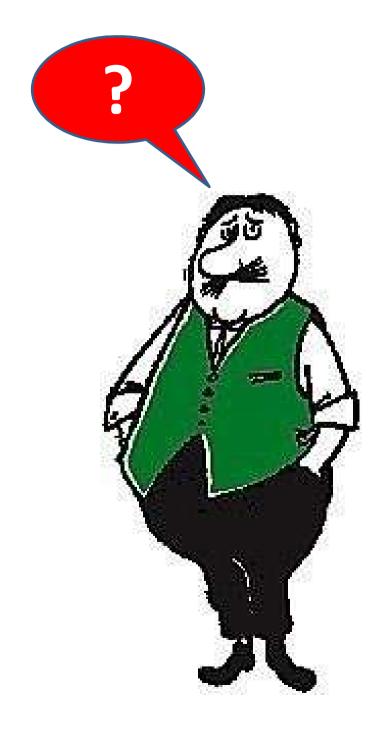
Visions and Horizons of IMI

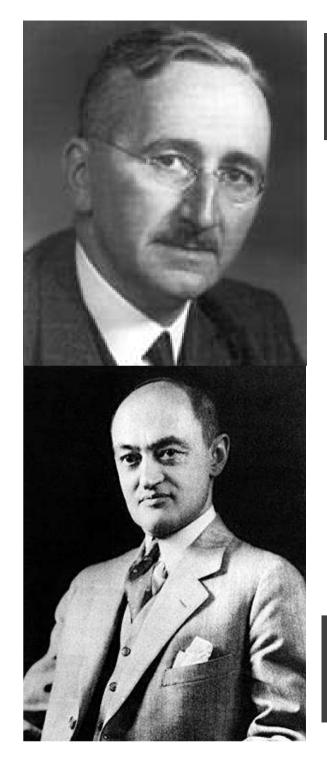
Perspective of the Scientific Committee

Christian R. Noe
Chairman of the Scientific Committee

Workshop on the Innovative Medicines Initiative Vienna, April, 30th, 2013







Friedrich August von Hajek 1899 - 1992 Flagship of Neoliberalism

Alois Schumpeter 1883 – 1950 Flagship of Entrepreneurship



A lesson learnt by Hayek and Schumpeter

Finance driven economy

Entrepreneurship driven economy



Post-industrial Europe – A Vision

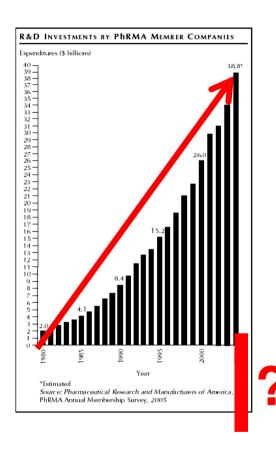


Innovation follows production!

Europe has to be re-industrialized.



IMI and the "Crisis of Innovation"





IMI has now a socioeconomic and political impact!

IMI – A story of success: Tool for project financing and entrepreneurial stimulus



Strategy:

- Motivating competitors to co-operate
- Creating a unique PPP in R&D
- Connecting academia to the industrial sector
- Connecting SMEs to big Pharma

Achievements:

- Changing the R&D landscape
- Improving the global and European R&D environment
- Opening up new Fields of Research through projects

IMI in Horizon 2020 - Keep the Equilibrium!



Main Objectives

EFPIA Improve general conditions for R&D

Promote innovation in target areas

More efficient industry – academia co-operation

Public Promote Pharma Entrereneurship in Europe

Re-industrialise Europe

Promote European position in global competition

Strengthen European co-operation on all levels

IMI – The Business Model

IMI is a novel approach of co-operation in pharmaceutical sciences, in which organized by the European Commission, industry, academia and regulatory are connected.

The business model has achieved a lot, but deserves some optimisation

IMI: The Public Private Partnership



Partnership in a competitive environment requires rules for fairness!

Recommendation:

Strengthen the Public Side!

- Structure the States Representative Group!
- Activate the academic public!
- Keep the SC as content managing tool!

