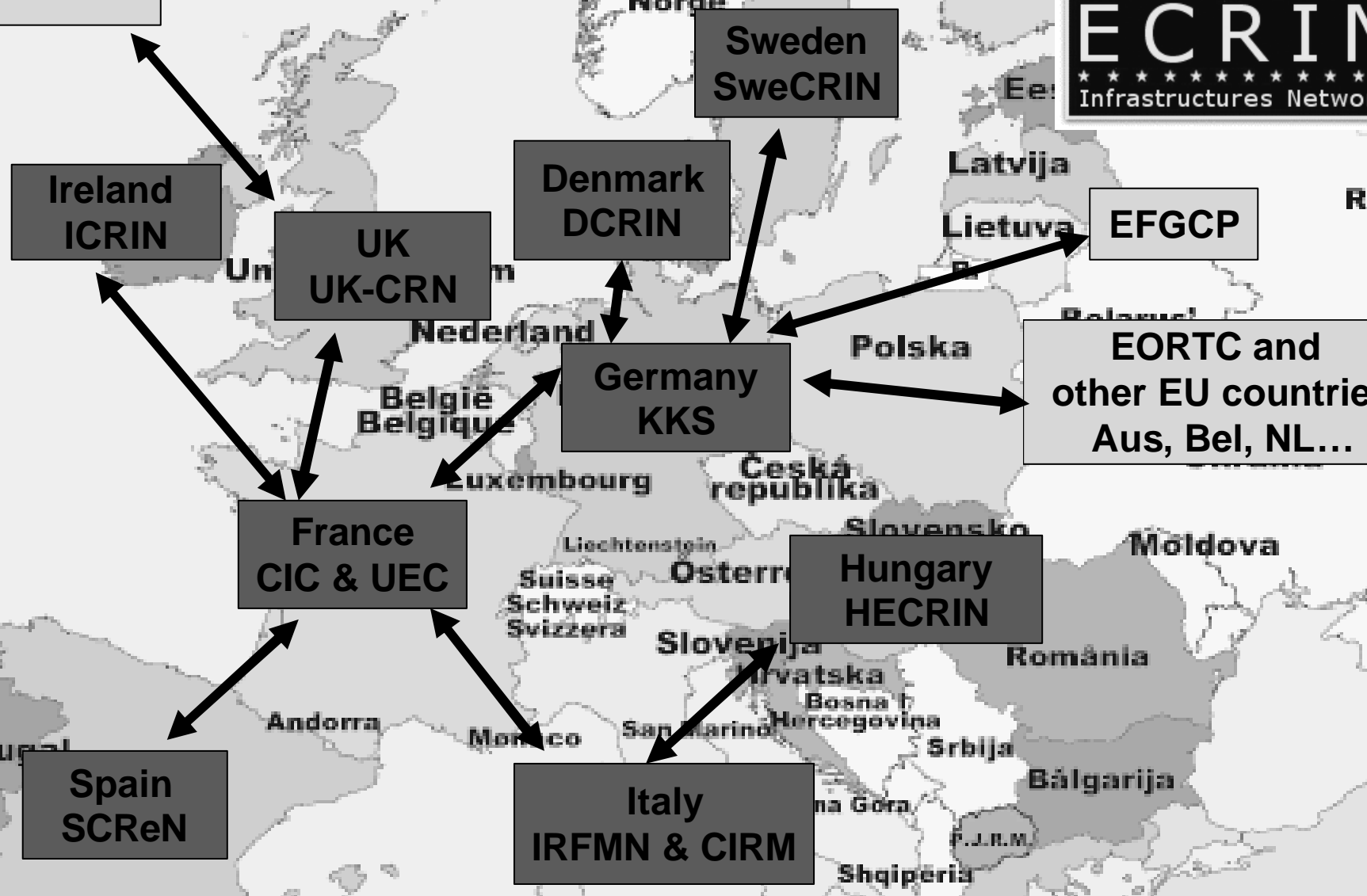




ECRIN-TWG kick-off meeting Tenerife, October 31, 2006

Other regions
Canada



International networks of Clinical Research Centres / Clinical Trial Units

ECRIN, an integrated infrastructure for clinical trials in the EU

ECRIN-1 (2004-2005) :

- Identifying bottlenecks



ECRIN-2 (2006-2008) :

- Preparing the infrastructure



ECRIN-3 (2008 ->) : FP7 ESFRI roadmap

- Preparation, construction and operation of the infrastructure supporting multinational clinical trials in the EU

In line with expectations of FP7 'Innovative Medicines Initiative'

