, intermediates and impurities
- Development of a more efficient and effective in vivo testing strategy based on in silico prediction
- 3R!

# Expert Systems for in Silico Toxicity Prediction

## Expectations from a Public Consortium

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- Experience in data base development and data sharing
- Experience in automated retrieval of legacy reports
- Statistical and model building expertise, algorithms
- Support in education of scientists: modelling and validation of models
- Biological interpretation / integration of results

# Improved predictivity of non-clinical safety evaluation: Deliverables

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- **Deliverables**

- A valid, relational, high quality database for improved predictivity of safety evaluations
- Novel non-clinical biomarkers
- Understanding of biological mechanisms underlying the relationship between identified biomarkers and toxicity

- **Project plan outline**

- In vivo animal studies, mainly in rats but also selectively in non-rodent species, using ~10-15 well characterized drug candidates from participating companies and ~10-15 reference compounds
- Compounds will be selected based on toxicity findings in liver and/or kidney
- Biomarker discovery for regulatory decision making will be based on cross-'omics comparison as a major part of the evaluations

# Improved predictivity of non-clinical safety evaluation : Expectations from a Public



## Consortium

- Capabilities in histopathological evaluation
- Transcriptomics technologies
- Quantitative mass spectrometry
- Proteomic profiling
- Capabilities in quantitative RT-PCR and in-situ hybridization
- Mechanistic and confirmatory studies
- Development of assays
- Provision, hosting, maintenance, and further development of the existing FP6 – InnoMed - PredTox database infrastructure
- Infrastructure and services for centralized assessment and processing of all data
- Development of approaches and infrastructure for integrated data analysis, building of biostatistical models based on all experimental data
- Support in education of scientists within Systems Toxicology
- Biological interpretation / integration of results

# Pharmacovigilance

## Deliverables

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- Establish new methods of pharmacovigilance data collection
- Evaluate methods and develop operational definitions for
  - signal detection and evaluation in spontaneous reports databases, and
  - population-based epidemiologic data sources
- Establish methods for graphical expression and comparison of the benefit : risk profile of medicinal products
- Investigate and develop standards and processes for interoperability of European epidemiology data sources

# Pharmacovigilance

## Expectations from a Public Consortium

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- Development of analytical methods and algorithms for signal detection in order to improve the performance of the signals
- Development of methods for integration of drug safety profiles from all sources
- Integration and/or Interoperability of healthcare databases across the EU for drug safety monitoring, signal detection, evaluation and management.

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- Islet cell research
  - Surrogate markers for vascular endpoints
  
  - Pain research
  - Psychiatric disorders
  - Neurodegenerative disorders
  
  - Severe asthma
  - COPD

- **Knowledge**
  - Improvement of our understanding in the key mechanisms for  $\beta$ -cell loss in Type 1 and Type 2 Diabetes
  - Understanding the mechanisms of  $\beta$ -cell proliferation
- **Tools**
  - Novel methods, including non invasive technologies, and diagnostic tools to measure function and mass of  $\beta$ -cells *in vivo*
  - Novel animal models for  $\beta$ -cell research
- **Diagnostics tools and target validation**
  - Novel biomarkers to measure  $\beta$ -cell mass and function
  - New avenues for therapeutic treatment of  $\beta$ -cell loss / restoration

# Surrogate Markers for Vascular Endpoints in Diabetes

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- **Deliverables**

- Surrogate markers for macrovascular complications (MI, stroke)
- Surrogate markers for microvascular complications (neuro-, retino- and nephropathy)

- **Project plan outline**

- Exploring data and samples from recent and ongoing landmark clinical studies
- Assess specific genotypes as biomarkers and/or surrogate endpoints in clinical studies
- Assessing innovative assays and invasive and/or non invasive imaging technologies
- Evaluating preclinical biomarkers as surrogate endpoints in different animal models

# Surrogate Markers for Vascular Endpoints in Diabetes

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Expectations from a public Consortium:

- Academic groups: expertise in diabetes clinical trials & research, database and samples from clinical trials
- Patient organizations: support for recruitment in the long term clinical trials, support to focus on specific groups and also reduce drop-out rate
- SMEs: support in special technologies (imaging, analysis of biomarkers)

### **1. Mechanisms involved in generating and sustaining pain:**

- 1.1. Peripheral sensitisation, central sensitisation and neuroplasticity
- 1.2. Translation back to animal models
- 1.3. Methods and techniques to analyse the placebo response in clinical trials on pain

