How can ECRIN support investigators for the initiation and conduct of international academic trials

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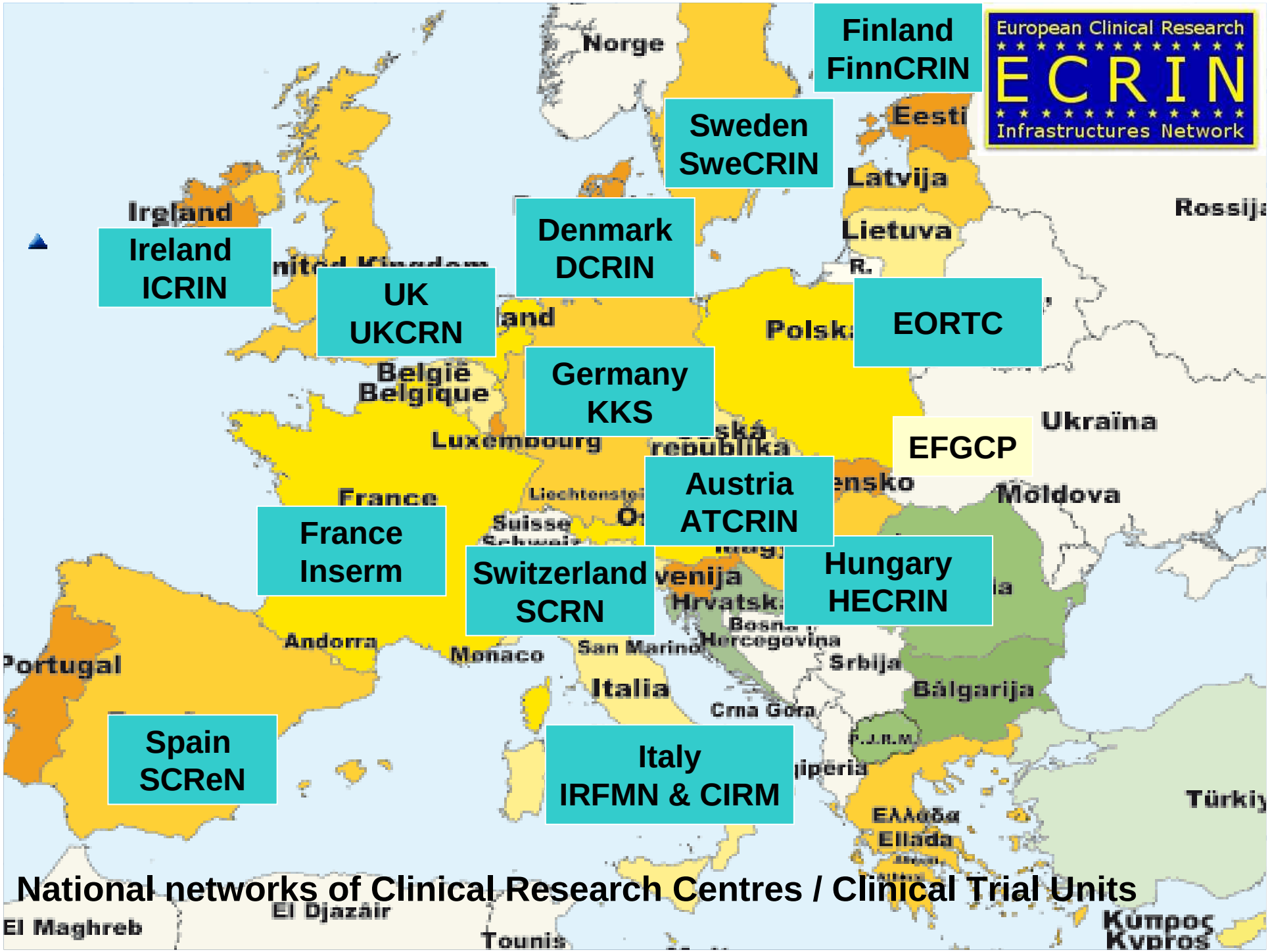


National networks of Clinical Research Centres / Clinical Trial Units

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 ?

