



# What assistance can ECRIN offer to investigators of international IIT

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# ECRIN

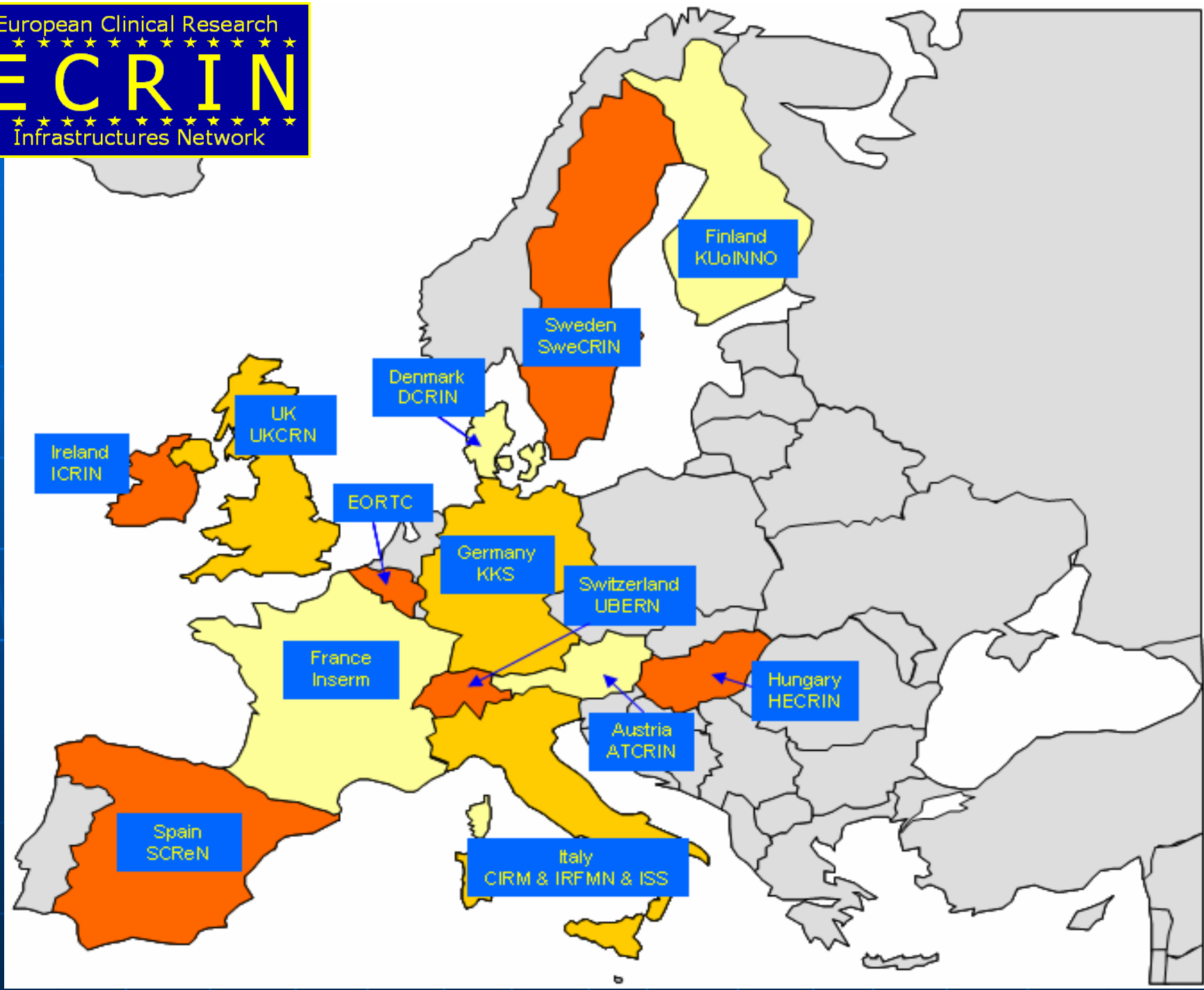
## INFRASTRUCTURES FOR CLINICAL TRIALS AND BIOTHERAPY



Pan-European, distributed infrastructure **facilitating clinical research in the European Union** :

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

European Clinical Research  
**ECRIN**  
Infrastructures Network



# ECRIN (European Clinical Research Infrastructures Network)

- First step (FP6)  
ECRIN-1 (2004-2005) : state of the art, identification of the bottlenecks to multinational clinical research
- Second step (FP6)  
ECRIN-TWG (Oct 2006- Sept 2008) : based on the outcome of the first programme, set up of guidelines, procedures, tools for multinational studies
- Third step (FP7- ESFRI Roadmap)  
ECRIN-PPI (Mar 2008 – Feb 2011) :  
Preparation phase for the development of an integrated European Infrastructure of clinical research