Recommendation:

Structuring the SRG

The SRG represents the Pharma fields. (Full coverage on the national level)

Academia - Ministries of Science Industry - Ministries of Industry Regulatory - Ministries of Health

- Setting up of inter- and intra- sectional panels
- Probing the "policy making" potential
- The SRG as European Meeting point
- The SRG as competent "voice".
- The scientific committee as tool

Recommendation:

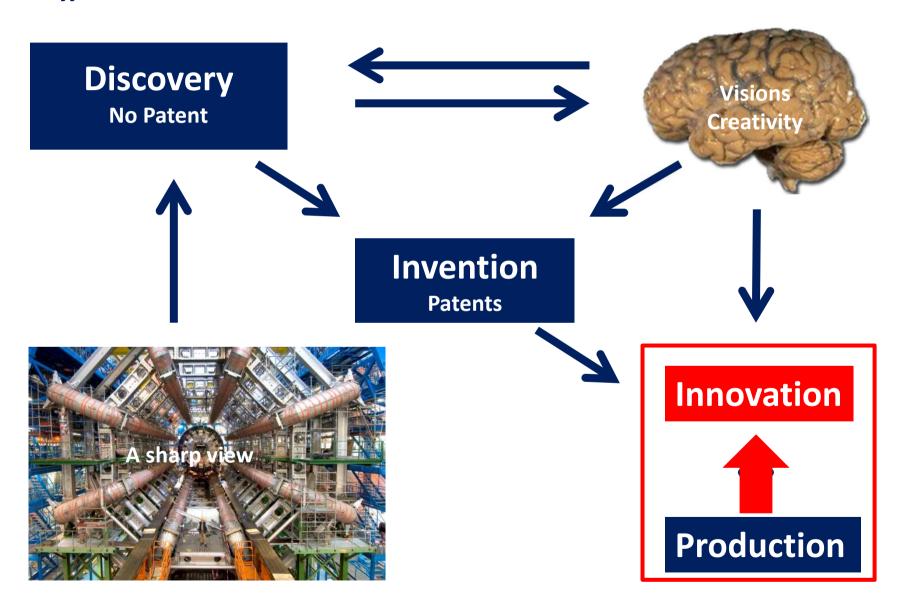
The Scientific Committee

Represents the public in IMI operations
Reports first of all to the SRG
Keeps its advisory role
Obtains veto right in specific issues
Has a broad coverage of competence

Member profile:

- Experienced with broad views
- No specialists, nevertheless "deep" competence
- No active role in National Funding Bodies
- No personal interest in promoting specific networks
- Enthusiasm for science

"Innovation": From Idea to Market!



Innovation – The central task of IMI

Innovation – precise goals, not aiming at verification or falsification of hypotheses.

IMI projects have concrete "deliverables"!

Implementation of novel "tools"
Development and validation of methods
Implementation of materialbanks and databanks
Harmonisation of methods
Recommendation to regulatory tasks
Proposal for "best practices"
Design of training courses
etc.

Focusing on Innovation

Recommendation:

