

The logo for the Austrian Research Promotion Agency (FFG) is positioned in the upper right quadrant. It features the letters 'FFG' in a bold, grey, sans-serif font. To the left of the letters is a grey circle containing a cluster of red dots, with several red, brush-like splashes extending from the circle towards the left side of the slide. The background of the slide is light grey with faint, overlapping circles in various shades of grey and white.

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Biobanks: Opportunities provided by European Research Programmes

Sabine Herlitschka

**European & International Programmes
FFG – Austrian Research Promotion Agency**

About...



- A new EC legal framework: ERIC - European Research Infrastructure Consortium
- Opportunities in FP7:
 - The BBMRI environment: further relevant research infrastructure initiatives in the Life Sciences area
 - Innovative Medicines Initiative (IMI)
 - Upcoming FP7-Calls: Research Infrastructures; Health
- Global context: Critical Path Initiative (USA)

7th Framework Programme: 2007 - 2013



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COOPERATION – Collaborative research
Predefined themes, refined “instruments”

IDEAS – Frontier Research
Individual grants, European Research Council

PEOPLE – Human Potential
Mobility of Researchers

CAPACITIES – Research Capacity
Infrastructure, SMEs, science & society,...

Joint Research Center –
non-nuclear

+

EURATOM

A new Community legal framework for a **European Research Infrastructure Consortium (ERIC)**:

- will provide a **legal personality** recognised in all Member States
- and some of the advantages of international organisations, such as **VAT exemptions**

-> rationale:

Cut down significantly the time necessary for setting up European research infrastructures.

Facilitate the implementation of the **ESFRI roadmap**: 44 key projects of European interest to be developed in the next 10-20 years.

Related European Research Infrastructures



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- ECRIN:** Pan-European Infrastructure for Clinical Trials, ATCRIN
- ELIXIR:** European Life Sciences Infrastructure for Biological Information
- EATRIS:** European Advanced Translational Research Infrastructure for Medicine
- INSTRUCT:** Integrated Structural Biology Infrastructure
- INFRAFRONTIER:** Infrastructure for Phenotyping and Archiving of Model Mammalian Genomes

ECRIN



Pan-European Infrastructure for Clinical Trials

Aims:



- **link** national networks of clinical research centres and clinical trials units; provide integrated '**one-stop shop**' **services** to investigators and sponsors in multinational studies,
- Support academic clinical research, research on rare diseases, neglected diseases, and for clinical trials sponsored by biotechnology, drug, and device enterprises that may face difficulties in conducting multinational studies in the EU.
- Foreseen as major tool for **FP7- or Innovative Medicines Initiative (IMI)-funded projects**
- Austrian „branch“: **ATCRIN**

<http://www.ecrin.org/>

<http://www.atcrin.at/>

ELIXIR



European life sciences infrastructure for biological information
(preparatory phase):



Aim:

Construct and operate a sustainable infrastructure for biological information in Europe to support life science research and its translation to medicine and the environment, the bio-industries and society

<http://www.elixir-europe.org/page.php?page=home>

EATRIS



European Advanced Translational Research Infrastructure for Medicine
(preparatory phase)

Aims:



Support a faster and more efficient translation of research findings into the development of innovative strategies for the prevention, diagnosis and treatment of diseases

Build on existing translational centres to build up a European network of translational infrastructure and excellence.

Priority areas:

Cancer

Diseases of the cardiovascular system

Brain disorders & advanced imaging

Metabolic syndrome

Infectious disorders

<http://www.eatris.eu/>

INSTRUCT

Integrated Structural Biology Infrastructure
(preparatory phase)

Aim:

Link the information obtained by the major structural biology methods with state-of-the-art cell biology techniques to provide a dynamic picture of key cellular processes at all scales

<http://www.instruct-fp7.eu/>



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INSTRUCT

INFRAFRONTIER



Infrastructure for phenotyping and archiving of model mammalian genomes

(preparatory phase):

Aim:

Organize and establish an efficient distributed infrastructure for the phenotyping, archiving and dissemination of mouse models on a well-concerted, large-scale and pan-European level.

