

# The Innovative Medicines Initiative (IMI)

---



## The IMI perspective on improving safety along the medication lifecycle

'eHealth and patient safety' Workshop  
Geneva, October 10th, 2006



# The Innovative Medicines Initiative

## *What is it?*

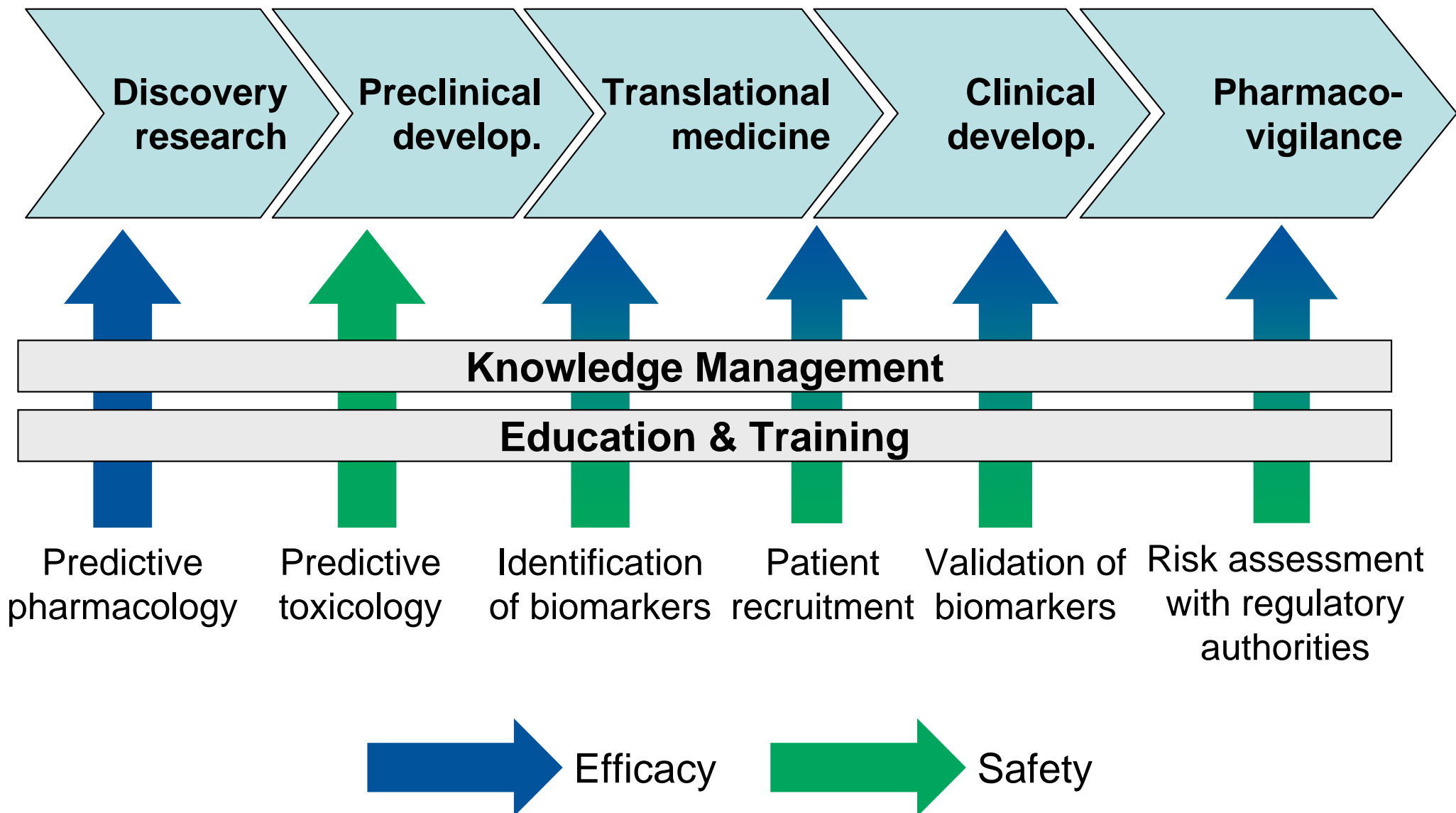


- IMI proposes a number of clear, practical paths to accelerate the discovery and development of more effective innovative medicines with fewer side-effects.
  - Strategic Research Agenda: [http://www.efpia.org/4\\_pos/SRA.pdf](http://www.efpia.org/4_pos/SRA.pdf)
- IMI will implement innovative Patient Centred Projects that address the principle causes of delay or bottlenecks in the current biomedical R&D process.
- IMI is a unique pan-European public and private sector collaboration in biopharmaceutical research.

