Innovative Medicines Initiative

The revised IMI Scientific Research Agenda

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12 October, 2011, Krakow

efpia

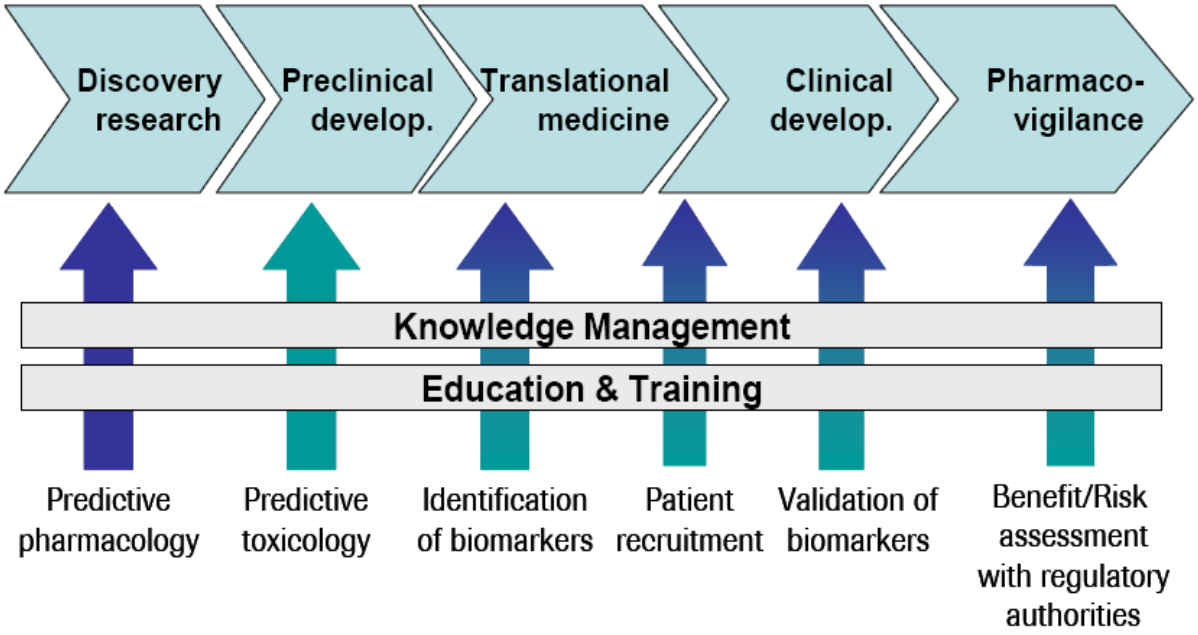
Focussing and Speeding up

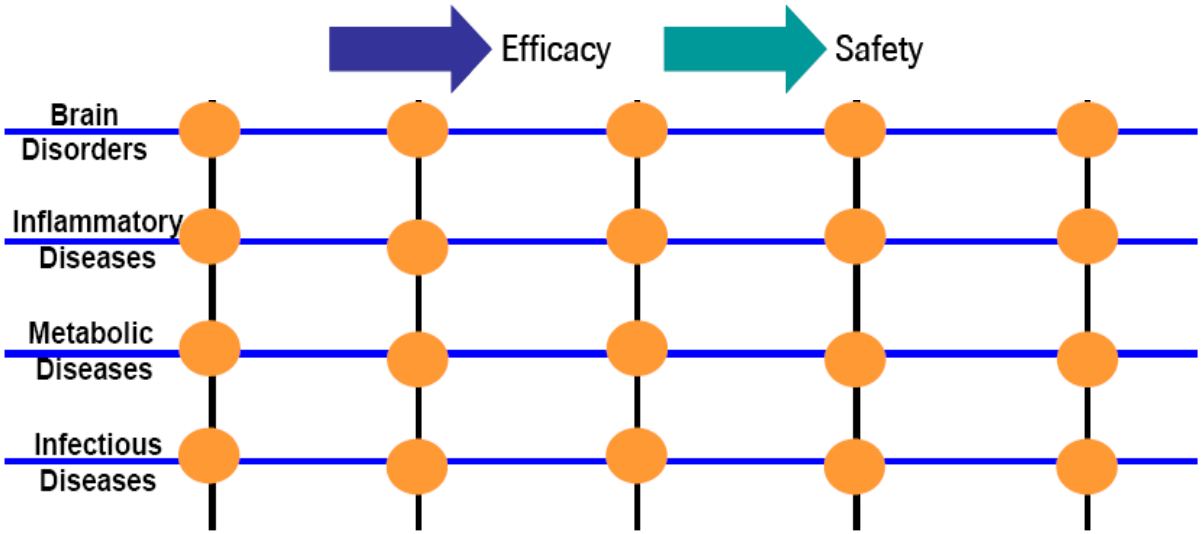
Scientific Advisory Board: its role.... Strategic Research Agenda