<http://www.infracontier.eu/about.php>

Opportunities in the upcoming Calls: FP7-Research Infrastructures



Expected Call Publication: **July 30th, 2009**

Example of relevant **Draft Topics** (*Support to existing research infrastructures*):

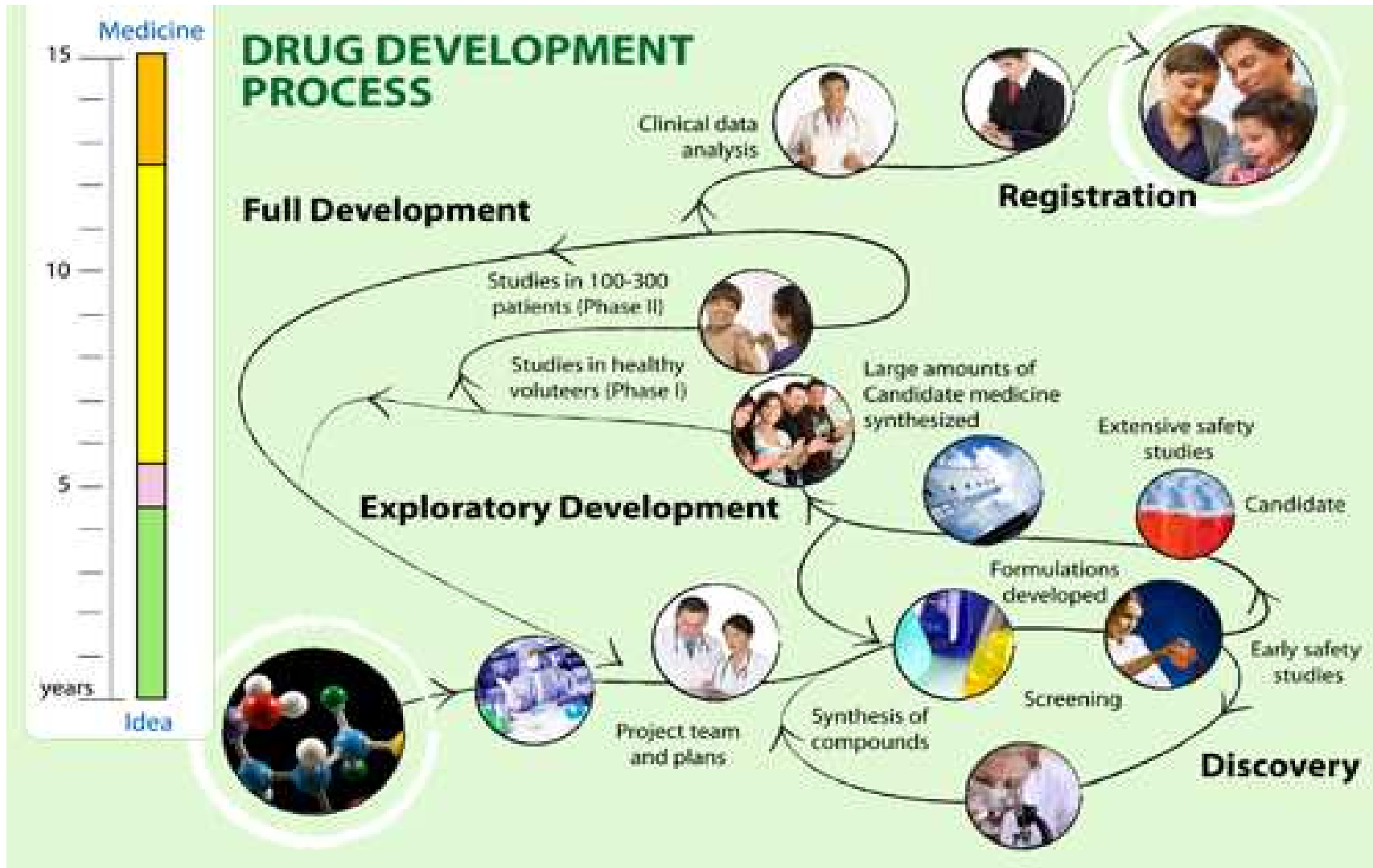
- Large-scale bio-banks for clinical and epidemiological studies
- Bio-NMR facilities
- EuroBioImaging (Research infrastructure for imaging technologies in biological and biomedical sciences)