# ECRIN TWG 2006-2008

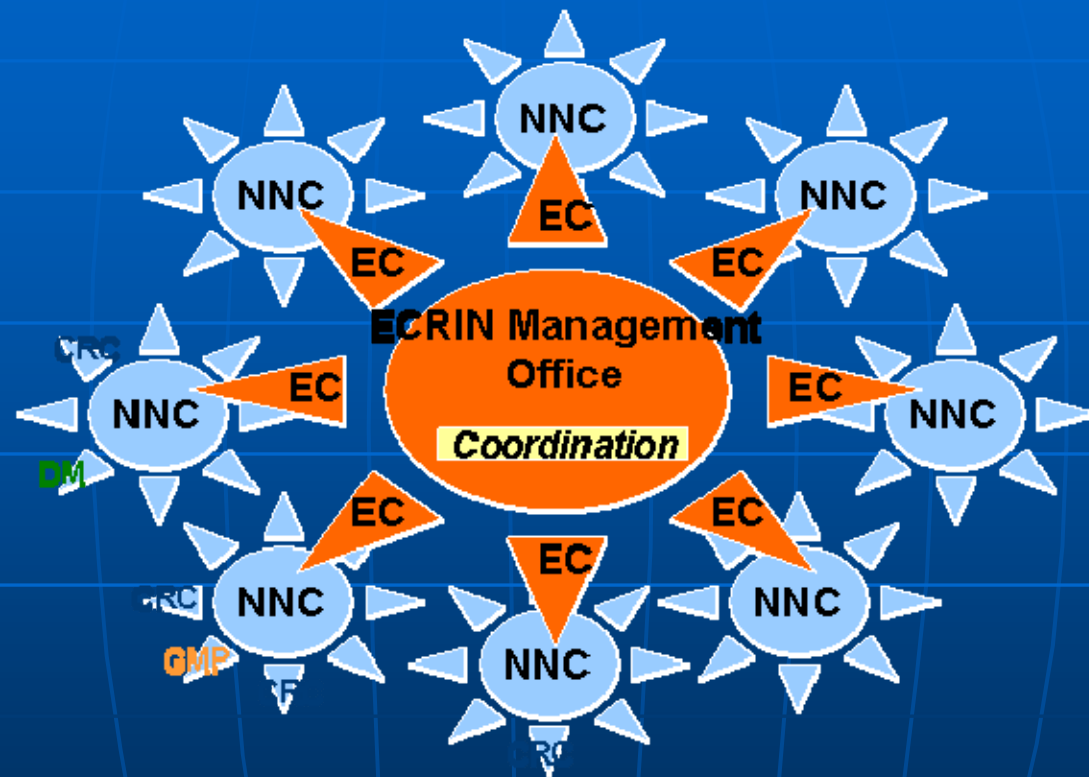
- Transnational working groups
- Comprehensive knowledge of the regulatory requirements in the different ECRIN countries for all categories of research



# ECRIN TWG

## 2006-2008

- Development of guidelines and SOPs for multinational studies (generic tools)
- Development of a network of European Correspondents able to provide support to multinational studies in each ECRIN country



**CRC** = Clinical research centre  
**DM** = Data centre  
**GMP** = GMP facility for biotechnology

**EC** = European Correspondent  
**NNC** = National Network Coordination



# ECRIN - PPI

## Preparation phase 2008-2011

- Change from a network of scientific partners into a sustainable European institution (integrated, distributed infrastructure) with a legal status of European Research Infrastructure and a representation of member states
- Start to provide integrated services to multinational studies

# What support?

- ECRIN Mission statement
  - ECRIN provides **integrated, 'one-stop shop' support to investigators and sponsors in multinational clinical research projects**, for any category of clinical research, in any disease area, particularly in rare diseases where multinational collaboration is a critical success factor.
  - ECRIN promotes the development of national networks of clinical research centres and clinical trial units with **professional staff and data management tools**, implementing **high quality standards** in the conduct of clinical studies.
  - ECRIN promotes education and training, as well as mobility programmes between countries, between preclinical and clinical research, and between academia and industry.
  - ECRIN **facilitates the connection of disease-oriented networks across the borders**.

*EU-wide disease-oriented networks*

*EU-wide infrastructures networks*

cancer

brain

diabetes

inflammation

infection

**Clinical  
(ECRIN)**

Infrastructures for multinational clinical research :  
**clinical research centres**, cohorts, biobanks, databanks, imaging

**Preclinical**

Infrastructures for preclinical R&D: toxicology models and  
databases, biopharmaceutical manufacturing facilities

**Drug discovery**

Infrastructures for drug discovery: high throughput  
'omic' facilities, in silico and animal models

**Research networks**  
**Investigators networks**  
**Patients' registries**

# What support?

- generic tools to support multinational clinical studies
- information and consulting during the preparation phase of the trial
- local correspondent