The Research Agenda 2008/9

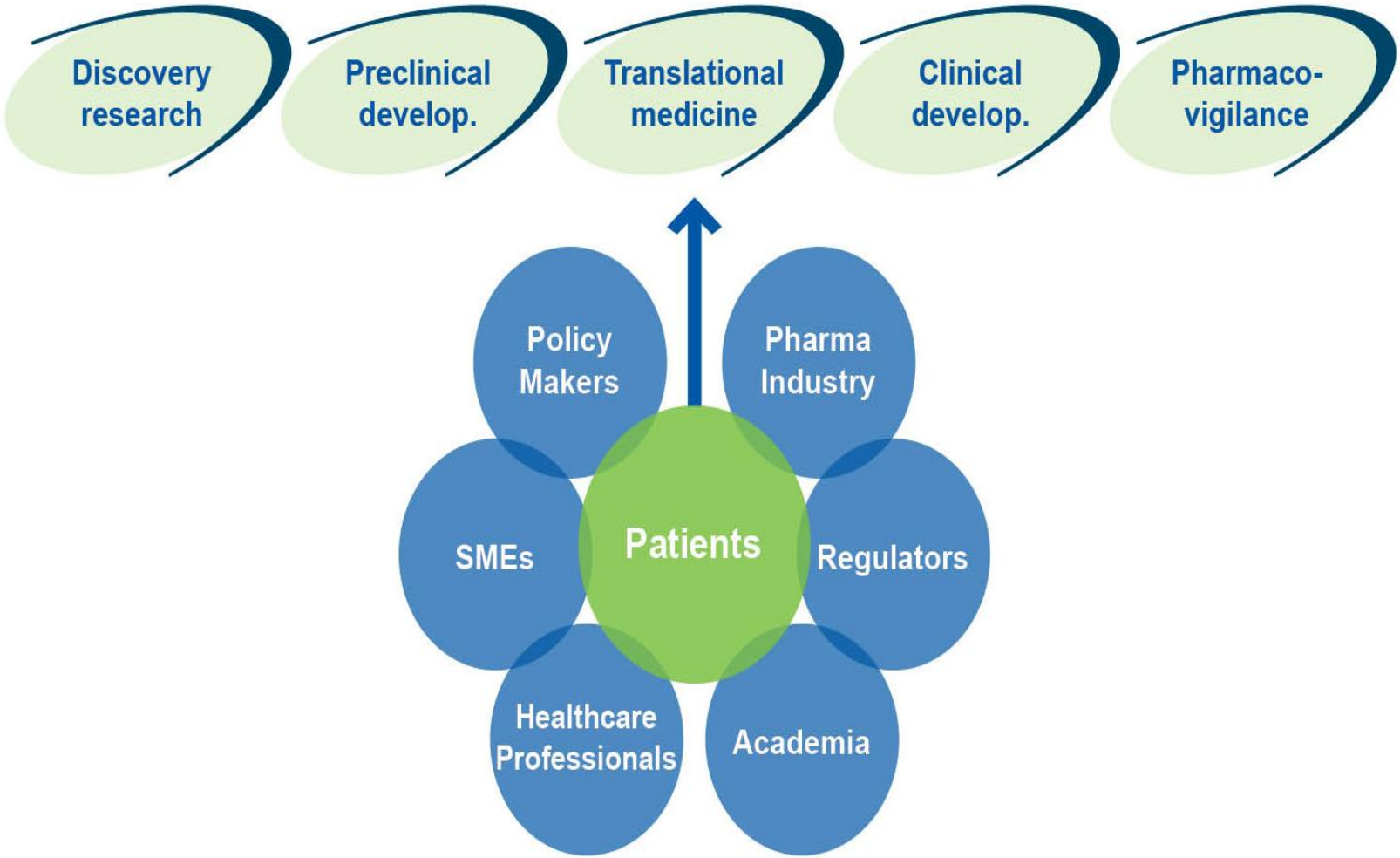
- The IMI Research Agenda is a multiannual plan.
- It identifies principal research bottlenecks in the biopharmaceutical R&D process.
- It describes recommendations to overcome these bottlenecks and a plan to guide their implementation.
- It focuses on four areas: predicting safety, predicting efficacy, knowledge management, education and training.
- It is a tool to communicate the IMI mission.