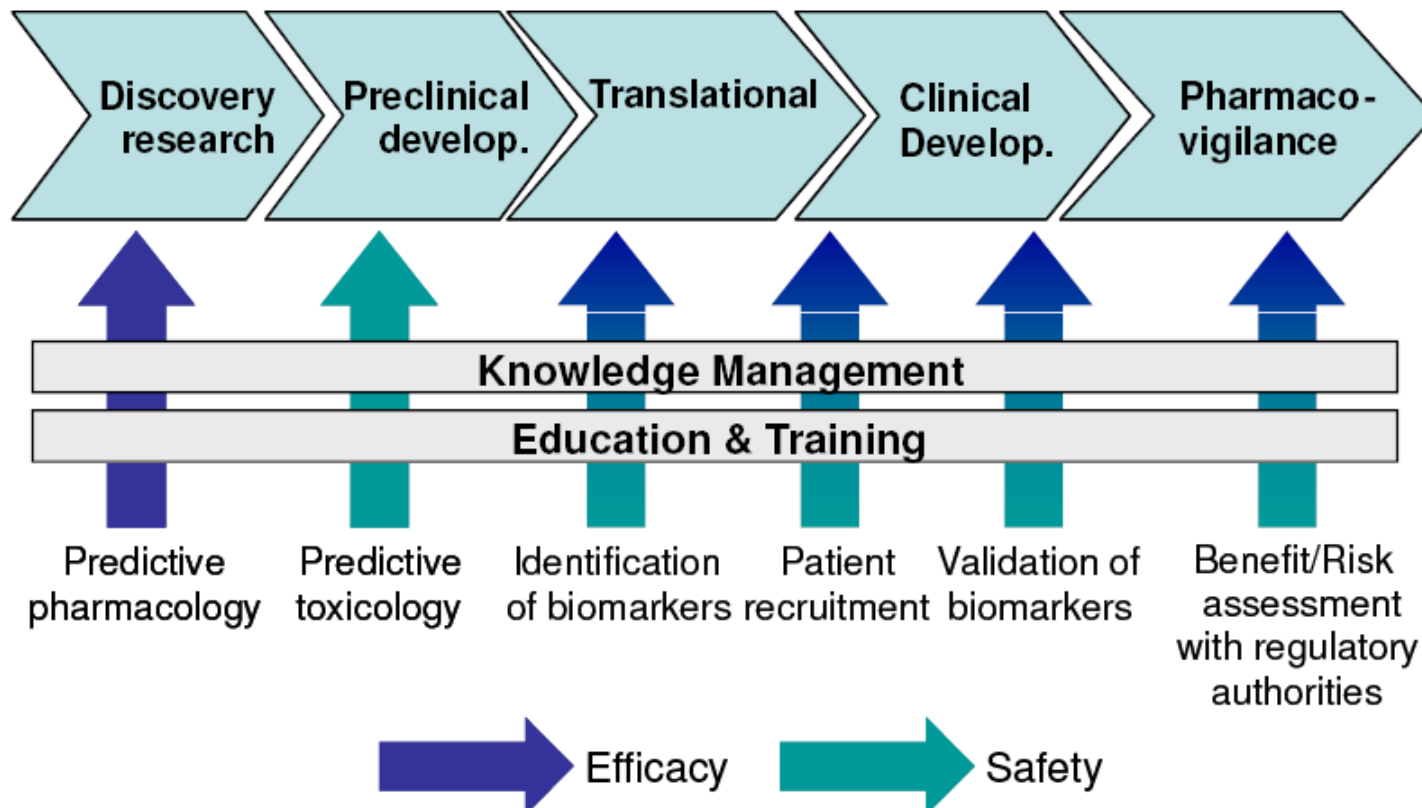
IMI – Innovative Medicines Initiative



INNOVATIVE MEDICINES INITIATIVE (IMI)



Pre-Competitive Bottlenecks in the R&D Process



INNOVATIVE MEDICINES INITIATIVE



Private-Public-Partnership (PPP) between European Commission and European Federation of Pharmaceutical Industries and Associations (EFPIA)

Budget: 2 bn Euro (largest initiative of its kind)