ECRIN-1 (2004-2005) : identifying bottlenecks



ECRIN-RKP (FP6-funded):

-> survey and comparative analysis on

- 1 - Structures and objectives of centres and networks
- 2 - Financing, sponsoring
- 3 - Ethics
- 4 - Legislation, regulatory affairs, insurance
- 5 – Adverse event reporting, drug dispensing
- 6 – Methodology, data management, data monitoring
- 7 - Quality management, SOPs, audits
- 8 - Communication, partnerships
- 9 - Study registers
- 10 – Education and careers

-> reports on www.ecrin.org

ECRIN-2 (2006-2008) :

preparing the infrastructure

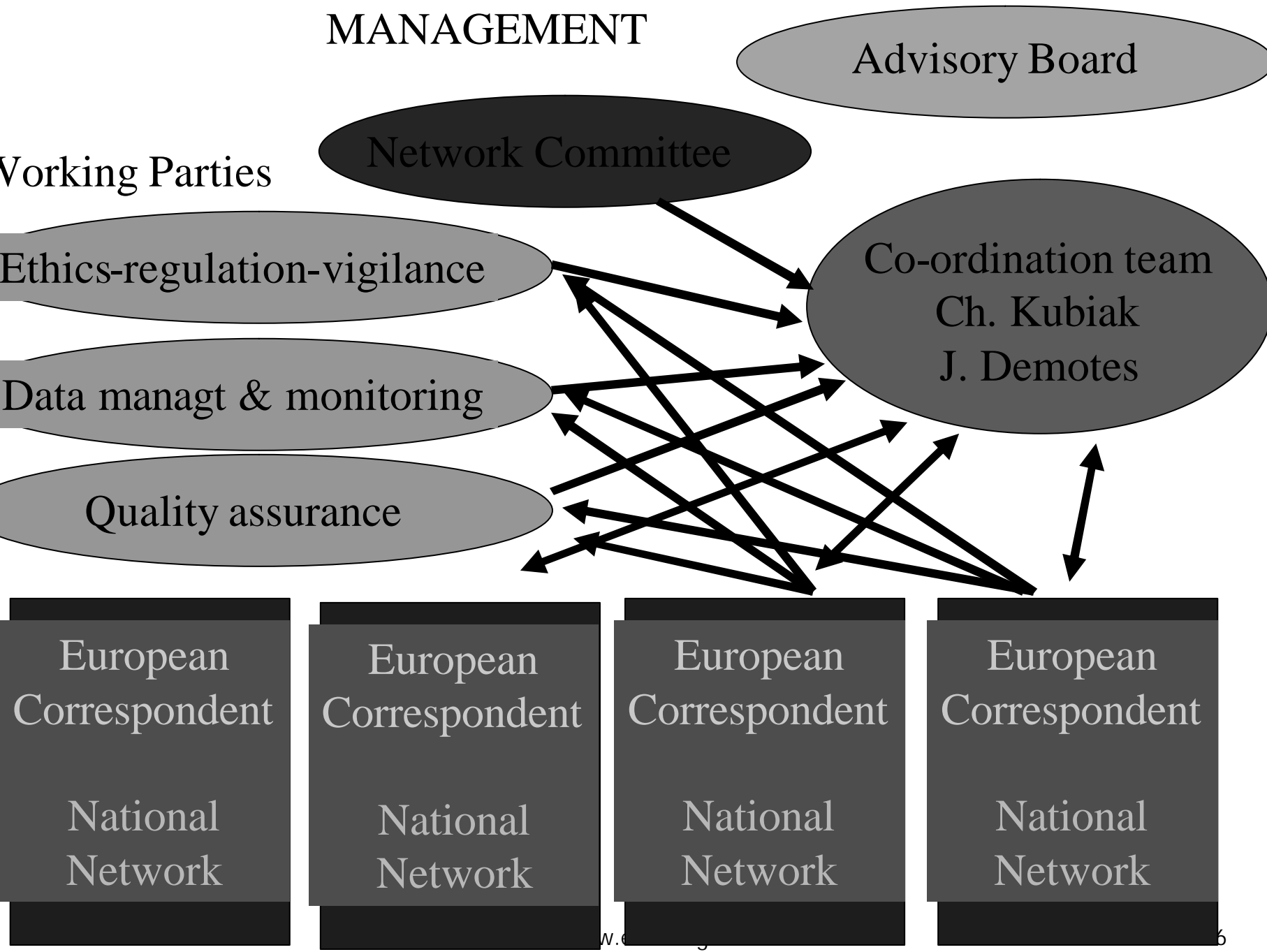
ECRIN TWG (FP6-funded)