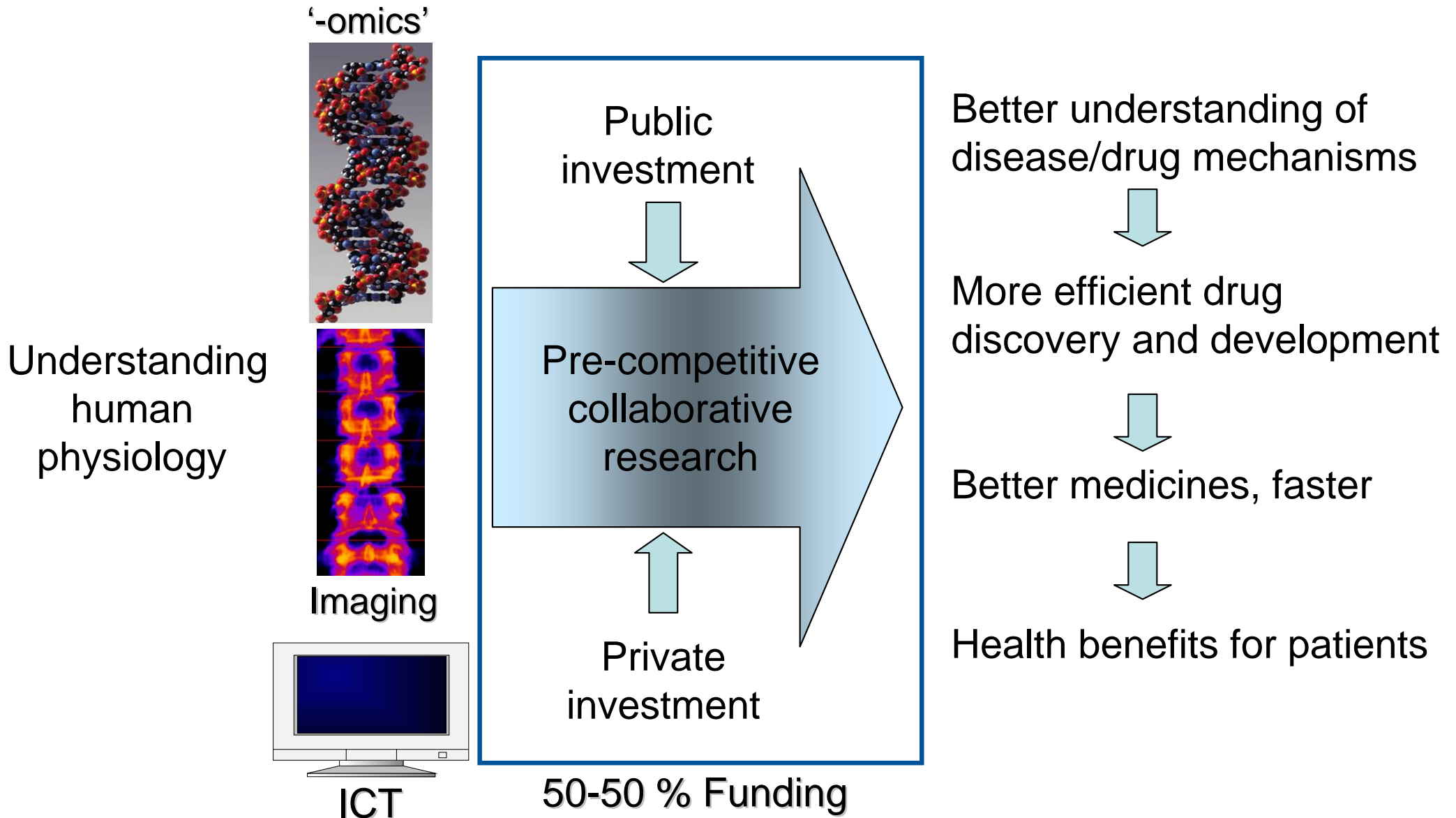
# Research Directors' Group Member Companies