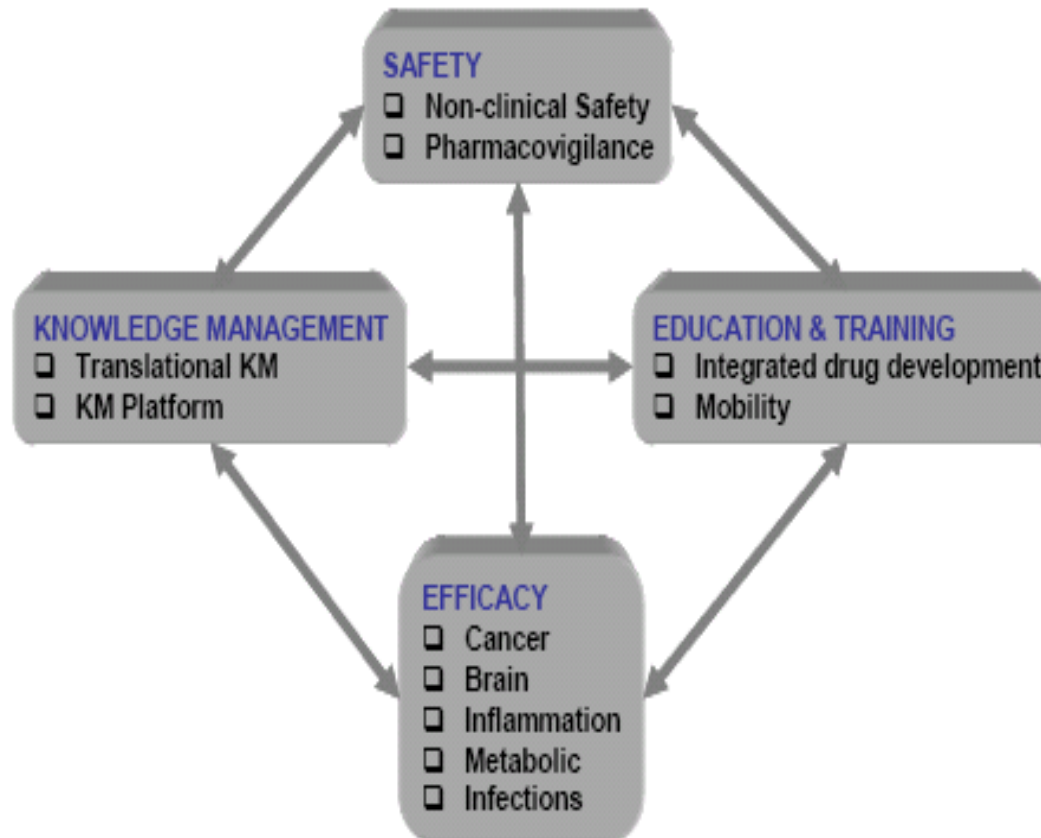
Objective:

Overcome bottlenecks in the development of innovative medicines by joint pre-competitive research (big pharma, universities, research organisations, SMEs, regulatory bodies, patient organisations, etc)

- > Improved prediction of Safety and Efficacy of new medicines
- > Education and Training
- > Knowledge Management

www.imi.europa.eu

IMI Strategic Research Agenda



IMI: High relevance of biobanks



Draft Scientific Priorities for **upcoming 2. IMI Call** (opening expected Sep.09) – Examples:

Cancer: e.g. imaging biomarkers for anticancer drug development; molecular biomarkers for acceleration of cancer therapy development

Inflammation: facilitate translational research in chronic IMD in order to bridge the gap between animal models and humans

Relevant Projects to be funded from 1. IMI-Call (examples):

Qualification of Translational Safety Biomarkers

Pain research

Understanding Severe Asthma

European Centre of Drug Safety Research: an element of the IMI Strategic Research Agenda, *as proposed in SRA*



Aims/characteristics:

- Improve safety of medicines in humans
- Support and drive research improving and innovating drug safety assessment, e.g. **development of databases; knowledge management tools** for pharmacovigilance
- Involving EU academic centres, pharmaceutical industry, regulatory authorities

Priority areas for research in **non-clinical safety**:

- Framework for biomarker development
- Relevance of non-genotoxic carcinogens
- Development of in silico methods
- Issue of intractable toxicities