The Original Matrix of the IMI SRA





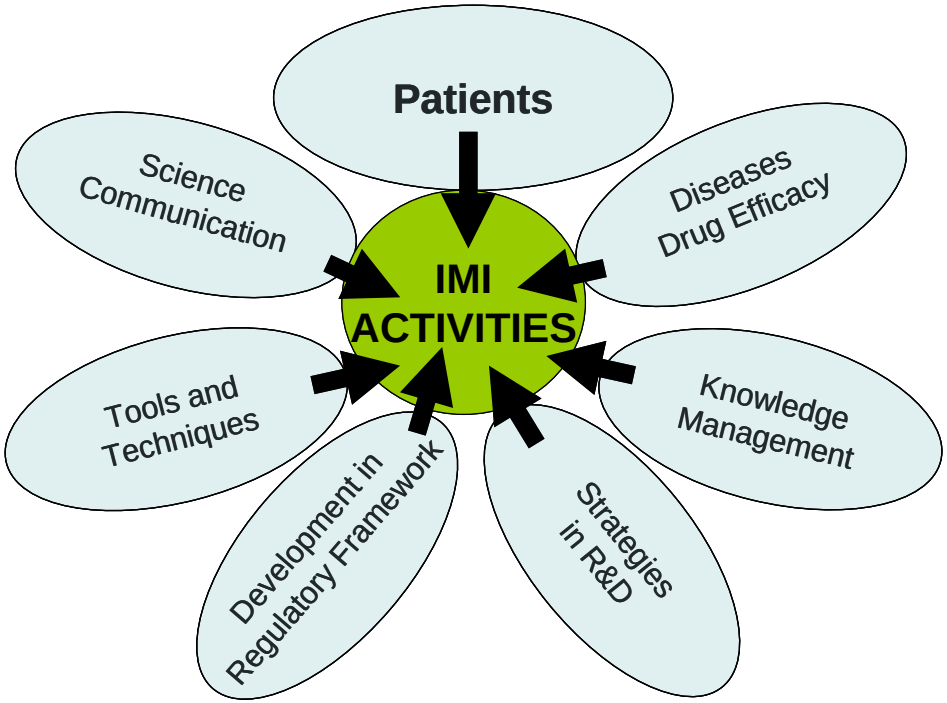
Need for a widened and revised scope of the IMI SRA



The Revision of the IMI Scientific Research Agenda

The Revised SRA builds on the **4** pillars of the original SRA:

Knowledge management – Efficacy – Safety – Education and Training

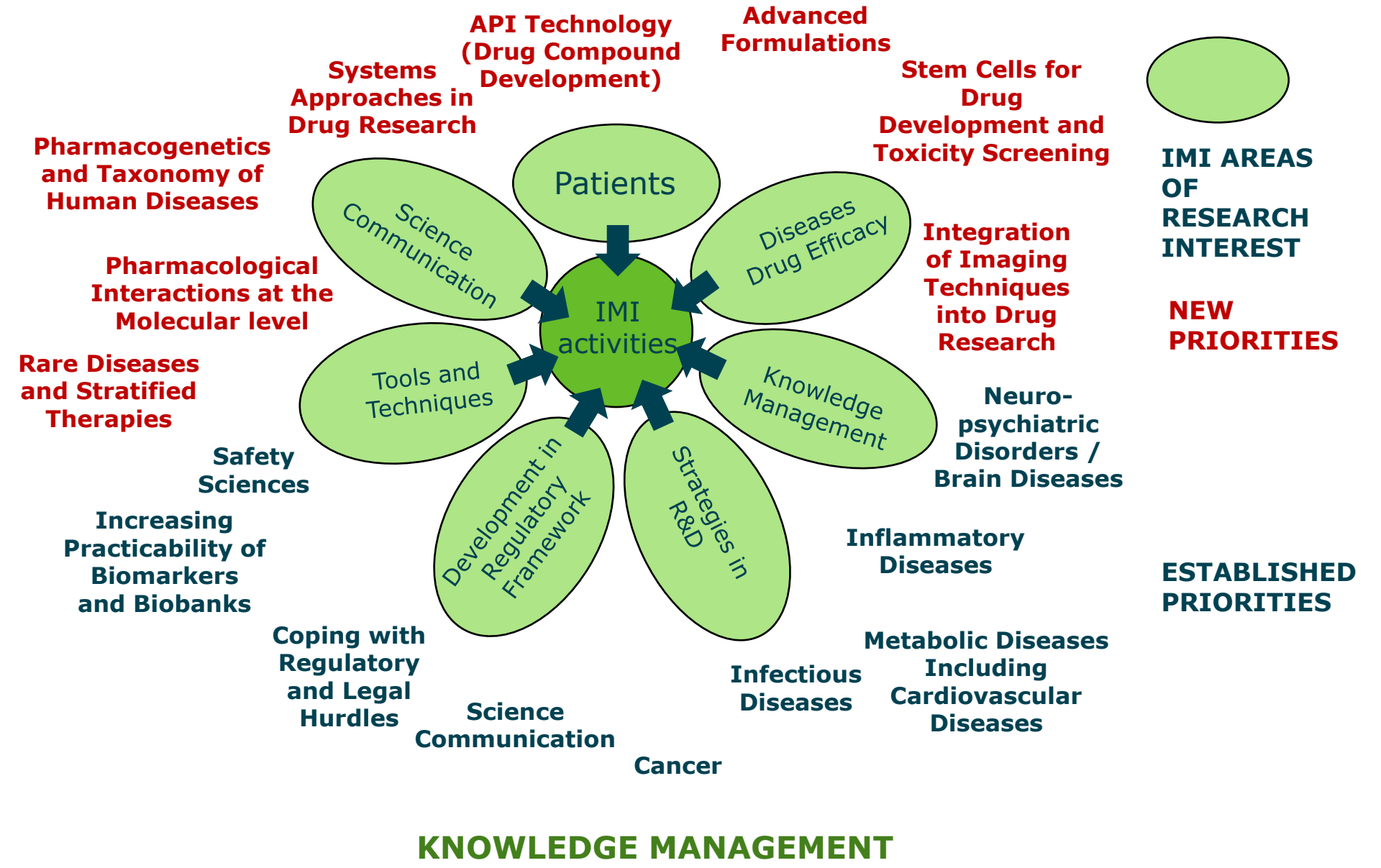


The Revision of the IMI Scientific Research Agenda

Eight new research areas are proposed to be addressed in addition to those originally included in the 2008 SRA:

- Pharmacogenetics and taxonomy of human diseases
- Rare diseases and stratified therapies
- Systems approaches in drug research
- 'Beyond high throughput screening'- pharmacological interactions at the molecular level
- Active pharmaceutical ingredients development (drug compound development)
- Advanced formulations
- Stem cells for drug development and toxicity screening
- Integration of imaging techniques into drug research

4th Call topics bridge the previous SRA and the revised SRA


API Technology (Drug Compound Development)
Advanced Formulations
Systems Approaches in Drug Research
Stem Cells for Drug Development and Toxicity Screening
Pharmacogenetics and Taxonomy of Human Diseases
IMI AREAS OF RESEARCH INTEREST
Patients
Science Communication
Diseases Drug Efficacy
Pharmacological Interactions at the Molecular level
Integration of Imaging Techniques into Drug Research
IMI activities
NEW PRIORITIES
Rare Diseases and Stratified Therapies
Tools and Techniques
Knowledge Management
Neuro-psychiatric Disorders / Brain Diseases
Safety Sciences
Development in Regulatory Framework
Strategies in R&D
Increasing Practicability of Biomarkers and Biobanks
Inflammatory Diseases
ESTABLISHED PRIORITIES
Coping with Regulatory and Legal Hurdles
Metabolic Diseases Including Cardiovascular Diseases
Infectious Diseases
Science Communication
Cancer
KNOWLEDGE MANAGEMENT

Looking forward

Combination therapy

Extreme phenotypes

Beyond HTS

Taxonomy

Stem cells

EU med info system

Idea generation

Basic Research and non clinical testing

Clinical studies

Regulatory approval

HTA & pharmaco-vigilance

Knowledge Management infrastructure and services

Implementing the Revised SRA: the IMI 4th Call for Proposals

- First “Think Big” topics are launched: **EMIF** (€ 24 million from both EFPIA and the public side) and **hiPS** topic (€ 26 million from both EFPIA and public side)