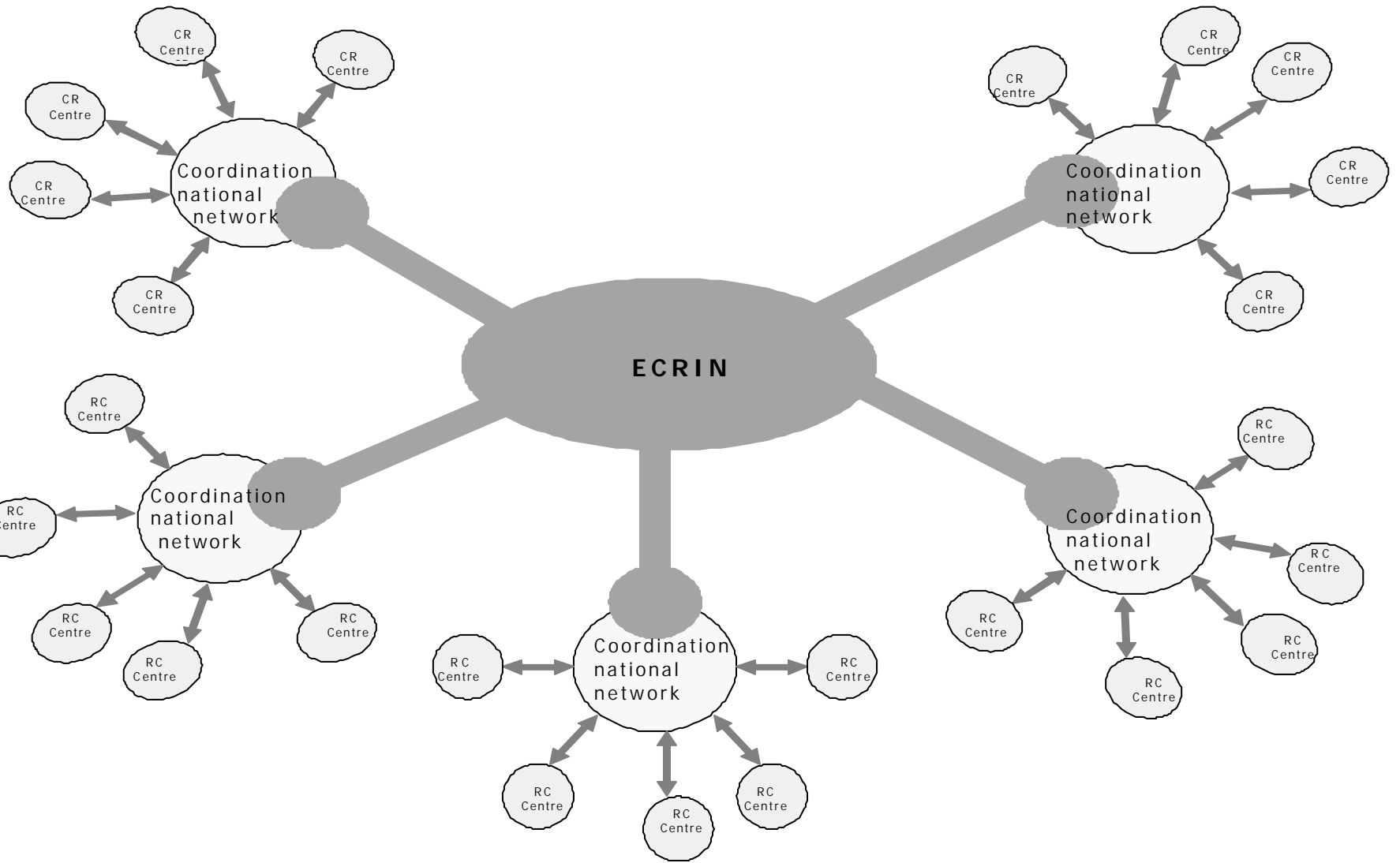
TRANSNATIONAL WORKING GROUPS :

-> Guidelines and procedures

- 1 - ethics
- 2 - regulation
- 3 - adverse event reporting
- 4 - data management
- 5 - monitoring
- 6 - quality assurance – SOPs
- 7 - education

MANAGEMENT





ECRIN

Coordination national network

Coordination national network

Coordination national network

Coordination national network

Coordination national network

CR = Clinical Research

ECRIN Advisory Board

- - **European stakeholders and regulators**

- 1 - Representative of the Commission / IMI

- 2 - Representative of European Medicines Agency (EMA)