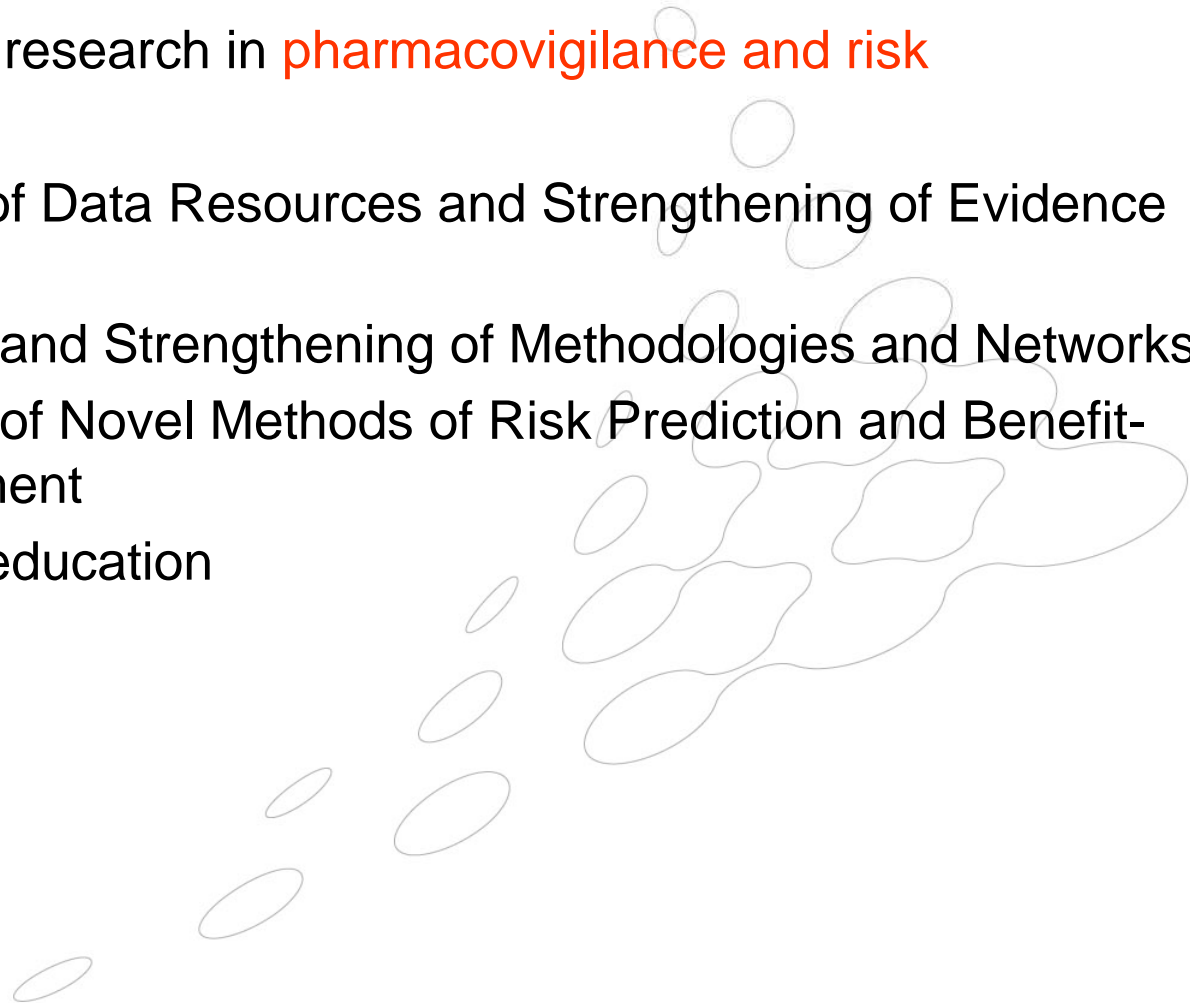
European Centre of Drug Safety Research (ECDSR)



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Priority areas for research in **pharmacovigilance and risk management**:

- Optimisation of Data Resources and Strengthening of Evidence Base
- Development and Strengthening of Methodologies and Networks
- Development of Novel Methods of Risk Prediction and Benefit-Risk-Assessment
- Training and education



European Centre of Drug Safety Research (ECDSR)



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Relevant topics of the **first IMI-Call** (projects to be **funded**):

- Non-genotoxic carcinogenesis
- Expert Systems for in silico Toxicity Prediction
- Safety Sciences for Medicines Training Programme
- Pharmaceutical Medicine Training Programme
- European Medicines Research Training Network

