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*Future Clinical Trials for Adjuvant Treatment of  
Osteosarcoma - Prioritising the Questions*

*Wellcome Collection, London, 15 & 16th March 2010*

# European Clinical Research Infrastructures Network

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[www.ecrin.org](http://www.ecrin.org)

## A pan-European infrastructure for clinical research in any disease area

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### European Clinical Research Infrastructures Network



Pan-European, distributed infrastructure providing integrated services to multinational clinical research in the EU:

- access to patients throughout the EU
- despite the fragmentation of health and legislative systems
- support to investigators and sponsors in multinational studies

## *BMS-ESFRI Roadmap*

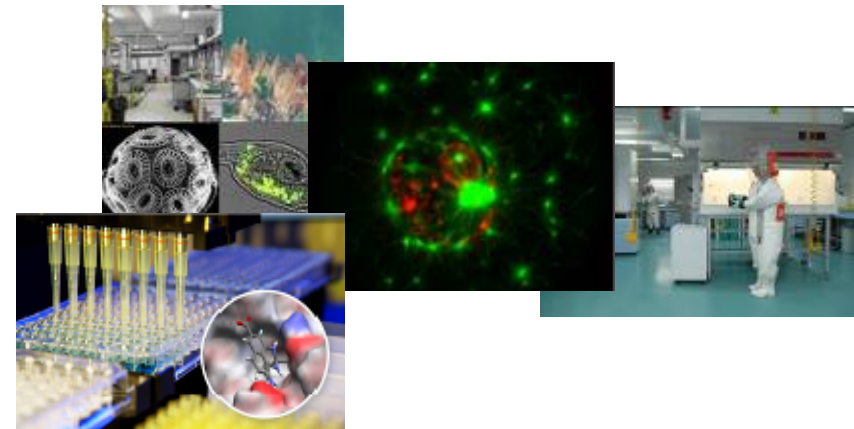
**2006**



INFRAFONTIER  
INSTRUCT  
ELIXIR  
ECRIN  
BBMRI  
EATRIS

**2008**

BSL-4  
BBMRC  
OpenScreen  
EuroBioImaging

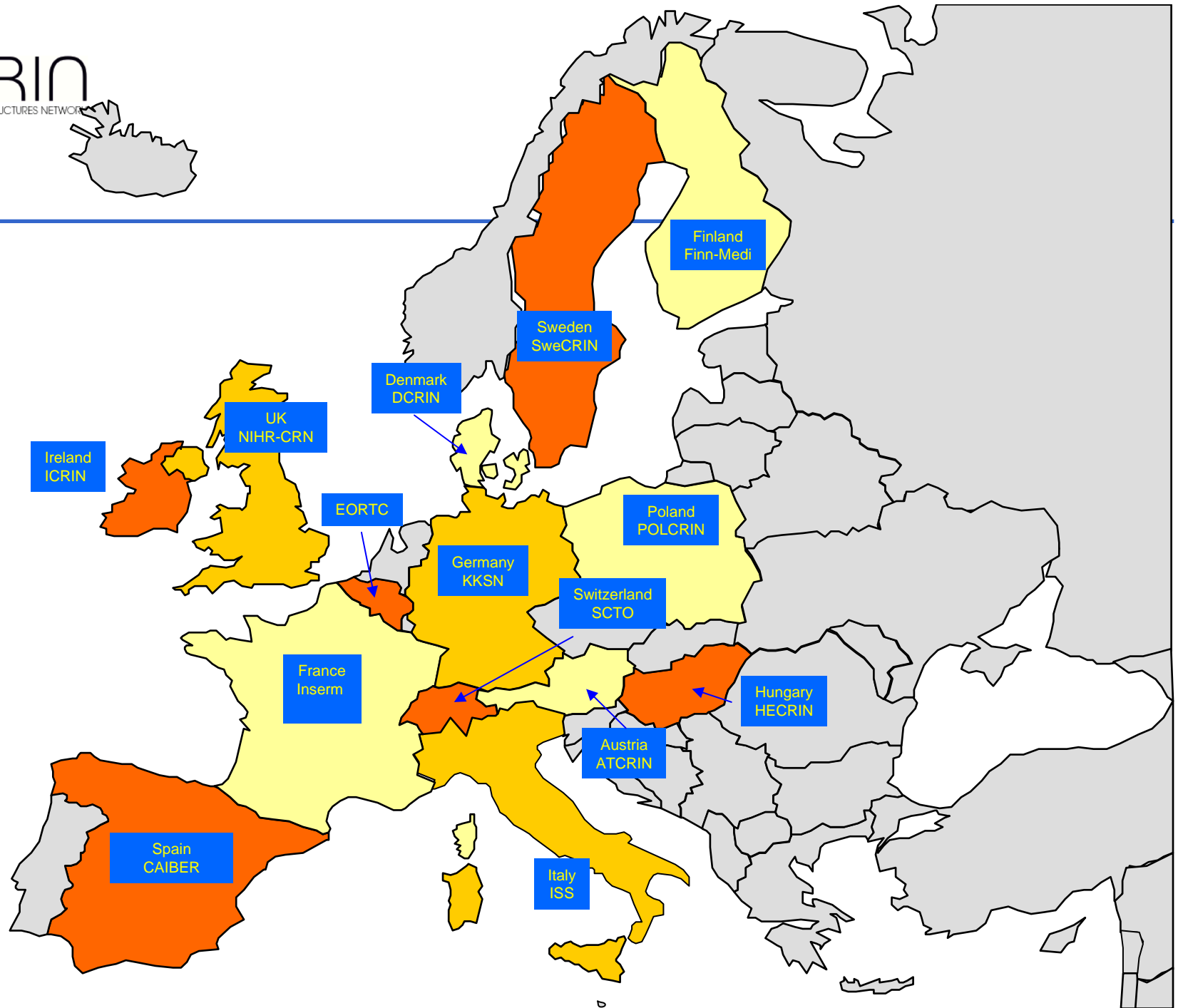


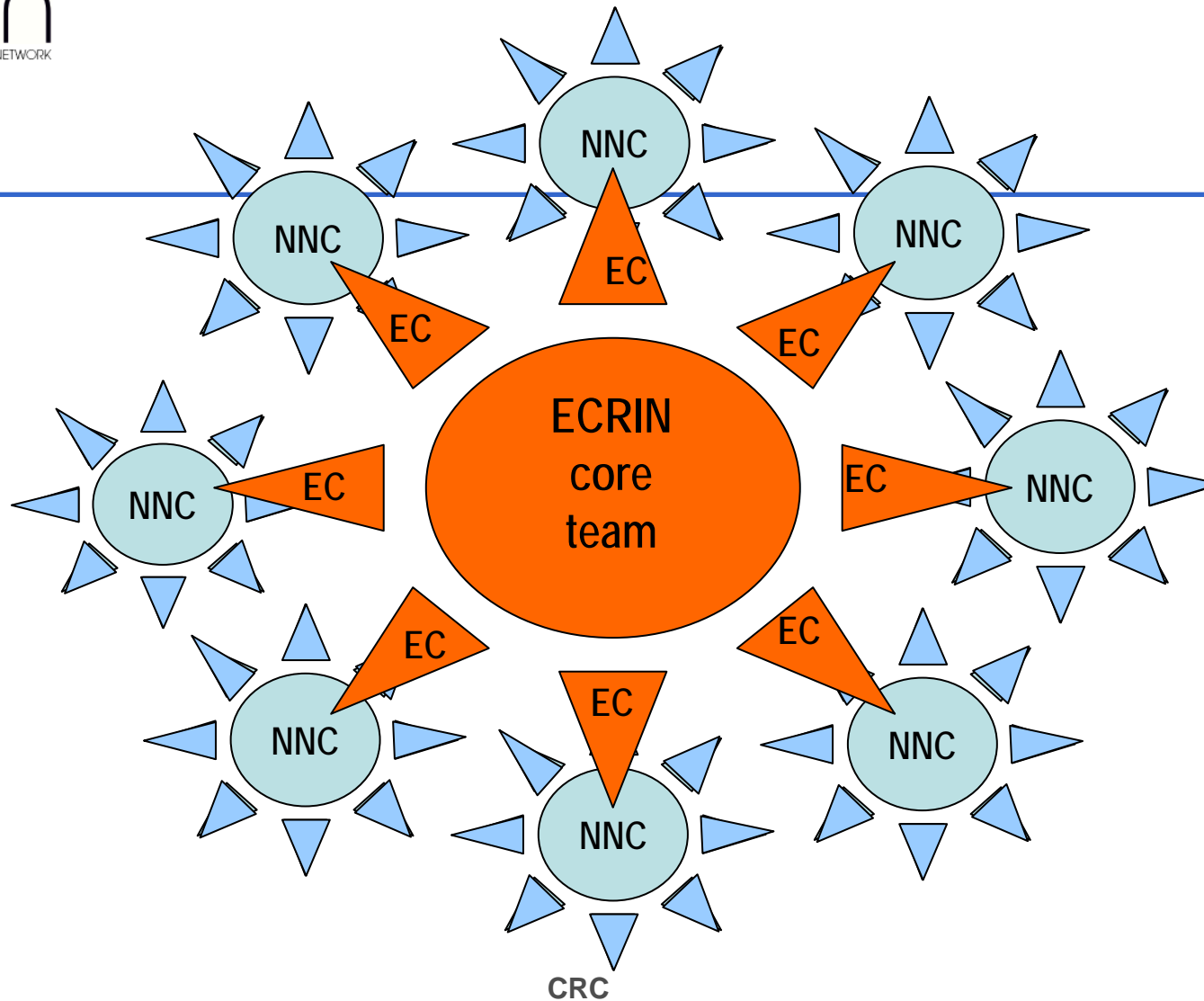
# ECRIN, a distributed infrastructure for clinical trials in the EU