### **2. Preclinical animal model development:**

- 2.1. Validate novel animal models:
  - mechanism and origin specific, RA, HIV, cancer, diabetic
- 2.2. Objective, quantitative and clinically translatable pain measures:
- 2.3. Development of pain-free animal models of pain (3Rs) imaging, molecular profiling, collateral behavioural markers)

# Pain

## Expectations from a Public Consortium

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1. **Academic centres, patient organisations, regulators and imaging centres could be part of the consortium**
2. **Consortium should consist of both preclinical and clinical investigators**
  - Excellent scientific track record in area of proposed research
  - Sufficient PhD or post-doctoral researchers to ensure delivery of key objectives in a timely manner
3. **Establish a network of expertise through a wide range of laboratories across Europe**
  - Innovation
  - Structured proposals highlighting how challenges will be addressed
  - Combine and apply numerous expertise areas
  - Infrastructure to support preclinical and clinical studies

- **Identify relevant markers to segment patient populations**
  - Identify blood markers related to distinct phenotypes, including intermediate phenotypes: used for early signs of clinical efficacy
  - Identify blood markers that predict treatment response: to enrich study populations
  - Validate pharmacodynamic markers to support regulatory submissions
  - Use transcription markers to guide genotyping.
  - Use markers to identify novel treatment targets
  - Link transcription patterns to phenotype
  - Experimental medicine models
- **Improve animal models**
  - Establish animal models that share marker changes identified in humans. Focus on 'translatable' read-outs, e.g. blood markers, neuroimaging, EPs, EEG
  - Develop models of PK/PD relationships on pharmacodynamic markers
- **Improve dose selection**
  - Establish functional neuroimaging read-outs that correlate with target occupancy and clinical efficacy to facilitate dose selection
  - Establish preclinical in vivo validation of clinical neuroimaging read-outs

# Psychiatric Disorders

## Expectations from a Public Consortium

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- **Expected contribution from academic groups and SMEs**
  - Innovative approaches for patient characterization, including intermediate phenotypes, that cross current diagnostic boundaries. Includes established infrastructure to recruit subjects
  - Disease biology understanding
  - Availability of blood samples from well-phenotyped subjects that are suitable for omics technology
  - Technology platforms (animal models, imaging technologies)
  - Access to animal models that mimic aspects of human disease
- **Seek synergies with other related global initiatives:**
  - US Biomarker consortium
  - CNS Metabolomics consortium
  - P1 Vital

- **Healthy Volunteer/Pharmacodynamic model development**
  - Cognitive impairment models predictive of effective dose range and eventual clinical efficacy
  - Academic and industrial agreement on predictive value to disease states
- **Pharmacodynamic marker development**
  - predicting pharmacologically active exposure range within 4-6 weeks dosing
  - For use across pre-clinical species, HVT and/or patient studies
- **Pre-clinical model development**
  - Identification of animal models using fully translatable endpoints and scientifically proven utility in the translation of efficacy from bench to bedside

**Delivery of academically and industrially validated models  
and markers to revolutionise future drug development.**

# Neurodegeneration

## Expectations from a Public Consortium

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- Innovative approaches to the challenge of pharmacodynamic model/marker development
- Combining clinical assessment with imaging, EEG/MEG and/or biochemical/genetic assessment
- The ability to conduct parallel pre-clinical and clinical studies ,forward and back translation
- Infrastructure required to recruit into and conduct experimental medicine studies in both HVT and patients

# COPD Patient Reported Outcome: Background

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- We have only a limited definition of a COPD exacerbation for use clinically and for drug trials
- This does not allow duration nor intensity to be recorded
- Presently development of therapies to combat exacerbations need 18 month studies of exacerbation frequency ~ thus slowing drug development especially for phase 2 studies
- As a way forward, a number of patient reported outcome measures have been developed to detect and diagnose exacerbations and enable duration and intensity to be recorded
- This call is to develop a validated instrument that can be used in drug development and is accepted across Europe
- Potentially it could be linked to the US and China

# COPD Patient Reported Outcome: What are we trying to solve?

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- **Needs**

- Definition of exacerbation
- Develop an method of detection on a daily record
- Use symptoms and function to determine severity and duration

- **Scope**

To build consensus by working across clinical practice, academic health outcomes and regulatory bodies ~ include patients and payers

# COPD Patient Reported Outcome: What are we expecting?

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- Validated questionnaire
- The questions to be development by a scientific committee drawn from the major customer groups
- Cross sectional study initially to validate utility
- Refined questionnaire to be developed and tested prospectively
- Use of Blackberry like device for home daily recording of the questions answers