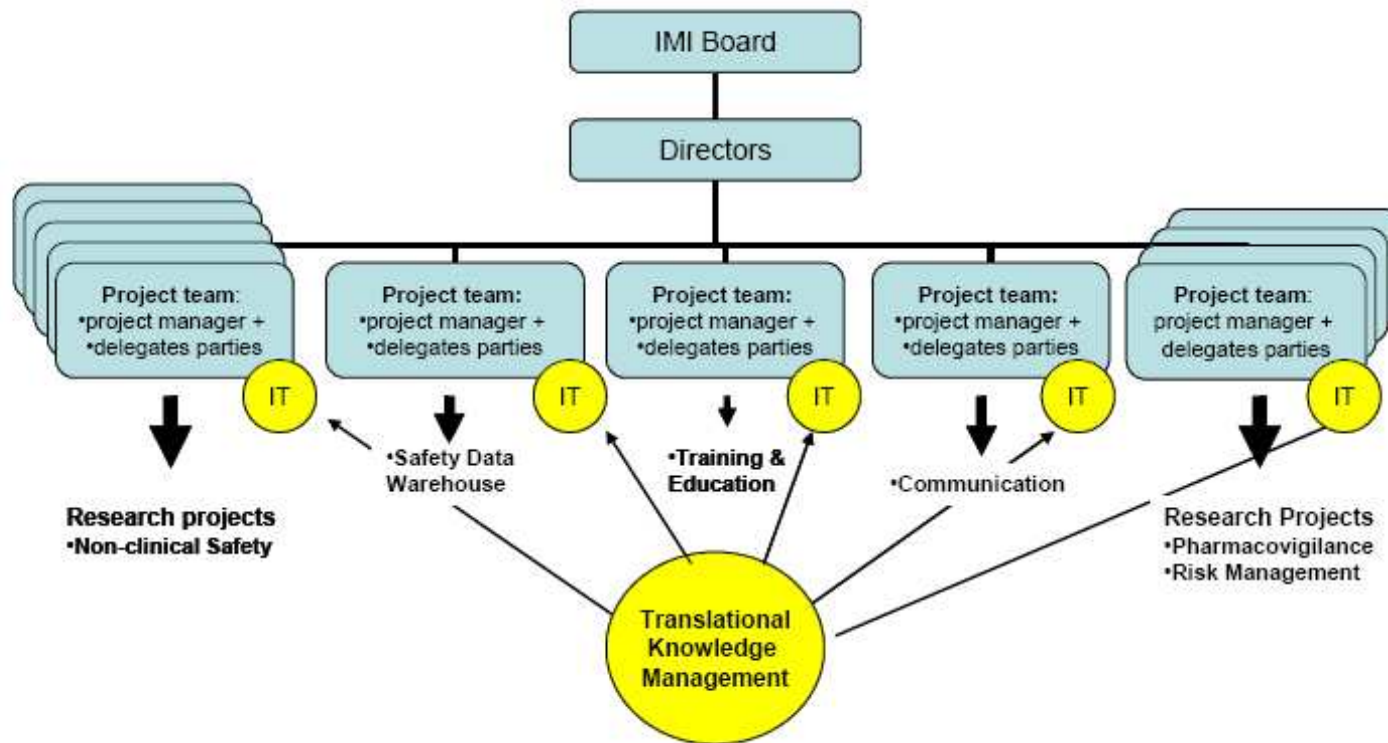
Relevant draft priorities of the upcoming **2. IMI-Call**:

- Open pharmacological space
- Drug/disease modelling: library and framework

European Centre of Drug Safety Research (ECDSR)