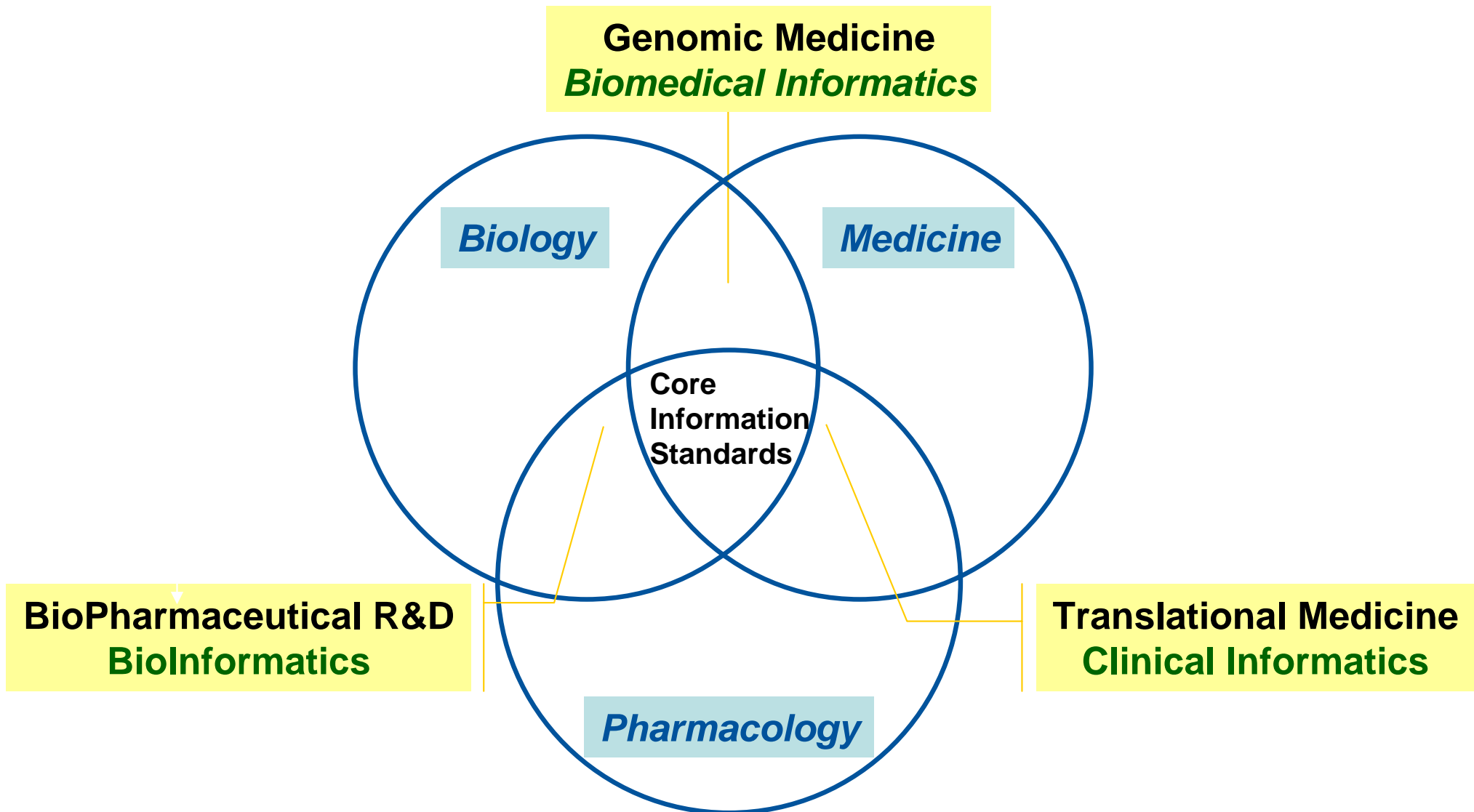
# The Strategic Research Agenda focuses on bottlenecks in biomedical R&D



