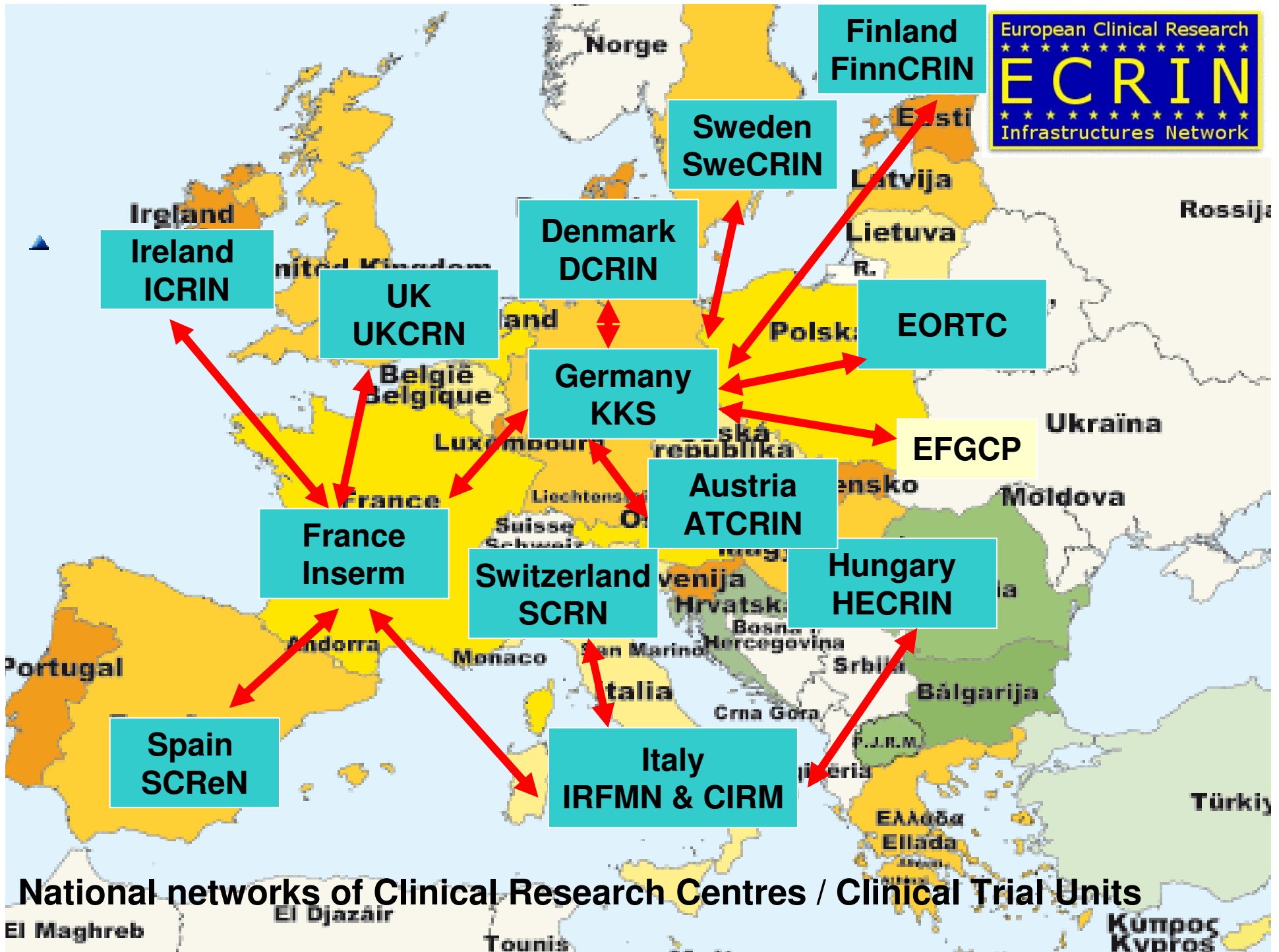


# Clinical Research Infrastructure at the European level: the ECRIN model

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**National networks of Clinical Research Centres / Clinical Trial Units**

# 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) : development of an integrated European Infrastructure of clinical research

# Objectives

- Integration of EU clinical research capacity
  - support to investigators
  - support to sponsors in multinational studies
  - > unlocking latent potential : scientific, patients
- Integration of public funding
  - > avoid duplication of studies & wasting of money
- Harmonisation of tools, training and practice
- Improved quality, credibility, transparency
  - > harmonisation of legislative systems ?