Proposed structure



FP7-Health: Opportunities in the upcoming 4th Call

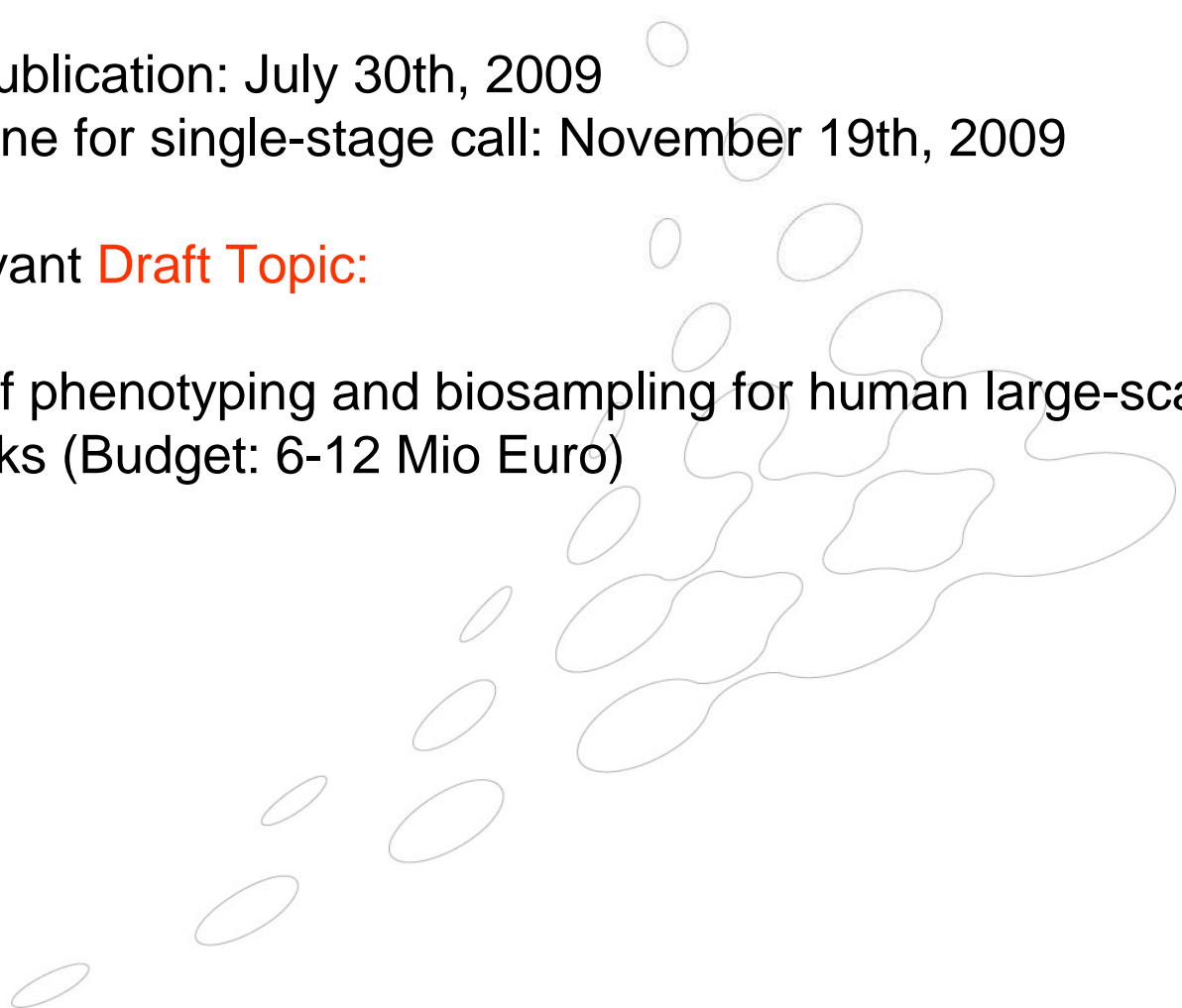


Expected Call Publication: July 30th, 2009

Expected Deadline for single-stage call: November 19th, 2009

Example of relevant **Draft Topic:**

Harmonisation of phenotyping and biosampling for human large-scale research biobanks (Budget: 6-12 Mio Euro)



USA: CRITICAL PATH INITIATIVE



Launch: 2004 by FDA

Aim:

- Stimulate and facilitate a national effort to **modernize** the scientific process through which a potential human drug, biological product, or medical device is transformed from a **discovery or "proof of concept" into a medical product**
- Examples for funded **projects**:
 - Medical Imaging Initiative
 - Clinical Trials Transformation Initiative
 - Genetic Basis of Adverse Drug Events
 - Accelerating the availability of an artificial pancreas

<http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/default.htm>

Context: currently high on the agenda: Agreement NIH and EC/FP7

Any Questions?

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