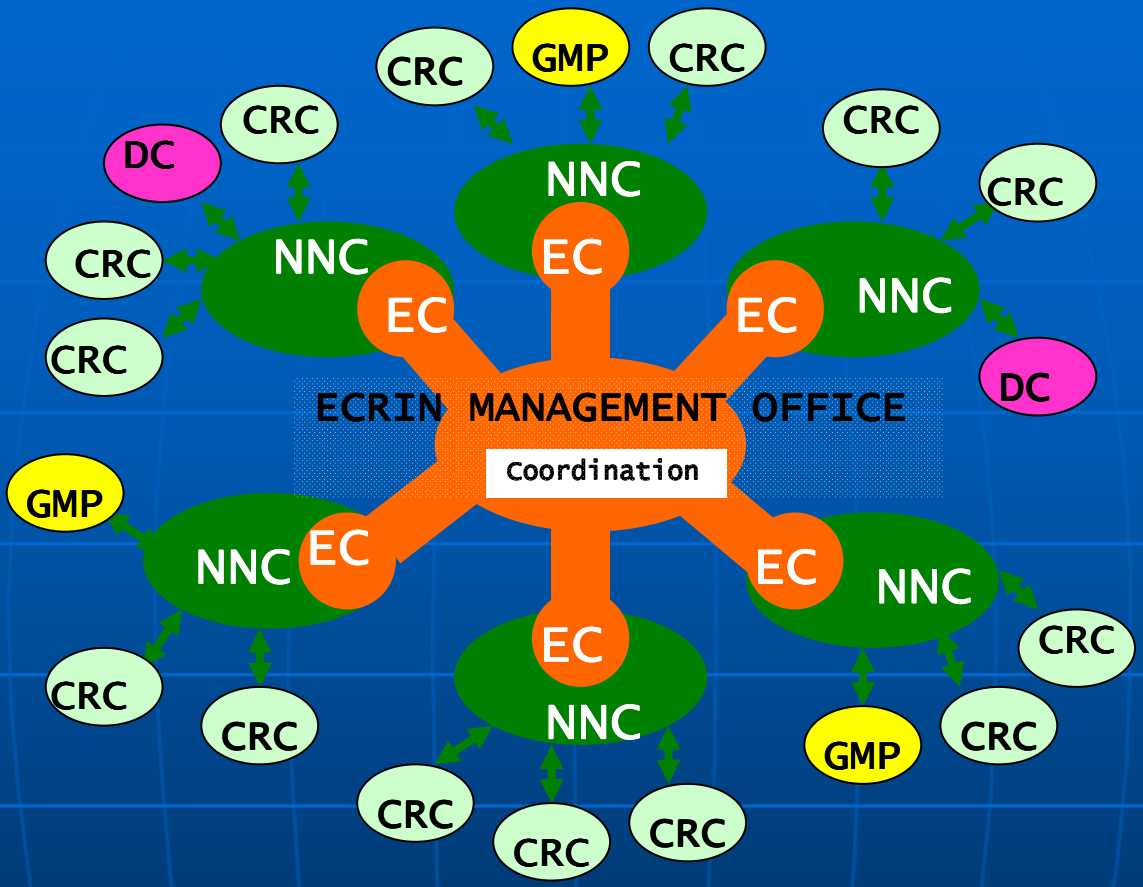
ECRIN TWG
Designing the infrastructure

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

Support to investigators

- Comprehensive knowledge 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, monitoring,
- Network of clinical research centres
- Network of European Correspondents able to provide support to foreign sponsor in each ECRIN country



NNC: National network coordination
EC: European correspondent

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

ECRIN - PPI
Integrated services

- Flexible, integrated services (one-stop shop) in the conduct of the study
  - interaction with ethics commitees
  - interaction with competent authorities, regulatory affairs
  - drug dispensing
  - adverse event reporting
  - data management – data centres
  - study monitoring
  - management of biological samples
  - GMP manufacturing of biotherapy products
  - patients recruitment and investigation

ECRIN - PPI
Integrated services

- Information and consulting during the preparation of the study
  - methodology, protocol review and adaptation of study protocol to transnational constraints
  - ethical review
  - meta-analysis
  - centre selection, stimulation of patients' enrolment
  - cost evaluation
  - funding opportunities
  - Biostatistics
  - data safety and monitoring committees
  - Insurance