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- ECRIN-1 (RKP, 2004-2005) :  
Identifying bottlenecks
- ECRIN-2 (TWG, 2006-2008) :  
Design of the infrastructure
- ECRIN-3 (PPI, 2008 - 2011) :  
ESFRI roadmap infrastructure supporting multinational clinical trials in the EU







**CRC** = Clinical research centre  
**EC** = European Correspondent  
**NNC** = National Network Coordination



Joint Strategic Board

Advisory Board

- Stakeholders
- Regulators
- Users/ Partners
- Scientific agencies
- Scientific networks
- Patient's associations

- Ministries
- Funding Agencies
- Network committee

Project Development Board

Network Committee

ECRIN Management Office  
(Coordination and European Correspondents)

Scientific Board  
(independent experts and ECRIN representatives)

Management

Structure

Development of services

QA Unit + Working parties

Design & Construction

Pilot Projects

Legal status

Governance

Financial Plan

Education

Capacity Building

Extension

Communication

Ethics

Regulation

Vigilance

Monitoring

Data centres

GMP Facilities

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- Practical information
    - 1 - Ethical requirements
    - 2 - Regulatory requirements
    - 3 - Insurance
    - 4 - Centre selection
    - 5 - Cost evaluation
    - 6 - Funding opportunities
  
  - Consulting on methodology
    - 7 - Systematic review, meta-analyses, and trial sequential analyses
    - 8 - Methodology, protocol design
    - 9 - Biostatistics
    - 10 - Data safety and monitoring board