- 3 – Representative of the Clinical Trials Facilitation Team

- - **Users and partners**

- ***Industry:***

- 4 - European Federation of Pharmaceutical Industries and Associations (EFPIA)/IMI

- 5 – EuropaBio (representing the biotechnology SME sector)

- ***Public sponsors and scientific agencies:***

- 6 - European Science Foundation (ESF)

- 7 - Europe & Developing Countries Clinical Trials Programme (EDCTP)

- ***Scientific associations and networks:***

- 8 - Paediatrics: representative of the TEDDY Paediatric network of excellence

- 9 - *European Organisation for Research and Treatment of Cancer (EORTC)*

- ***Patients' associations:***

- 10 - European AIDS Treatment Group (EATG)

- 11 - European Association for Rare Diseases (EURORDIS)

- ***Partner in communication:***

- 12 - Orphanet

Network committee

- Denmark : Ch Gluud
- France : G Chêne, J Demotes
- Germany : Ch Ohmann
- Hungary : C Farsang
- Ireland : P Meulien
- Italy : S Garattini, N Fabris
- Spain : X Carné
- Sweden : P Lafolie
- United Kingdom : P Selby
- Canada : JP Collet
- EFGCP : JP Tassignon
- EORTC ?*

Meetings and teleconferences

Vote (including for extension, budget, amendments)

ECRIN-2 (2006-2008) :

7 working groups



- 1 - ethics
- 2 - regulation
- 3 - adverse event reporting
- 4 - data management
- 5 – monitoring
- 6 - quality assurance – SOPs
- 7 – education

ECRIN working party members

- Two per country, one responsible for the deliverables, supported by a substitute. The European Correspondent participates in every working party.
- Additional input for the industry, regulators, ethics committees, partner organisations (EFGCP, EORTC), and from the paediatric field

ECRIN-2 : deliverables

Guidelines and procedures for multinational studies, posted on the *internal* website, and updated.

- Clinical studies on medicinal products : sept 2006 -> june 2007
- Other clinical research : -> june 2008

ECRIN TWG budget

700.000 € over 2 years, start date October 1st 2006

- 80% in december 2006 (45 days after signature of the contract)

- 20% 45 days after final scientific and financial report

Follow-up of expenses by the coordination with the support of EU correspondents

One single audit certificate at the end of the project

Expenses should fit with the financial plan, however changes are allowed if justified

For AC cost models, salaries should correspond to personnel specifically hired for the project.

ECRIN-3 (2008-) : Integrated services to multinational studies (1)

- Flexible, integrated services (one-stop shop) in the conduct of the study
 - 1 - interaction with ethics committees
 - 2 - interaction with competent authorities, regulatory affairs
 - 3 - drug dispensing
 - 4 - adverse event reporting
 - 5 - data management
 - 6 - data monitoring
 - 7 - management of biological samples

ECRIN-3 (2008-) : Integrated services to multinational studies (2)

- Information and consulting during the preparation of the study
 - 1 - Methodology, protocol review and adaptation of study protocol to transnational constraints
 - 2 - Ethical review
 - 3 - Meta-analysis
 - 4 - Centre selection, stimulation of patients' enrolment
 - 5 - Cost evaluation
 - 6 - Funding opportunities
 - 7 - Biostatistics
 - 8 - Data safety and monitoring committees
 - 9 - Insurance

ECRIN-3 and FP7 ESFRI roadmap

FP7 infrastructures 1.850M€	Targeted call	Open call
Access (60%) to existing infrastructures	6 in biomedical science (BMS) health priority-IMI	<i>Later ???</i> <i>Networking activities,</i> <i>joint research projects,</i> <i>access activities</i>
Preparation and construction / upgrade (30%)	ESFRI (500M€), 35 projects, 6 in BMS, <i>ECRIN</i>	Design studies 70M€

- preparation (ESFRI) : EU
- construction (GMP facilities, datacentres) EU+member states
- access to research projects : EU open call ?