# Science and technology advances present significant opportunities



# The Strategic Research Agenda identifies ICT opportunities in biomedical R&D



# Focus on five disease areas with significant scientific challenges



S

E

Predictive pharmacology

Predictive toxicology

Identification and validation of biomarkers

Patient recruitment

Regulatory Risk assessment

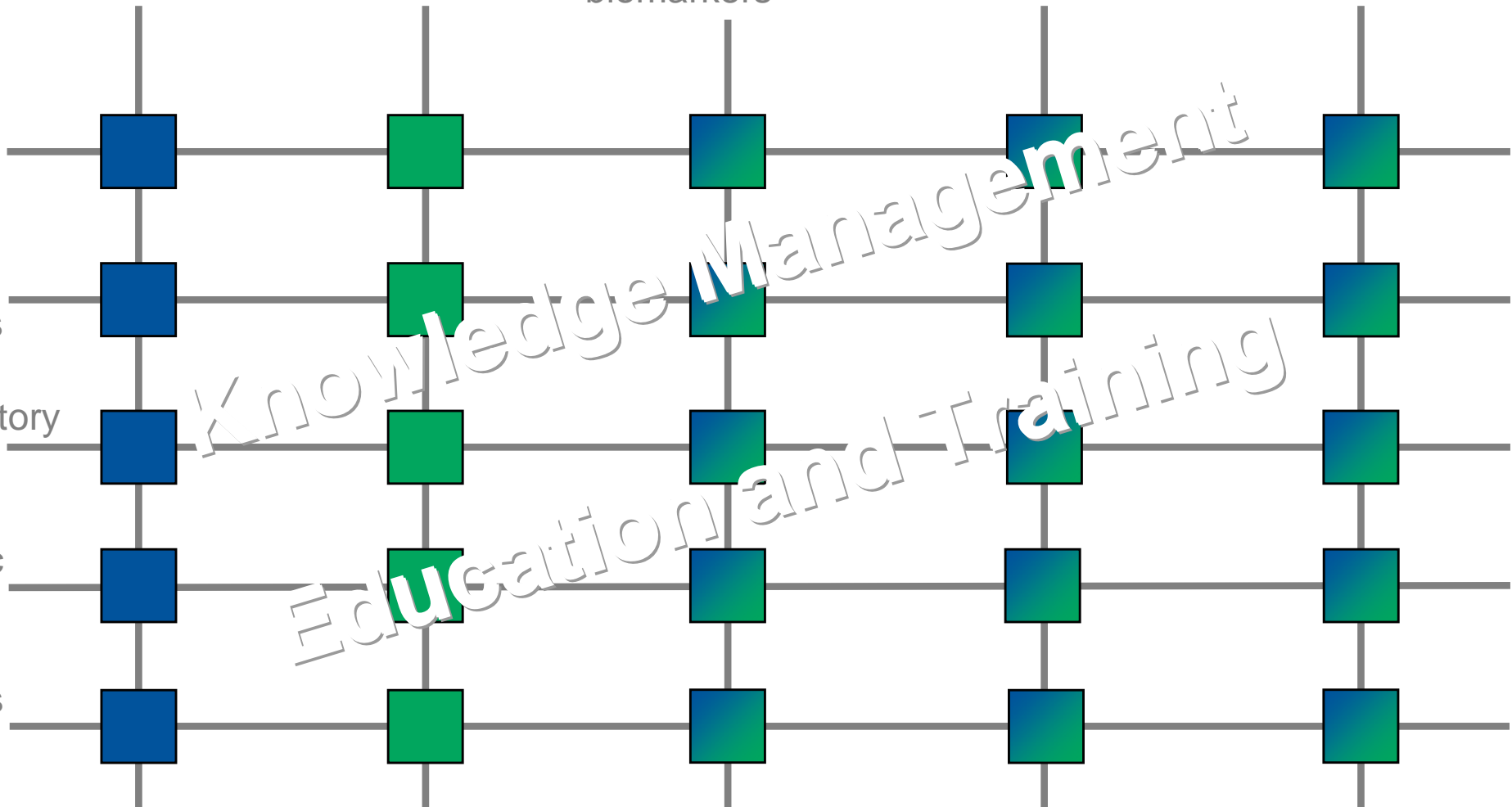
Cancer

Brain Disorders

Inflammatory Diseases

Metabolic Diseases

Infectious Diseases



# *SAFETY: Making Medicines Safer*

## *Non-Clinical Safety*



- Goal: improve the predictability of toxicological observations
- Main recommendations:
  - Create a European Centre for Drug Safety Research
  - Promote the curriculum of ‘Safety Scientist’
  - Establish a framework for biomarker development to study human relevance and regulatory utility
  - Preclinical Drug Safety Datawarehouse
  - Determination of the relevance of rodent non-genotoxic carcinogens
  - Develop computational methods for predicting toxicity
    - Improve the predictivity of endpoints; target organ toxicity, reproductive toxicology
    - Identify specific structural elements linked to safety issues
    - Toxicodevelopability model for early development
    - Tools to screen candidate drugs
    - Develop specific toxicity testing programmes
  - Develop a better understanding of of ‘intractable toxicities’

# *SAFETY: Making Medicines Safer*

## *Pharmacovigilance*



- Goal: strengthen the evidence base in pharmacovigilance
- Main recommendations:
  - Optimise data resources; EU datawarehouse
  - Develop lifecycle approach to pharmacovigilance
  - Develop novel methods of risk prediction and benefit-risk assessment
  - EU academic network of pharmacoepidemiology



- Goal: improve clinical performance and early access to innovative medicine
- Main recommendations:
  - Focus on areas of high scientific challenge
  - Regional Biomarker Centres and Community of Experts for the identification and validation of biomarkers and novel targets
  - Biomarker database to underpin the the validation process
  - Systems Biology, i.e. disease mechanistic modelling and simulation
  - Stem cell Community of Experts
  - Stimulate translational medicine in an integrated fashion incl. new ways and tools for conducting clinical trials
  - Create disease-specific imaging networks