# Severe Asthma: Background



- Disease understanding including epidemiology, diagnosis, assessment of severity, phenotyping, biochemical and genomic markers of severe asthma is key
- Focus of 2008 call is to build network to enable Disease Understanding as most immediate priority
- The intent will be to harness efforts of already established groups who are presently working independently. This can be done through establishment of a common protocol for patient identification and assessment together with a common database or prospective registry



- **Issues, Needs, Background**

- A. Understanding natural history of severe asthma and disease mechanisms presents considerable challenges in the setting of disease heterogeneity, including its frequent comorbidities
- B Need for research into disease mechanisms to provide for true-disease modifying therapeutic opportunities, biochemical and genomic biomarkers to identify patient characteristics associated with different phenotypes
- C There are groups working independently to address some of these questions eg ENFUMOSA, BIOAIR. Need for standardised approach

- **Scope**

- **The asthma call for 2008 is to build an EU Severe Asthma network focused on disease understanding.**
- Harness efforts of already established groups who are presently working independently such as ENFUMOSA, BIOAIR and the UK severe asthma network

# Severe Asthma: What are we expecting?

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- Deliverables

- A. Identification of novel targets for pharmacological intervention and biomarkers
- B. Identification of targets relevant to specific phenotypes of severe asthma
- C. Understanding of aetiology of asthma exacerbations as mechanism to identify new targets and therapeutic approaches and deliver significant pharmacoeconomic benefits
- D. A European network, able to collaborate in a standardised manner and able to link-in with global efforts.

## Education & Training

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- European Medicines Research Academy (EMRA) Hub
- Safety sciences training programme
- Pharmaceutical medicine training programme
- Integrated medicines development training programme
- Pharmacovigilance training programme

# What is expected from a public Consortium?

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- Academic Groups:
  - Course organisation
  - Faculty
  - Venue
  - Training materials
  - Case studies
- Other stakeholders (SMEs, patients, regulators, etc):
  - Relevance to the various groups
  - Case studies
  - Promotion of the course

## EMRA: What are we trying to solve?

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- Establish a pan-European platform of excellence for education and training, covering the whole lifecycle of a medicine, from research to pharmacovigilance.
  - A platform for 480 IMI PhD students
  - Provide training courses for professionals
  - Coordinate training activities
  - Guarantee quality
  - Stimulate mobility, innovation and PPP
- Scope
  - EMRA hosted by one of the participating universities as a co-ordinating unit (the hub) at a location characterised by high-quality industry contacts and recognised science

# EMRA: Estimation of “in kind” contributions and budget from Industry

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- Cost of EPIA employee’s participation in course development
- Senior staff members to be members of faculty for lecturing and as assessors
- Preparation for lectures
- Travelling and accommodation in connection with lectures
- Development of case studies
- Sharing/updating existing relevant in-house training programmes and/or educational materials
- Hosting courses/modules, lecture rooms & facilities
  
- Total “in kind” estimate: € 3 mio (~ €100K per RDG member)

# EMRA: What is expected from a public Consortium?

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- Types of Academic Groups and SMEs contributions
  - Hosting the EMRA Hub, location and personnel
  - Course organisation including Faculty, Venue, Training materials, Case studies
- Other global initiatives to be followed/contacted to avoid redundancies and build on synergies
  - Existing university networks, e.g. the European University Consortium for Advanced Pharmaceutical Education & Research (ULLA)

## Safety: What are we trying to solve?

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- Predictive safety, bridging pre-clinical and clinical
  - Safety scientists are needed
    - Broader spectrum than the trad. toxicologist
  - Multidisciplinary approach
  - Linking animal and human safety data
  - Address late phase attrition due to safety issues
- Scope
  - A master's programme for scientists holding a degree in life sciences

# Safety: What are we expecting and going to do?



- Deliverables, 5 years
  - Formation of a **European Network of Faculties** able and willing to support the project
  - A **programme/curriculum, Full time + part time**
  - Establishment of programme
  - Innovative approaches to distance learning
  - More than 50 participants in programme
  - At least 20 participants completed full programme
  - A process for an European accreditation of such programme
  - Link to IMI Safety pillar
- Project plan outline
  - Establishment of consortium
  - Establishment of curriculum
  - Start of programme
  - 1<sup>st</sup> cohort completed
  - European Accreditation

# Safety: Estimation of “in kind” contributions from Industry

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- EPIA employee's participation in course development
  - Senior staff members lecturing and assessors
  - Preparation, travelling etc. in connection with lectures
  - Development of case studies
  - Sharing/updating existing relevant in-house programmes and/or materials
  - Creation of “training positions” in the companies with adequate support of in-house mentors
  - Hosting courses/modules, lecture rooms & facilities
  - Fees for employees participating in programme
  - Travel and accommodation for employees on programme
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- Total “in kind” estimate: € 4 mio (~ €150K per RDG member).