# Access for pilot projects

## Scientific board

- *Independant*
- *Composed of experts in the field of clinical research*
- *Give access to the network during the preparation phase*
  - *Scientific and methodological assessment of project with defined criteria (2 steps: eligibility, acceptance) (procedure and criteria available on the ECRIN website [www.ecrin.org](http://www.ecrin.org))*
  - *Faisibility study from the ECRIN management office*

# practical example

- German investigator who would like to set up a clinical study in France, Spain and UK
  - PI has the scientific idea
  - PI has already good collaboration with centres in Spain and UK

# Consulting /Information

PI /Sponsor



ECRIN  
European Correspondant

Germany

Methodology  
Biostatistics  
Data safety and  
monitoring  
committees

France

ECRIN Correspondent  
+ National Coordination

Regulatory requirements  
Cost evaluation  
Funding opportunities  
Insurance  
**Proposal of centres**

Spain

ECRIN Correspondent  
+National Coordination

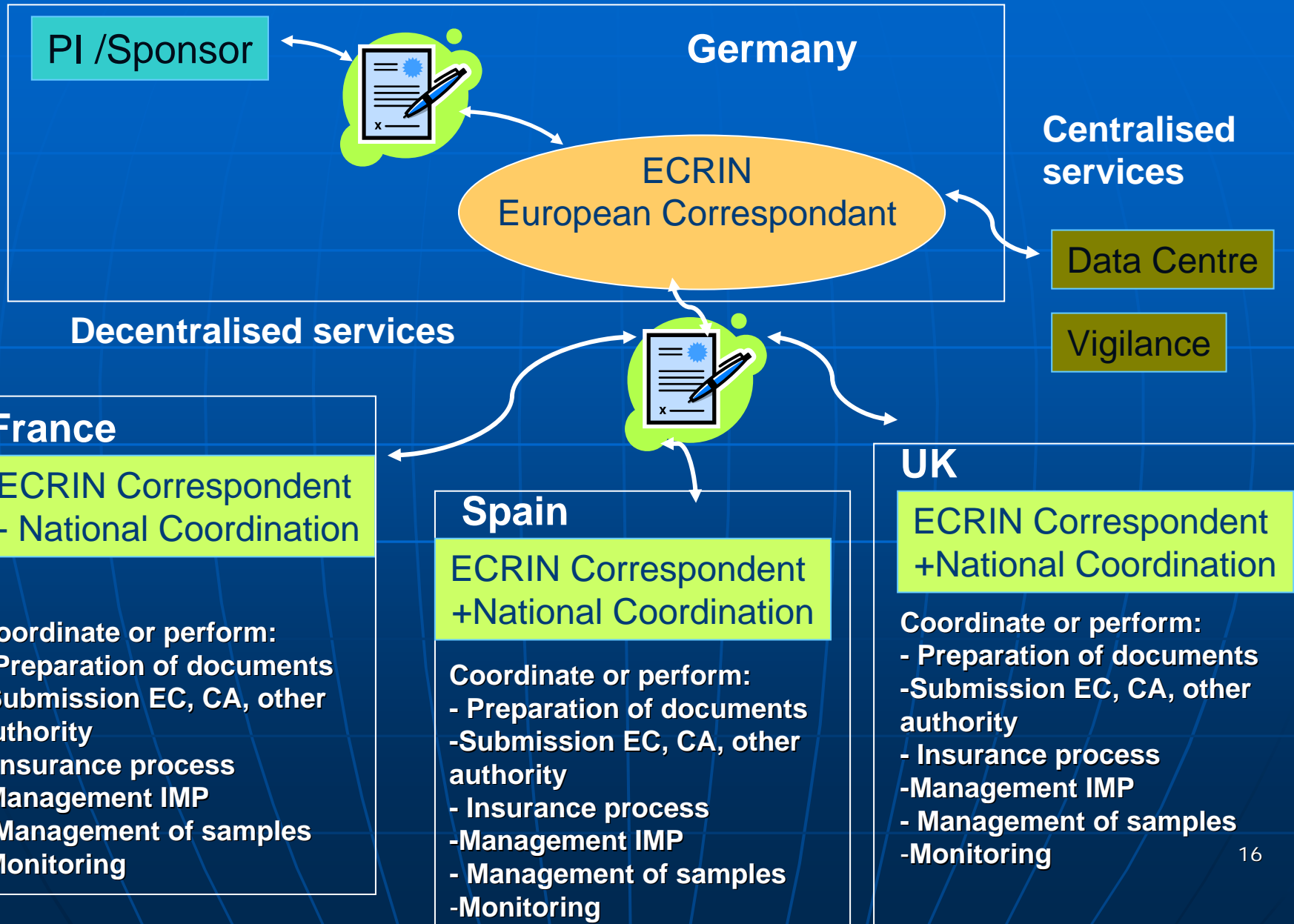
Regulatory requirements  
Cost evaluation  
Funding opportunities  
Insurance

UK

ECRIN Correspondent  
+National Coordination

Regulatory requirements  
Cost evaluation  
Funding opportunities  
Insurance

# Set up and management





Thank you