# Flexible, coordinated services in the conduct of the study

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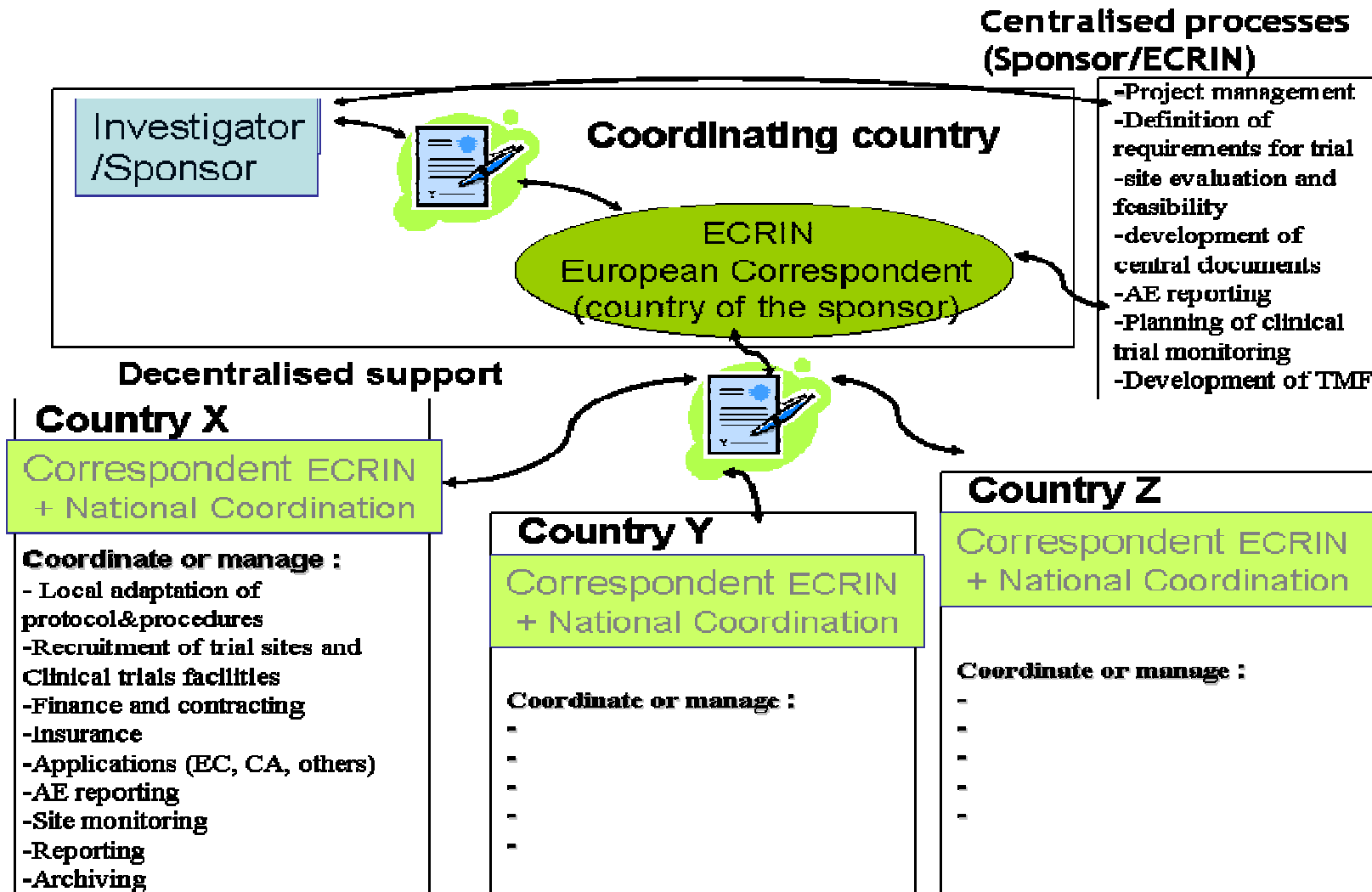
## - Decentralised

- 1 - interaction with ethics committees
- 2 - interaction with competent authorities
- 3 - participant recruitment and investigation
- 4 - drug dispensing
- 5 - circulation and storage of blood and tissue samples
- 6 - study monitoring