- In addition, new research areas in **pharmaceutical chemistry, oral drug delivery, binding kinetics, optimising delivery of biological macromolecules** are addressed

- The topics will continue to bring together data, resources and expertise from the public and private sectors to improve pharmaceutical research

EMIF: European Medicines Information Framework, 4th call

Patient level health information has potential to significantly advance medical and pharmaceutical research;

→ Potential so far not used because of hurdles

By submitting a proposal to this topic, researchers can contribute to fulfilling the vision for EMIF to create a lasting and comprehensive framework to use patient level data:

- Broad network for access to existing data
- Governance model for ethics and privacy
- Data management and analysis

Three topics under EMIF

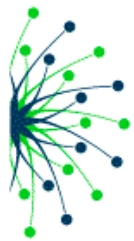
- Information framework / knowledge management service layer
- Metabolic complications of obesity in adults and children
- Protective and precipitating markers for the development of AD and other dementias

EMIF will Address Important Unmet Medical Needs

- Patient level data contributes to harnessing the power of the extreme phenotype approach for understanding less extreme variations in the phenotype, which represent a much larger share of the patient population; also important for diagnosis and the development of innovative therapeutics

- Obesity is an important health problem with limited success so far in addressing it through modifying behaviour or pharmacological intervention; only some obese individuals develop complications and it would be important to be able to identify them

- Patient level data in the field of AD will help to deal with the multiple challenges of developing treatments in this area such as absence of predictive biomarkers, efficacy markers and the slow progression of the disease



hiPluripotent Stem cells, 4th call

hiPS cells have opened up many new areas of research, including access to improved in vitro systems for disease modelling, drug discovery and safety assessment

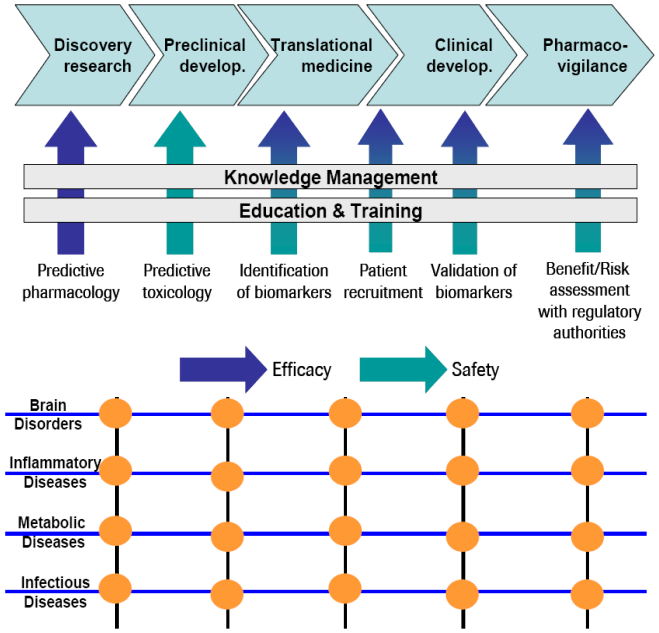
Focus of topic is patient-derived iPS cells to be used in

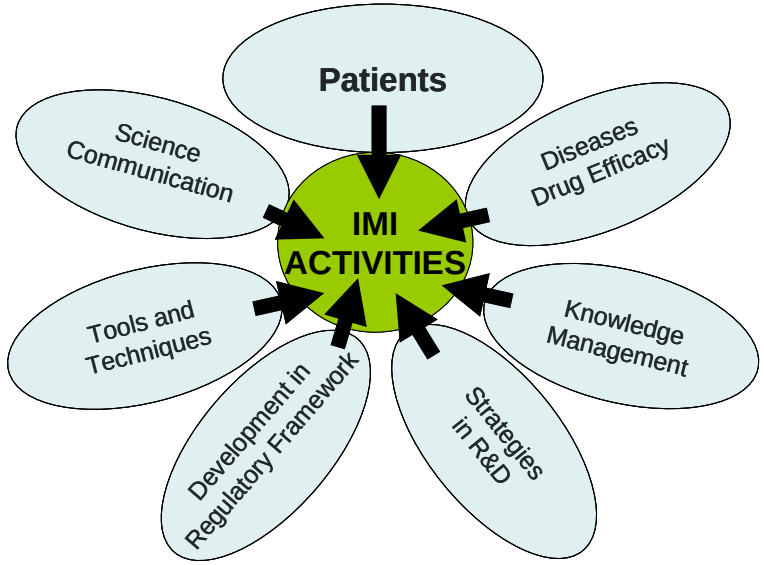
- Neurodegenerative/neuro-dysfunctional diseases
- Diabetes
- Safety assessment

