



European Clinical Research Infrastructures Network

www.ecriin.org

Challenges to clinical research in Europe

■ Main bottlenecks :

- Access to patients:
 - fragmentation of health systems
- Cost:
 - fragmentation of public funding
- Quality of infrastructures

AER

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ECRIN proposals

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

Which clinical research projects ?

- Any type of clinical research
 - Clinical trials on health products, biotherapy
 - Surgery, radiotherapy, multimodal trials
 - Diagnostic, imaging, biomarker, genetic studies
 - Physiology, physiopathology, epidemiology
- Any medical field
- Special focus on rare diseases / orphan drugs
- Any sponsor : public institution, public-private partnership, biotechnology & medical device SMEs, pharmaceutical industry
- -> support to investigators
- -> support to sponsors in multinational studies

ECRIN, an integrated infrastructure for clinical trials in the EU

- ECRIN-1 (2004-2005) :
Identifying bottlenecks
- ECRIN-2 (2006-2008) :
Design of the infrastructure
- ECRIN-3 (2008 ->) : 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.eclin.org

ECRIN-2 (2006-2008) : designing the infrastructure

ECRIN TWG (FP6-funded)

TRANSNATIONAL WORKING GROUPS :

-> Guidelines and procedures

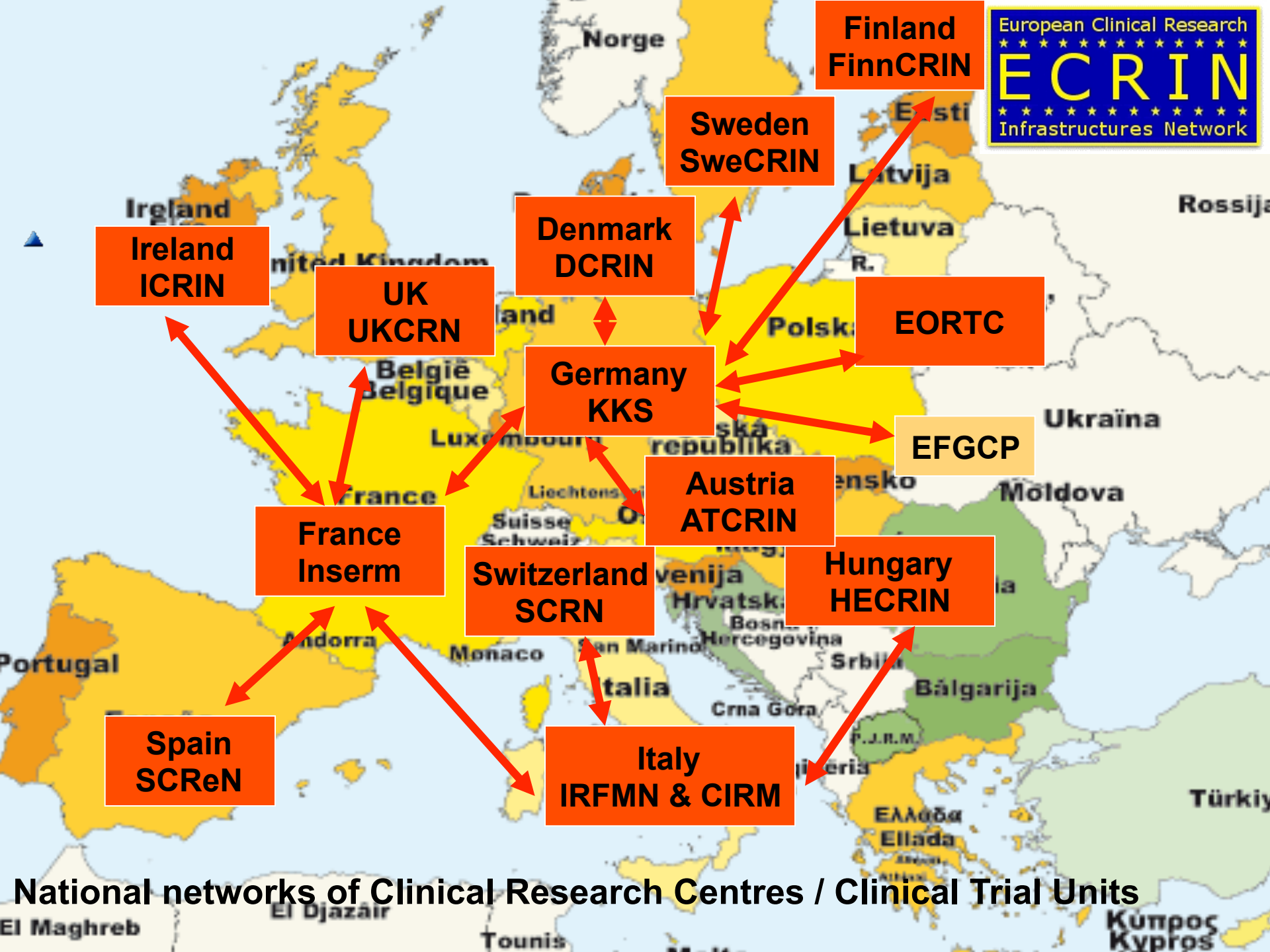
- 1 - ethics
- 2 - regulation
- 3 - adverse event reporting
- 4 - data management
- 5 - monitoring
- 6 - quality assurance – SOPs
- 7 - education