  - Develop partnership with regulators for innovative clinical trial design and acceptance of biomarkers

# *KNOWLEDGE MANAGEMENT: Making Science More Effective*



- Goal: manage and organise data to create knowledge to predict benefit and risk of new therapies
- Main recommendations:
  - Develop enhanced knowledge representation models and data exchange standards for complex systems
  - Design standards for and build an expert tool to allow the federation of local databases in a secured environment
  - Systematically integrate ICT/KM in the Safety and Efficacy projects through the Translational KM approach
  - Build a core reference database of validated experimental data
  - Integrate mechanistic multi-scale modeling and simulation tools that operate on top of the reference database

# *EDUCATION & TRAINING: Making Scientists More Effective*



- Goal: support the interdisciplinary education essential for the bioscience sector
- Main recommendations:
  - Create a European Medicines Research Academy for education and training for professionals involved in biomedical R&D and regulation
  - Map existing activities within E&T and develop programmes for the critical areas of need
  - Foster mobility between academia and industry

# 'eHealth and Patient Safety' opportunities

1



- The pre-clinical datawarehouse
  - Organisation of data from control animals, vehicles used in animal experiments, non-proprietary preclinical study results
  - The mining, signal detection techniques and data visualisation that allow for the maximal reuse of existing knowledge in order to realise the 3R objective (reduce, refine, replace)
  - KM Roadmap project to scope this vastly complex but breakthrough opportunity
- Computational methods for predictive toxicity
  - Tools for the modeling and analysis of chronic toxicity endpoints such as the repeated dose reproductive toxicity
- Molecular Imaging technologies for in-vivo and in-vitro compound screening and clinical application for therapy monitoring

# 'eHealth and Patient Safety' opportunities

## 2



- New ways and tools for clinical research and pharmacovigilance
  - Find ways to integrate clinical trial (protocol driven) with clinical care data.
  - Evaluate the ways and means to conduct 'virtual clinical trials'
  - Evaluate the ways and means that support pharmacovigilance and pharmacoepidemiology

*The ultimate beneficiaries ...*



... All EU citizens