ECRIN - PPI
Integrated services

- Scientific board
  - to evaluate the scientific relevance and feasibility of the studies
- Quality management unit
- Data centres

After the preparation phase

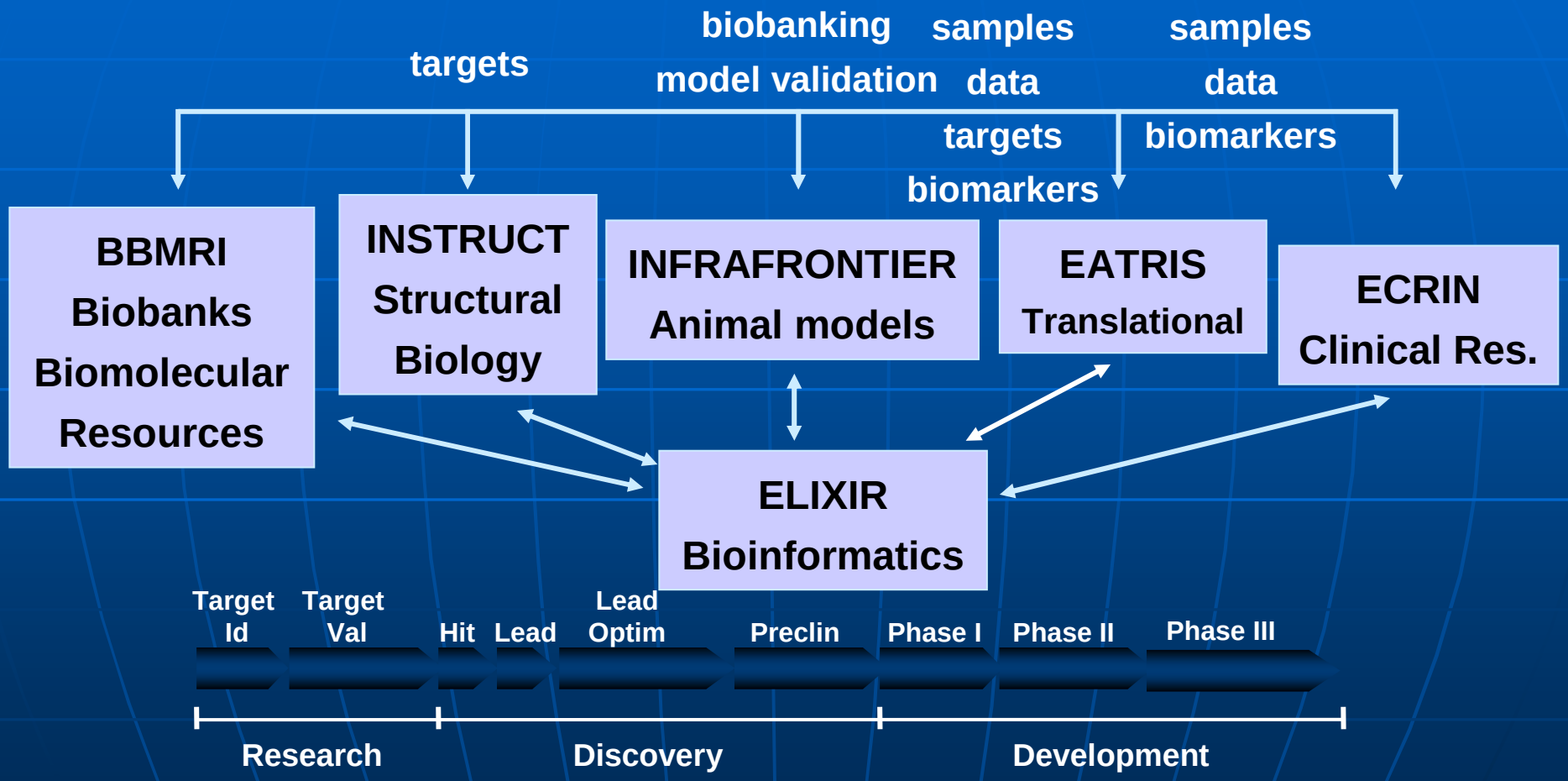
- 1 – Operation phase
  - Progressive development of services to investigators and sponsors

  -> 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



Thank you