# ECRIN TWG

## Designing the infrastructure

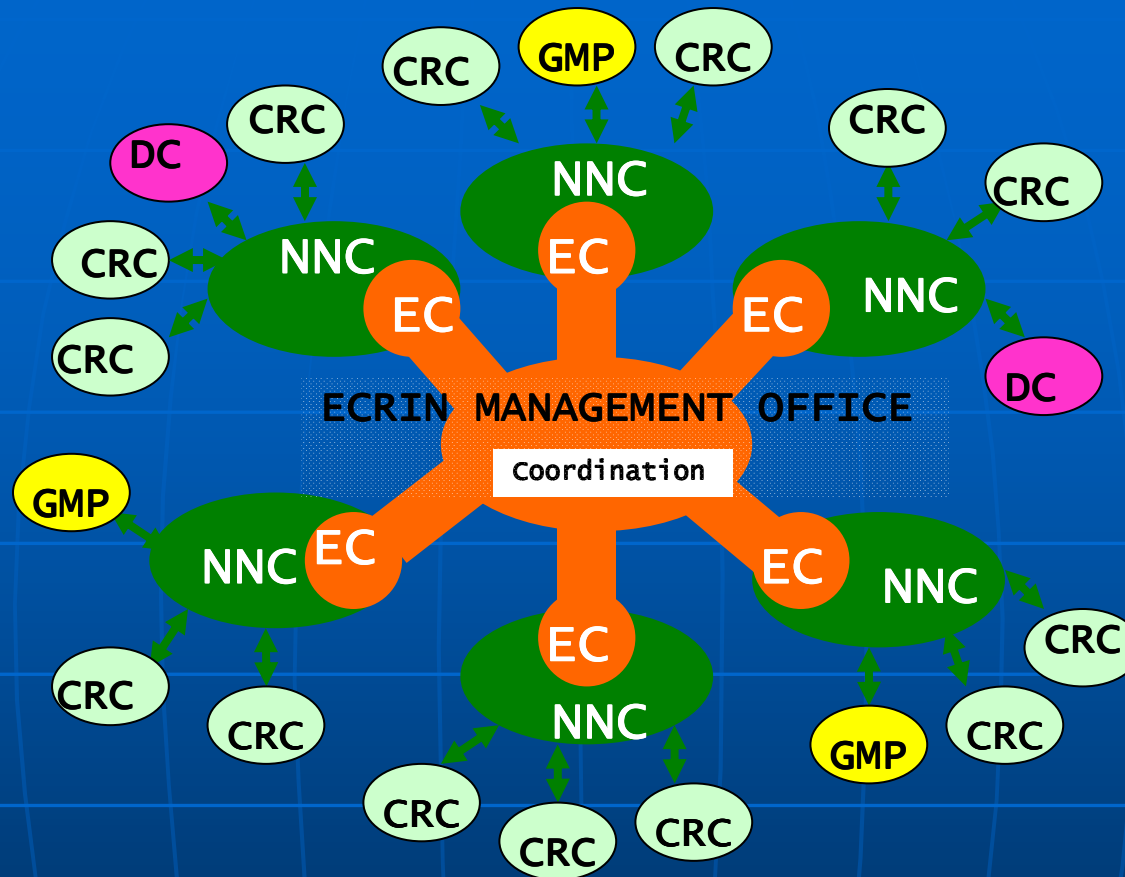
TRANSNATIONAL WORKING GROUPS :

-> Guidelines, tools and procedures

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

# ECRIN TWG

- Comprehensive approach of the regulatory requirements in the different ECRIN countries for all categories of research
- Development of SOPs for multinational studies
  - Informed consent, protocol, interaction with EC
  - Interaction with CA, insurance, management of IMP, management of samples, archiving
  - Adverse event reporting
  - Risk assessment tool, study visits,
- Network of European Correspondents able to provide support in each ECRIN country
- Network of clinical research centres



NNC: National network coordination  
 EC: European correspondent

DC: Data centres  
 GMP: GMP facility for bioterapy  
 CRC: clinical research centres

# ECRIN - PPI

## Integrated services

- 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 – data centres
  - 6 - study monitoring
  - 7 - management of biological samples
  - 8 – GMP manufacturing of biotherapy products
  - 9 – patients recruitment and investigation
- Information and consulting during the preparation of the study

# ECRIN - PPI

## Integrated services

- Scientific board
- Quality management unit
- Data centres

# After the preparation phase

- 1 – Operation phase
  - Progressive development of services to investigators and sponsors
  - > Sustainability : self-financing / operation revenues (public, industry, PPP), open I3 calls, national support
  
- 2 – Construction phase
  - Capacity building: public institutions acting as sponsors
  - GMP facilities for biotherapy
  - Datacentres
  - > National funding, loan to EIB (RSFF), structural funds, limited funding from the Capacity programme

# Synergies with other ESFRI Infrastructures