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

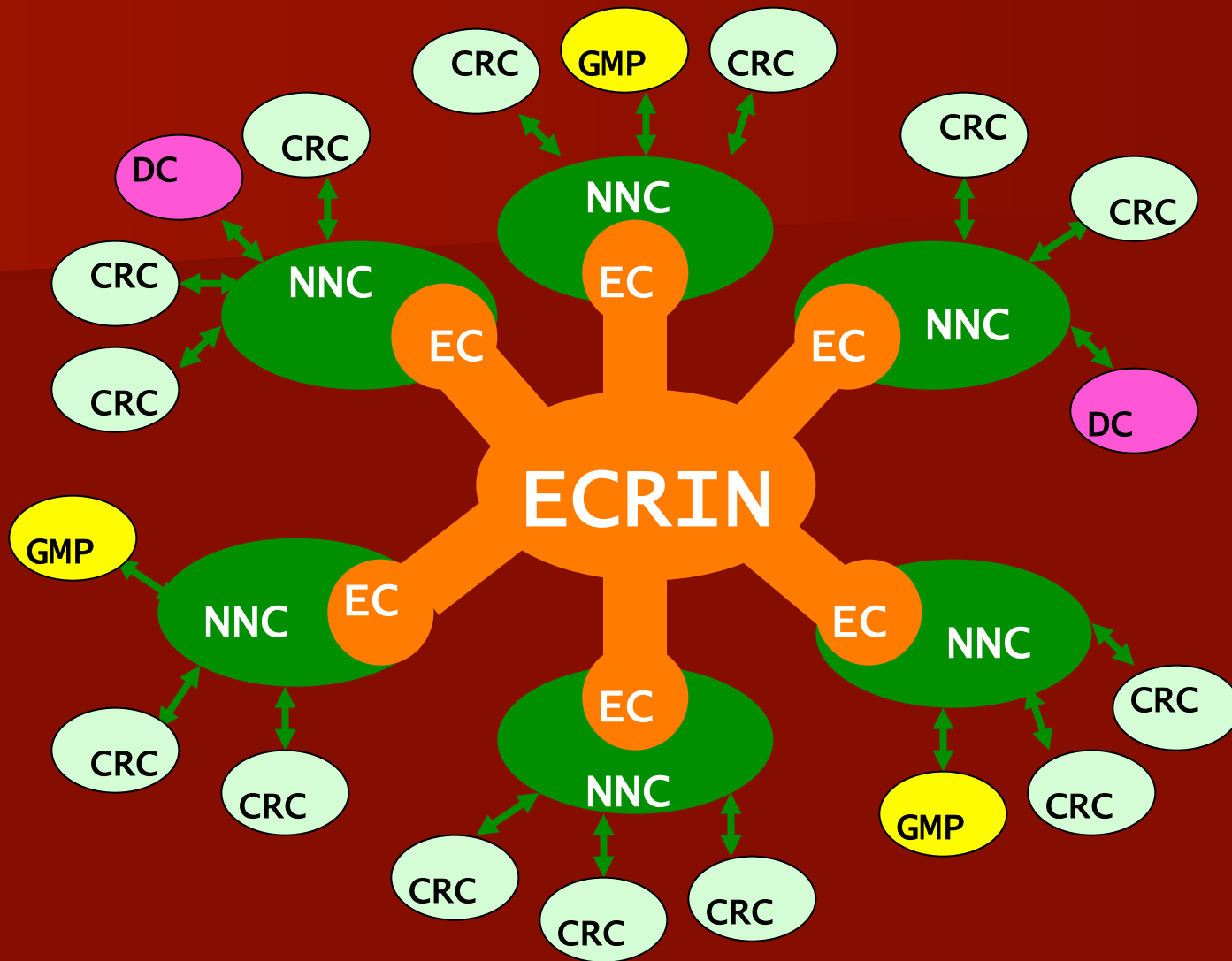
- Flexible, integrated services (one-stop shop) in the conduct of the study
 - 1 - interaction with ethics committees
 - 2 - interaction with competent authorities, regulatory affairs
 - 3 - drug dispensing
 - 4 - adverse event reporting
 - 5 - data management – data centres
 - 6 - study monitoring
 - 7 - circulation and storage of blood and tissue samples
 - 8 - GMP manufacturing of biotherapy products
 - 9 - patients recruitment and investigation