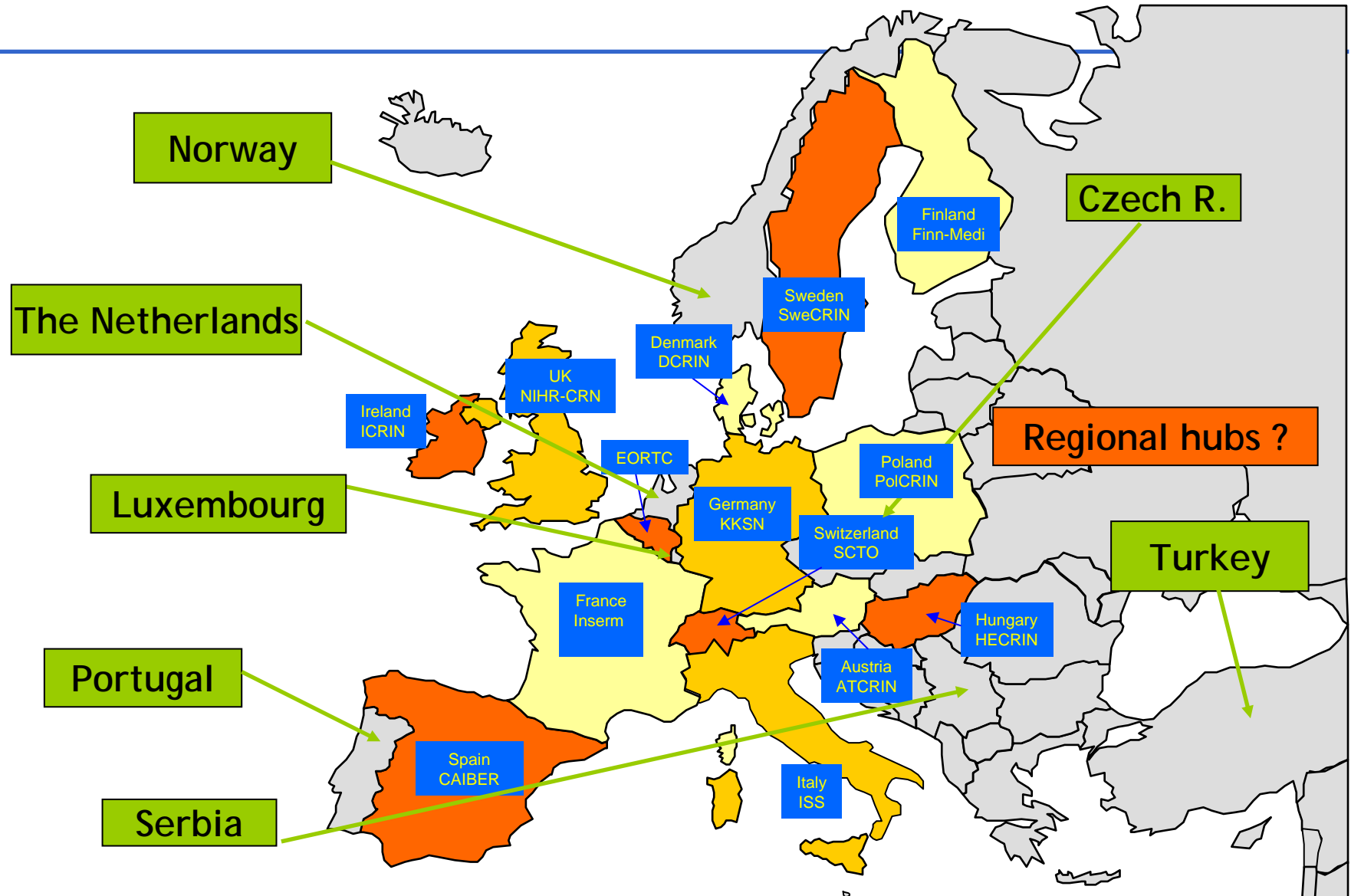
## - Centralised

- 7 - adverse event reporting
- 8 - data management - data centres

# Support/services



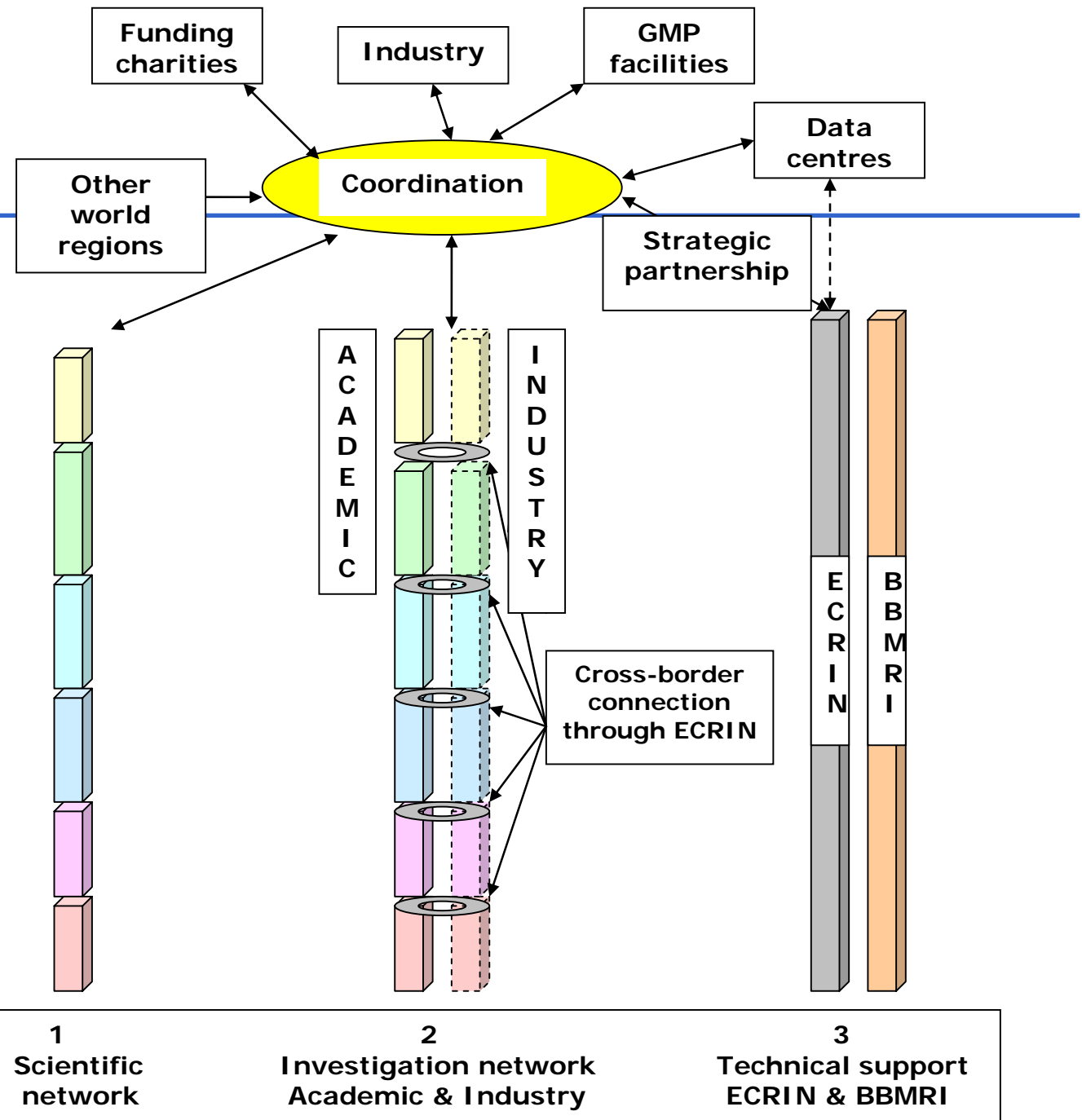
# New contacts



# Structuring clinical research in the EU

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- Development of national networks and hubs
- Development of multinational disease-oriented networks
  - FP7 ENBREC
- Funding to clinical research infrastructures (national / EU)
- Funding to clinical research projects (national / EU)
  
- Communication with patients, citizens, stakeholders
  - International clinical trials' day
  
- Pan-EU platform for Education and Training
  - IMI EMTrain ([www.emtrain.eu](http://www.emtrain.eu))
  
- Improvement of the legislative framework
  - ESF/EMRC Forward Looks
  - ICREL FP7 (Impact on Clinical Research of European Legislation) ([www.efgcp.be/icrel](http://www.efgcp.be/icrel))



A model for pan-European connection of disease-oriented networks :