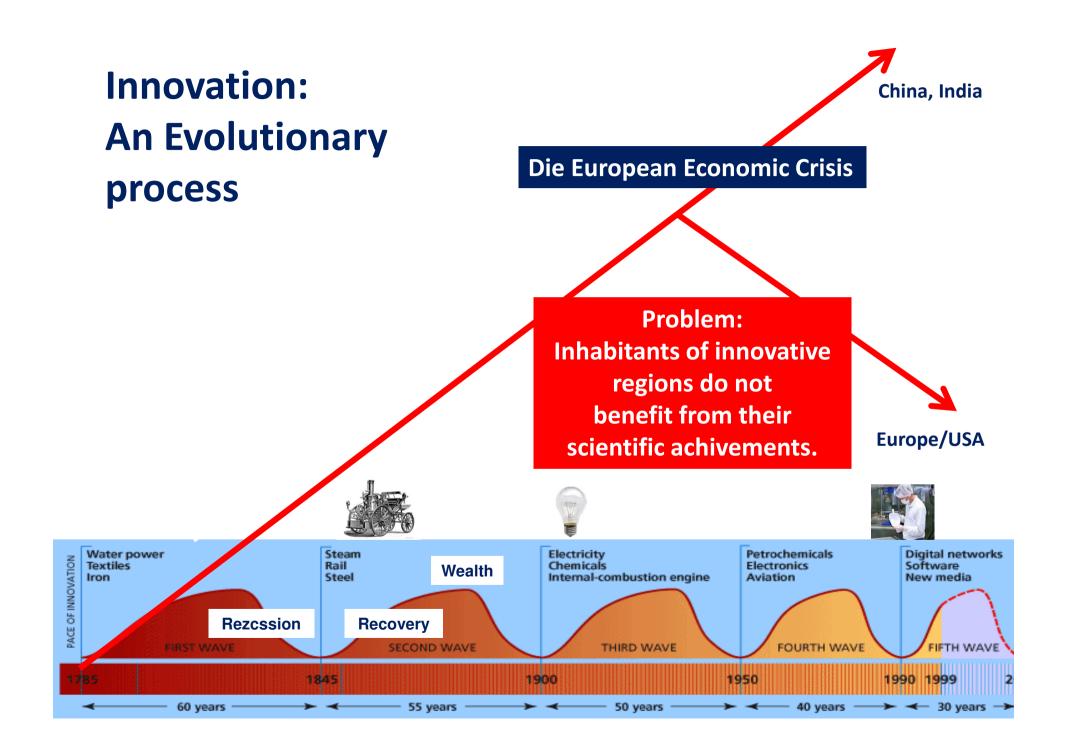
Re-Industrialization of Europe as long-term goal!

"Innovation" means to get new things in!
Renewal can only take place, where something exists to be renewed."

Strengthening existing European facilities

New Business Models for Renewed Pharma Sector in Europe

Sustainable Start-ups
PPP in time limited project companies



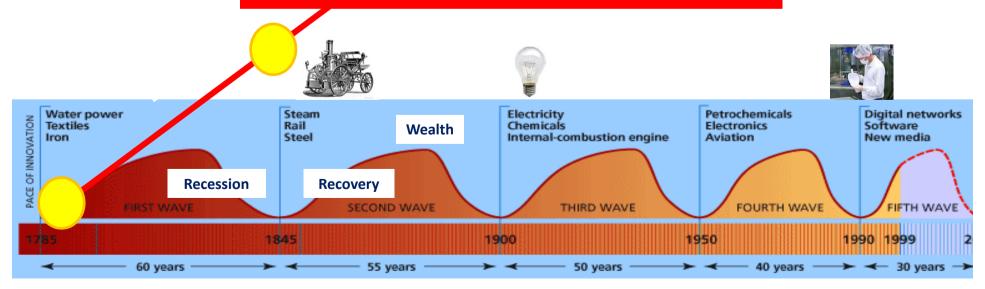




Creative Distruction

"The "better" is the enemy of the "good"

Innovation ist intrinsisally competitive! A contest of ideas.



Pre-competitive = Before the contest!

Regulatory science has to be an indispensable element of IMI.

Improved rules in the research environment strengthen co-operation!



Rules for teams and players "academia – industry – regulatory"

The Research Environment

Recommendation:

The political task:

Improve general conditions for R&D in Europe

- Legal framework
- Economic framework taxation
- Education

Knowledge Generation and Invention:Pre-competitive Aspects

Recommendation:

Knowledge Generation:

- Joint activities with ERC and other institutions
- Platform with leading European Research Institutions
- Regular thematic Academia-Industry Meetings

Invention:

- Provide fair business models for young inventors!
- Co-operate with translational institutions!
- Check models for legal status of IMI projects!

Funding of Competitive Innovation

The present model of industrial in kind contributions is sub-optimal.

Recommendation:

Expand IMI financing to typical industrial innovation promotion tools, which exist on the national level.

- Tax preferences for R&D
- European Loans (EIB)
- Complementing direct financial contributions
- PPP Academic R&D Institutions

Goal: Boosting the financial power of IMI

Co-operation secures survival





IMI is a co-operative undertaking.