# Safety: What is expected from a public Consortium?

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- Types of Academic Groups and SMEs contributions
  - Course organisation
  - Faculty
  - Venue
  - Training materials
  - Case studies
  - Promotion of course
- Other global initiatives to be followed/contacted to avoid redundancies and build on synergies
  - EUFEPS safety sciences working group
  - EUROTOX and similar organisations

# Pharmaceutical Medicines: What are we trying to solve?

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- Satisfy the demand of highly qualified professionals in the field of **Pharmaceutical Medicine**
  - **Interdisciplinary** approach
  - **Harmonised** activity of existing and new courses in pharmaceutical medicine
  - **Integrated view of drug development** for scientists involved
- Scope
  - A **master's programme** for scientists holding a degree in life sciences

# Pharmaceutical Medicines: What are we expecting and going to do?



- Deliverables, 4 years
  - A European Network of established academic centres using harmonised contents and similar educational and assessment methods: A common Pharmaceutical Medicine Syllabus
  - A programme/curriculum, Full time + part time
  - New academic centres in European areas where needed (e.g. accession countries)
  - A CME/CPD programme
  - Innovative approaches to distance learning
  - Training programme for investigators to include GCP
  - First cohorts of students started on the programmes
  - A process for an European accreditation of such programme
- Project plan outline
  - Establishment of consortium
  - Establishment of curriculum
  - Start of programme
  - 1<sup>st</sup> cohort completed
  - European Accreditation

# Pharmaceutical Medicine: Estimation of “in kind” contributions from Industry



- EPIA employee's participation in course development
  - Senior staff members lecturing and assessors
  - Preparation, travelling etc. in connection with lectures
  - Development of case studies
  - Sharing/updating existing relevant in-house programmes and/or materials
  - Creation of “training positions” in the companies with adequate support of in-house mentors
  - Hosting courses/modules, lecture rooms & facilities
  - Fees for employees participating in programme
  - Travel and accommodation for employees on programme
- 
- Total “in kind” estimate: € 2.5 to 3 mio. (~ €100K per RDG member)

# Pharmaceutical Medicine: What is expected from a public Consortium?

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- Types of Academic Groups and SMEs contributions
  - Course organisation
  - Faculty
  - Venue
  - Training materials
  - Case studies
  - Promotion of course
- Other global initiatives to be followed/contacted to avoid redundancies and build on synergies
  - Council for Education in Pharmaceutical Medicine (IFAPP)
  - Federation of European Courses in Pharmaceutical Medicine (including Faculty of Pharmaceutical Medicine, UK)

# Integrated Medicine: What are we trying to solve?

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- Satisfy the need for **information on the medicines development process for people not directly involved** in the research
  - **Short track** (week) for e.g. journalists, patients, members of ethics committees, venture capitalists, and politicians with a special interest in health, research, environmental, or industrial matters
  - **Long track** (months) for e.g. SME personnel, project managers, general managers
- Scope
  - Providing an **integrated overview** of the process including regulatory requirements
  - Courses in English, **translatable to other EU languages**

# Integrated Medicine: What are we expecting and going to do?

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- Deliverables, 3 years
  - A European Network of Faculties (universities and private institutions) able and willing to support the course
  - A programme, modular approach for long track
  - More than 100 participants completed each of the courses
  - Administration of courses
- Project plan outline
  - Establishment of consortium
  - Establishment of programme
  - Start of programme
  - 200 participants completed programme

# Integrated Medicine: Estimation of “in kind” contributions from Industry

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- Cost of EPIA employee’s participation in course development
- Senior staff members to be members of faculty for lecturing and as assessors
- Preparation for lectures
- Travelling and accommodation in connection with lectures
- Development of case studies
- Sharing/updating existing relevant in-house training programmes and/or educational materials
- Hosting courses/modules, lecture rooms & facilities
- Fees for employees participating in programme
- Travel and accommodation for employees on programme
- Total “in kind” estimate: € 2.5 to 3 mio (~ €100K per RDG member).