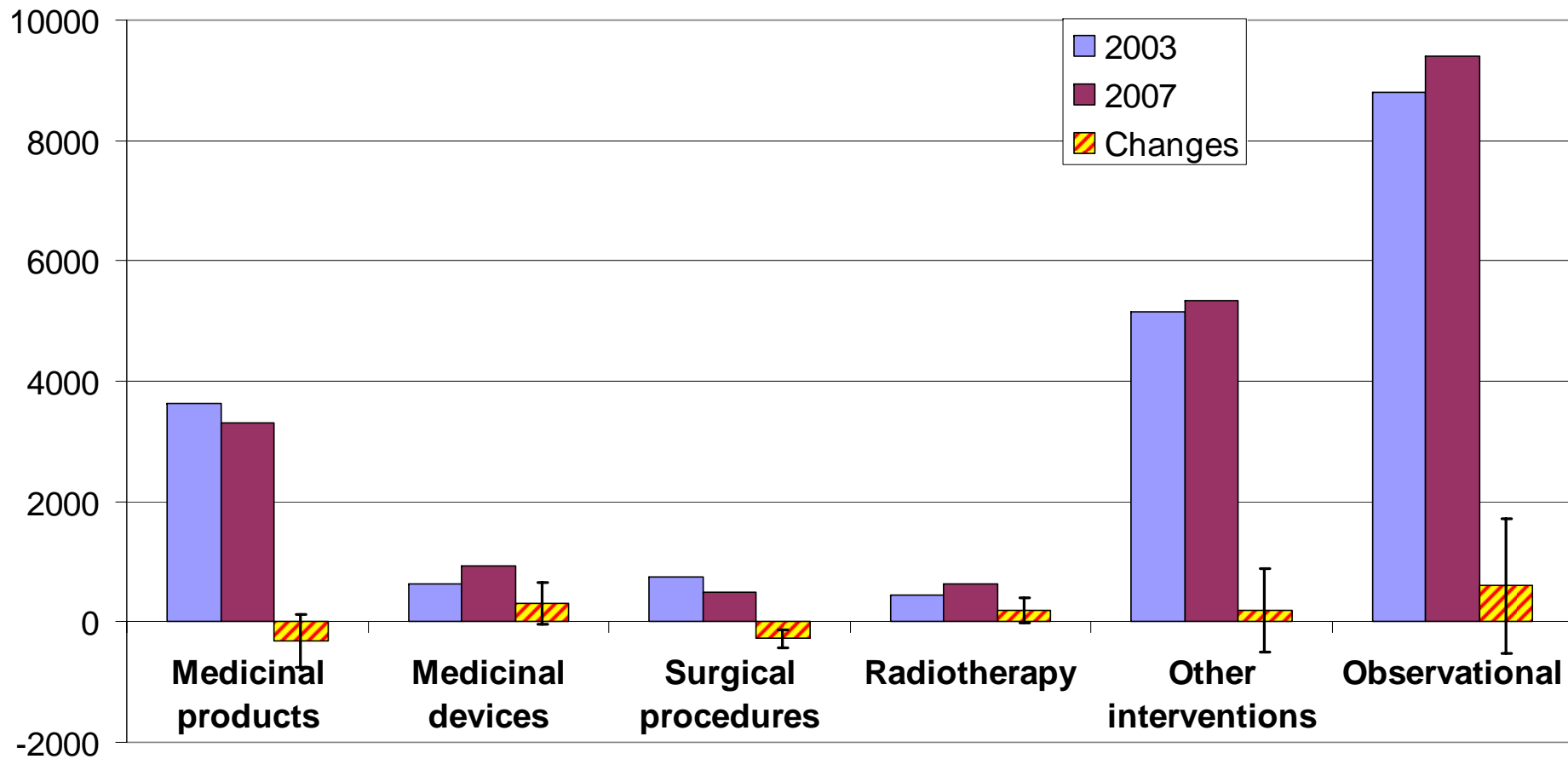
1 - Scientific collaboration

2 - Investigation network

3 – Technical support: pan-European infrastructures

- Clinical research
- Biobanks
- Imaging
- Other

# CTs performed before and after the CTD implementation

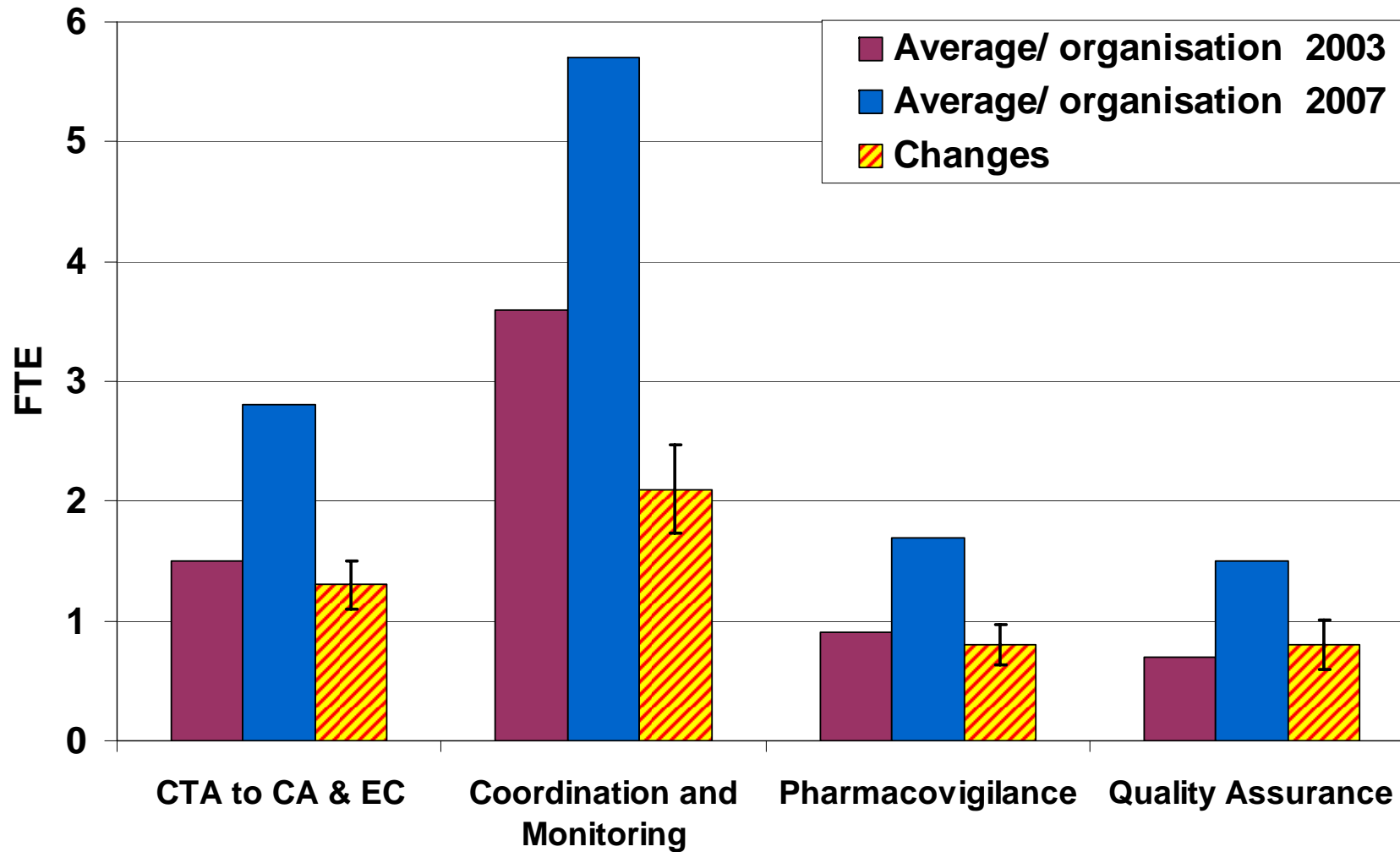




# ICREL

Impact on Clinical Research  
of European Legislation

## Workload before and after CTD implementation



# Forward Looks 'Investigator-Driven Clinical Trials'

EUROPEAN  
SCIENCE  
FOUNDATION  
SETTING SCIENCE AGENDAS FOR EUROPE

FORWARD LOOK

Investigator-Driven  
Clinical Trials





# Roadmap Initiative for Clinical Research in Europe

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# Risk-based requirements : proposed categories

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- category 1 : clinical trial on IMP without marketing authorisation in the EU
  - *additional requirements could be proposed for trials with novelty-associated risks, as advanced therapies or first-in-human studies, and this would correspond to 1a and 1b categories ?*
- category 2 : clinical trial on IMP with a marketing authorisation in the EU, but for another indication/population/condition.
  - *also including low-novelty treatments, like drugs already available under slightly different formulation (different salt, different routes of administration, slow release etc) ?*
- category 3 : clinical trial on IMP with a marketing authorisation in the EU, used in the licensed indication/population/condition.

# Pan-European funding for investigator-driven clinical trials

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- HEALTH.2011. 2.4.1-1: Investigator-driven, treatment trials for rare cancers. FP7-HEALTH-2011-two-stage.
- Research must focus on either solid or haematological rare cancers which are defined as cancers affecting not more than five in ten thousand persons in the European Union. The successful consortium will perform multicentre clinical trials aiming at the validation of novel therapeutic strategies, including targeted therapies, which improve patient survival. The project should focus on radiotherapy, chemotherapy, surgery, gene therapy, cell therapy or immunotherapy, or any combination of those. *Clinical studies into off-patent medicinal products under the paediatric use marketing authorisation (PUMA) initiative and into devices are excluded.*
- **Funding scheme:** Collaborative Project (small or medium-scale focused research project).
- **EC contribution per project:** Maximum EUR 6 000 000.
- **One or more proposals can be selected.**
- **Impact:** The results of research in this area will ultimately benefit patient survival, integrate investigator-driven, clinical research networks on rare cancers as well as structure European scientific excellence and competitiveness on rare cancers.

Thank you !