"Cultures" in Translational Sciences Target Search **First** Phase 1 **NDA** Neν **Income** B ad - First Claims Phase 2 Phase 3 First marketing activities L. Optimisation Drud late G Н Drug Preclinical Clinical Development Drug Marketing Reg. Discovery Phase 2012 2016 **Biologist – Designer** В **Pharmacologist - Designer** Pharmacodynamics, -kinetics Academia – Industry В Lab - Plant Toxicology **Industry – Regulatory** Galenic Development Bench - Bed **Industry – Health System** Chemical Development **Doctor – Patient**

IMI promotes co-operation across the whole field.

Fields of Drug Research

Areas of unexploited and growing research demand

Discovery Development Production Utilisation

Clinical Development



"Flow technology"
"Green chemistry"
Processes
Formulation
Process simulation
etc.

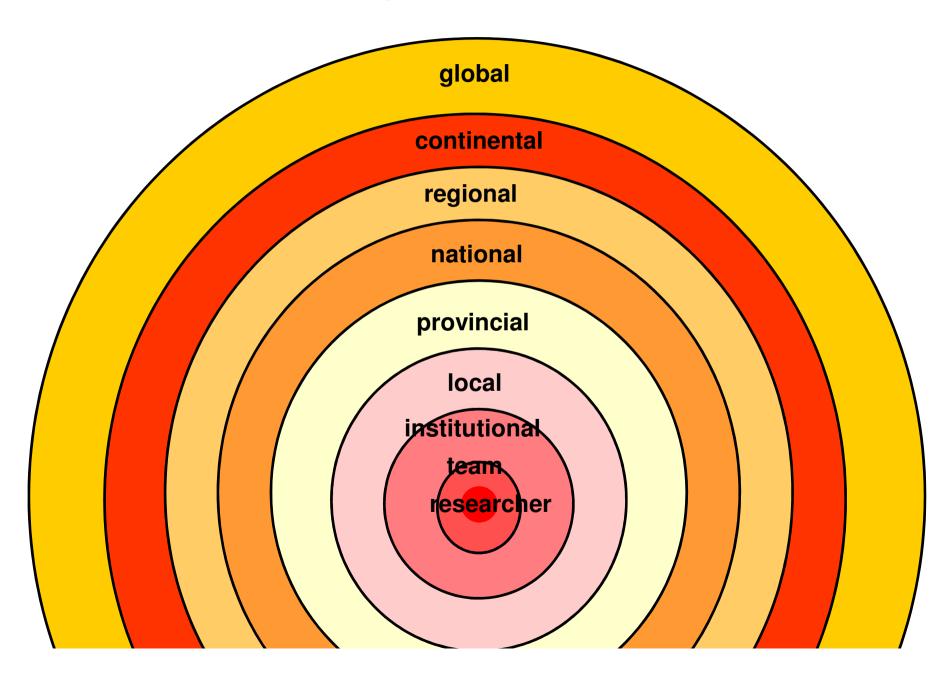
Pharmakogenomics
Pharmakogenetics
Stratification
Personalised Medicine
Pharmacoepidemiology
Pharmakovigilance
Pharmakoeconomics
HTA
Compliance
etc.

Global Role of IMI – A Conflict of interests?

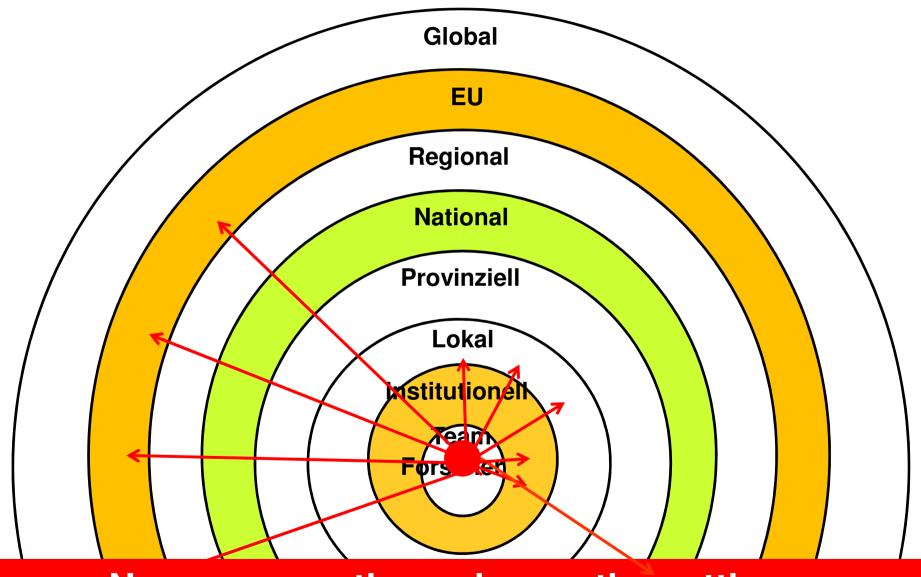


Europe for Europe or Europe for the world?