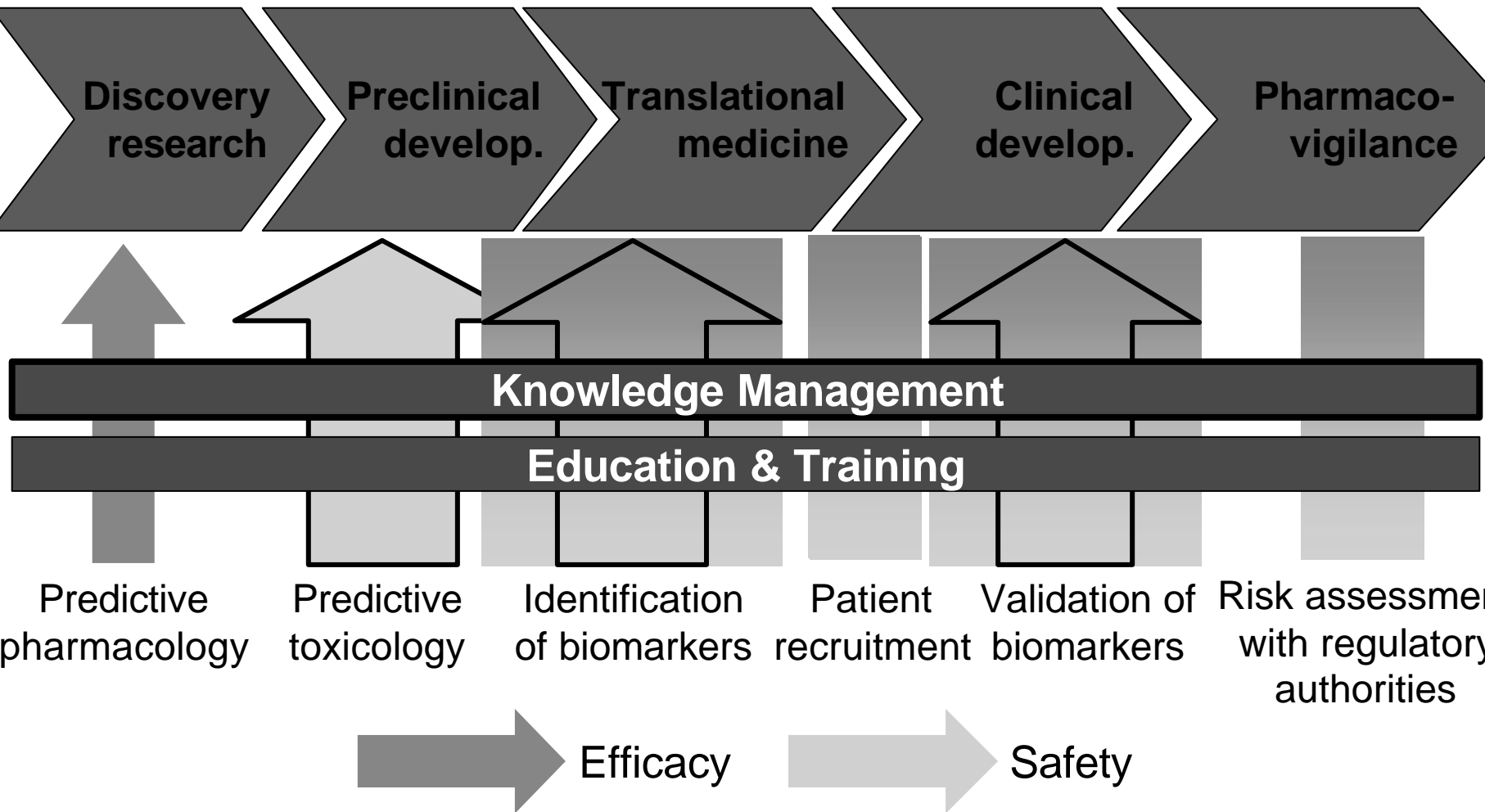
ECRIN: preparation step, 3-4 years

- | Building / strengthening institutional sponsor capacity and the coordination of national networks in EU countries
- | Extension to other national (or EU-wide) infrastructures networks
- | Design of datacenters, and prototypes
- | Design of, and connection with GMP facilities (with EATRIS)
- | Education, training, mobility
- | Communication : International Clinical Trials day (May 20th)
- | Legal status, contracts with sponsors
- | Website
- | Cost of access (industry, SME, academia), financial rules, sustainability, business plan
- | Support to pilot projects
- | Support to the connection of disease-oriented networks across the borders
- | FP7 Innovative Medicines Initiative

Communication with patients and citizens (FP7 SSA ?)

- 'International Clinical Trials Day' on May 20
- Discussion forums on evidence-based medicine with
 - Patients
 - Investigators
 - Sponsors
 - Ethics Committees
 - Competent Authorities
- How to foster
 - Active participation of patients and education
 - Protection of participants and safety of treatments
 - Quality of data, transparency and unbiased report

Bottlenecks identified in the Innovative Medicines Initiative (IMI) Strategic Research Agenda



FP7 Innovative Medicines Initiative : Europe-wide infrastructures and disease-oriented networks