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



National networks of Clinical Research Centres / Clinical Trial Units



CRC= Clinical research centre

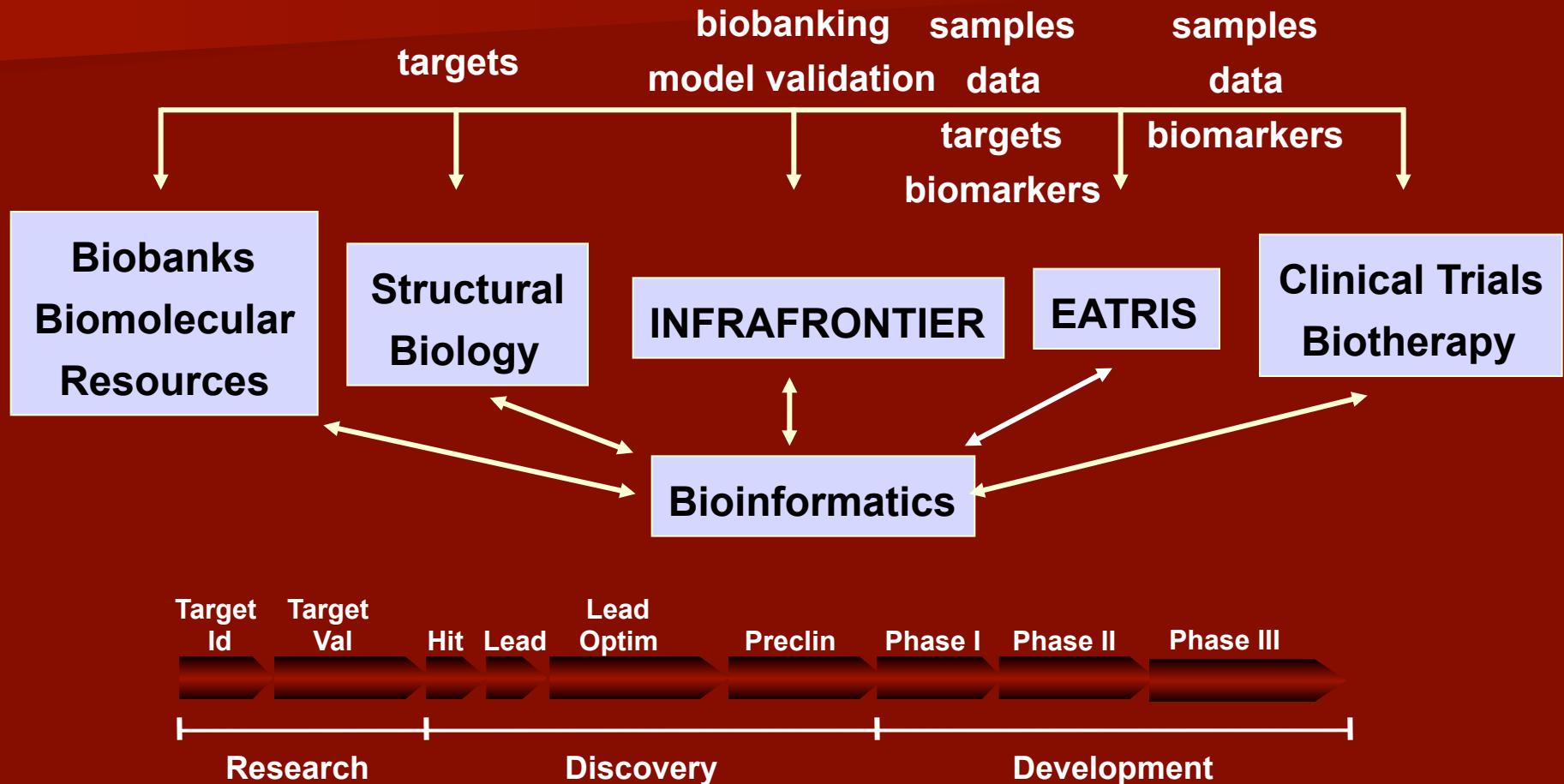
DC= Data centre

GMP= GMP facility for biotherapy

EC= European Correspondent

NNC= National Network Coordination

Synergies with other ESFRI Infrastructures



FP7 IMI : Europe-wide infrastructures and disease-oriented networks