Stratification of Co-operation

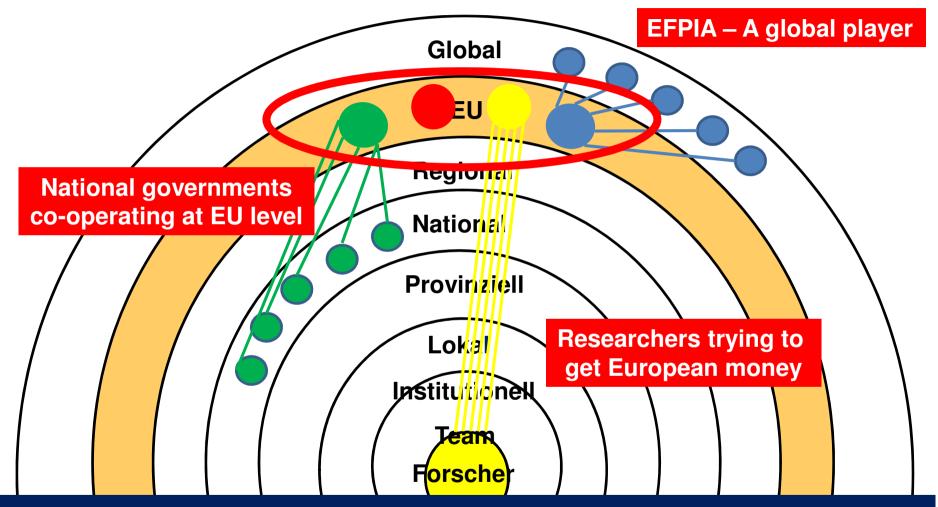


The number of possible co-operative interactions is limited.



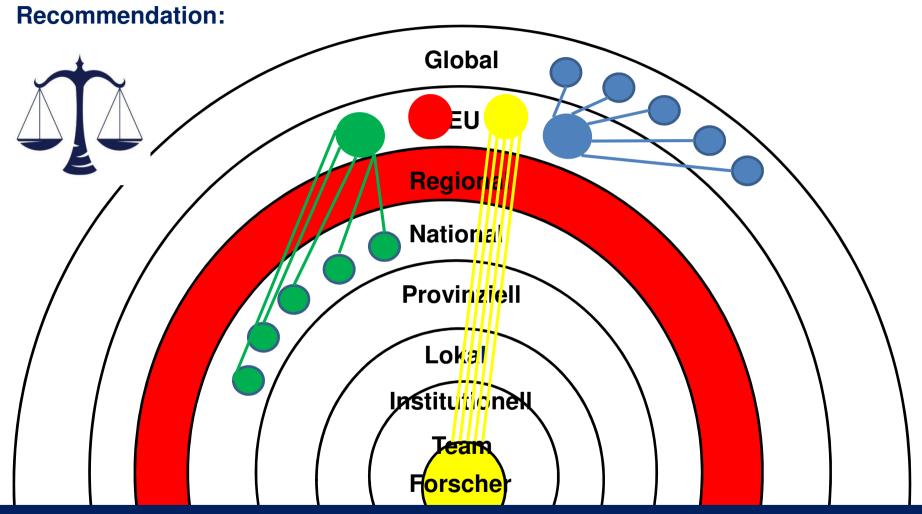
New co-operations change the setting.

IMI: Stratification of Partner Interest



The intra-European focus is legitimate!
The global impact is also legitimate!

IMI: Balancing the global focus by regional activities



Complementing regional "medicines initiatives" will strengthen the intra-European "motor" role of IMI.