# Integrated Medicine: What is expected from a public Consortium?

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- Types of Academic Groups and SMEs contributions
  - Course organisation
  - Faculty
  - Venue
  - Training materials
  - Case studies
  - Promotion of course
- Other global initiatives to be followed/contacted to avoid redundancies and build on synergies
  - Synergy with call for Pharmaceutical Medicine

# Pharmacovigilance: What are we trying to solve?



- Satisfy the need for **training in contemporary pharmacovigilance**
- Proactively ensure a **common basis** for pharmacovigilance
- 3 levels
  - **Short course on risk communication** for e.g. journalists, patients, HC providers, venture capitalists, etc.
  - **Master's training programme** for professionals in industry and regulatory agencies
  - **PhD programme** to identify current gaps, and assess and develop methods for benefit-risk communication
- Scope
  - Common understanding and active use of pharmacovigilance in industry and regulatory agencies

# Pharmacovigilance: What are we expecting and going to do?



- Deliverables, 5 years
  - Short
    - A programme for the course,
    - A European Network of Faculties (universities and private institutions) able and willing to support the course,
    - More than 100 participants completed the course
  - Master
    - A programme/curriculum for multidisciplinary training of scientists involved in pharmacovigilance,
    - A European Network of Faculties (universities and private institutions) able and willing to support the project,
    - Establishment of programme,
    - More than 50 participants in programme with at least 20 completed full programme,
    - A process for an European accreditation of such programme
  - PhD
    - Project description(s) for PhD project(s)
    - Each PhD project should involve the co-operation of a university, a regulatory authority, a PhD fellow and an EFPIA company according to the SRA
  - Administration of courses

# Pharmacovigilance: What are we expecting and going to do?

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- Project plan outline
  - Establishment of consortium
  - Establishment of programme
  - Start of programme
  - Participants completed programme according to detailed plan

# Pharmacovigilance: Estimation of “in kind” contributions from Industry

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- Cost of EPIA employee’s participation in course development
- Senior staff members to be members of faculty for lecturing and as assessors
- Preparation for lectures
- Travelling and accommodation in connection with lectures
- Development of case studies
- Sharing/updating existing relevant in-house training programmes and/or educational materials
- Facilitate training by creating/maintaining recognised “training positions” in the companies with adequate support of in-house mentors
- Hosting courses/modules, lecture rooms & facilities
- Fees for employees participating in programme
- Travel and accommodation for employees on programme

# Pharmacovigilance: “In kind” contributions, ctd.

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- PhD
  - 50% of the standard PhD salary
  - Industry bench costs, i.e. location, use of apparatus etc.
  - Administration of salary, employment contract etc
  - Industry supervisor
- Total “in kind” estimate: € 3 to 3.5 mio. (dependent on No of PhDs) (~ €130K per RDG member)

# Pharmacovigilance: What is expected from a public Consortium?

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- Types of Academic Groups and SMEs contributions
  - Course organisation
  - Faculty
  - Venue
  - Training materials
  - Case studies
  - Promotion of course
- Other global initiatives to be followed/contacted to avoid redundancies and build on synergies
  - Pharmacovigilance programme at University of Hertfordshire, UK
  - EMEA activities



# The Innovative Medicines Initiative (IMI)

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Intellectual Property Policy

Full document:

[http://www.imi-europe.org/DocStorage/PublicSiteAdmin/Publications/IMI\\_IPR\\_policy\\_1\\_August\\_2007.pdf](http://www.imi-europe.org/DocStorage/PublicSiteAdmin/Publications/IMI_IPR_policy_1_August_2007.pdf)

# Intellectual Property Rights Policy *Objectives*

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- Promote knowledge creation and dissemination
- Promote knowledge exploitation
- Promote participation in IMI Projects of:
  - Academic institutions
  - Small biopharmaceutical companies
  - Large biopharmaceutical companies



# *Intellectual Property Rights Policy*

## *'Dissemination'*

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- Participants shall disseminate the results of the Project as soon as reasonably practicable but not later than one 1 year after the termination or expiry of the Project.
- 1 year period allowed to enable protection of IP where required.
- Once knowledge is in the public domain, all can access either directly or through licence on pre-determined fair and reasonable terms.

# Intellectual Property Rights 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
<b>Project Participants</b>	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
<b>Third Parties</b>	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

# *Intellectual Property Rights Policy*

## *'Direct Exploitation'*

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### 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.**