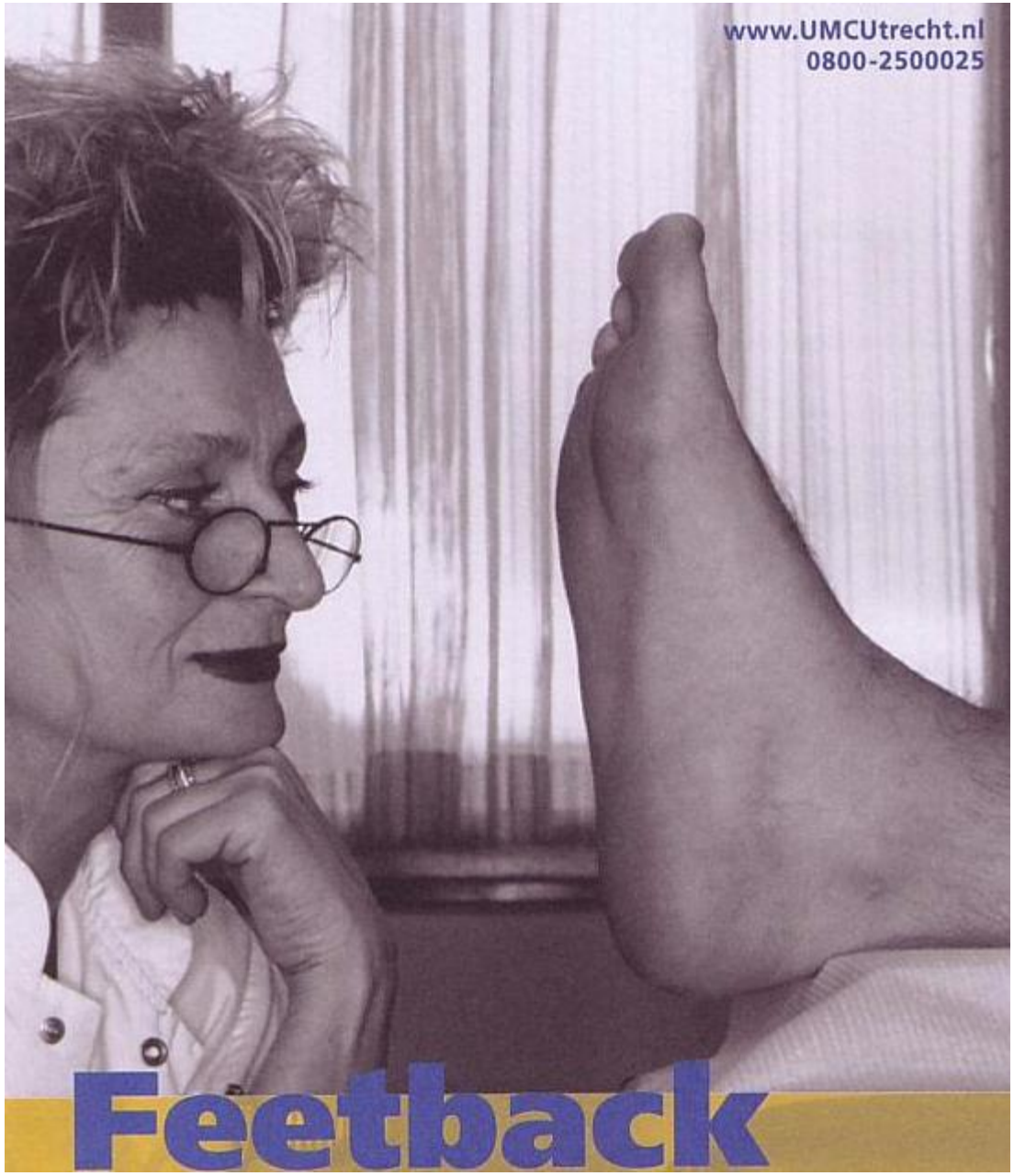
Need for public/private collaborative research to

- Establish biobank
- Making accessible iPS cell lines from different ethnicities and patients with defined phenotypes/genotypes
- Establish standardised biological assays
- Strong communicative and collaborative links with other consortia

SRA and the Scientific Advisory Board..... an evolving relationship



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