OECI 2011, June 17th, Amsterdam

Session 3:

Organizing research / translational research facilities

ECRIN

European Clinical Research Infrastructures Network

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www.ecrin.org

Make Europe a single area for clinical research

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

Pan-European, distributed infrastructure providing coordinated services to ***multinational*** clinical research in Europe:

- access to ***patients*** and to ***expertise*** throughout Europe

- despite the ***fragmentation*** of health, legislative and funding systems

- ***support*** to investigators and sponsors in multinational studies

ECRIN – PPI Preparation phase 2008-2011

ESFRI - Biological and Medical Sciences

2006

BBMRI - Biobanks

EATRIS - Translational research facilities

ECRIN - Clinical trial plateform

ELIXIR – Data repositories

Infrafrontier - Mouse archives and clinics

INSTRUCT - Structural biology facilities

2008

EMBRC - Marine biology resources

ERINHA - High-security labs

EuroBioImaging – Imaging facilities

EU-Openscreen - Chemical libraries

ANAE - Analysis and experimentation on ecosystems

2010

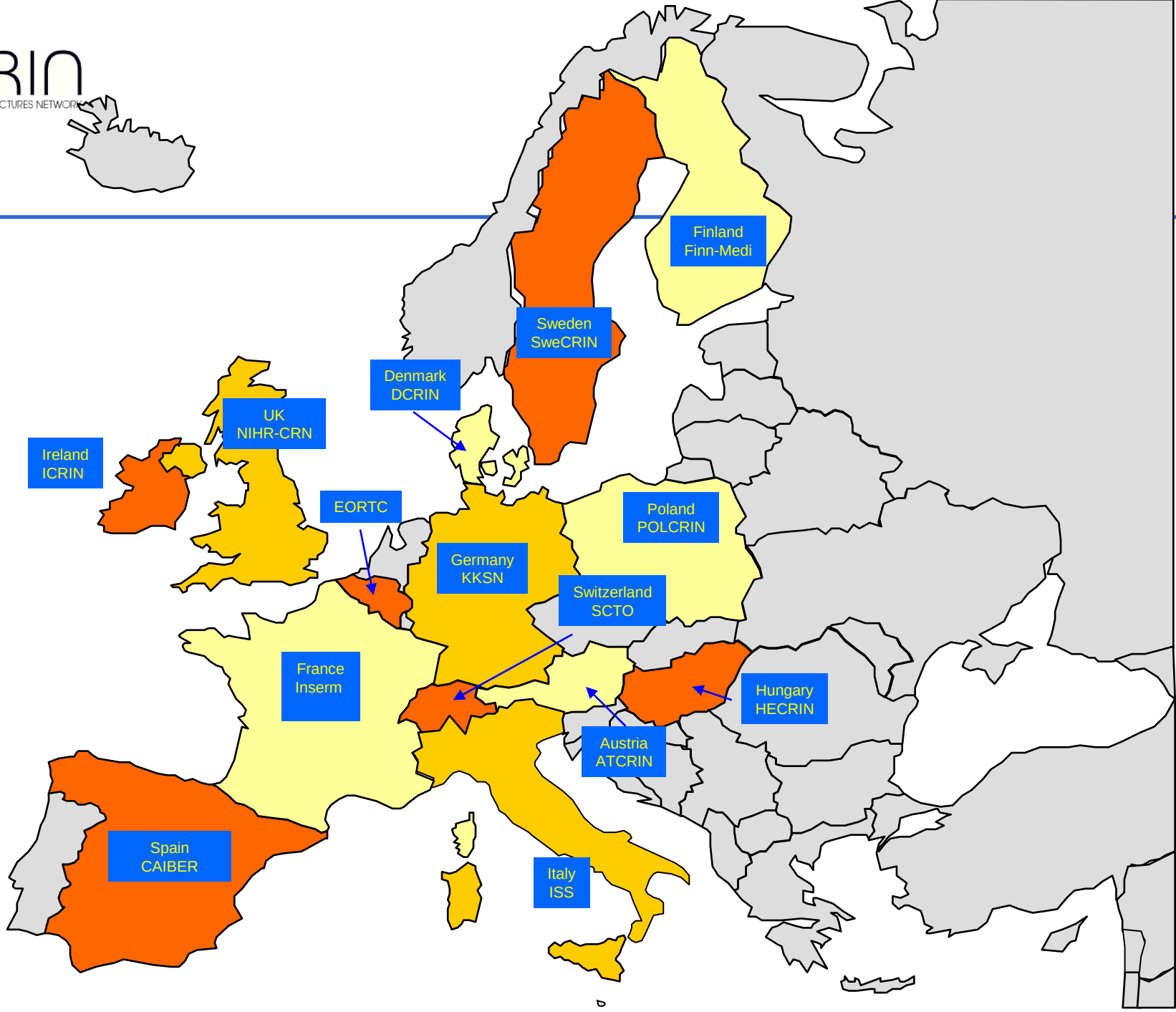
ISBE – Infrastructure for systems biology

MIRRI – Microbial resources

ECRIN development steps

	ECRIN-RKP (2004-2005) identifying bottlenecks	
	ECRIN-TWG (2006-2008) developing know-how	
	ECRIN-PPI (2008-2011), building the infrastructure and supporting pilot multinational trials	
	ECRIN-ERIC (2011->) operating the ESFRI-roadmap infrastructure for multinational trials	
	ECRIN-Integrating Activity (2011->15) Expanding connections	

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURES NETWORK



Germany

nationwide network

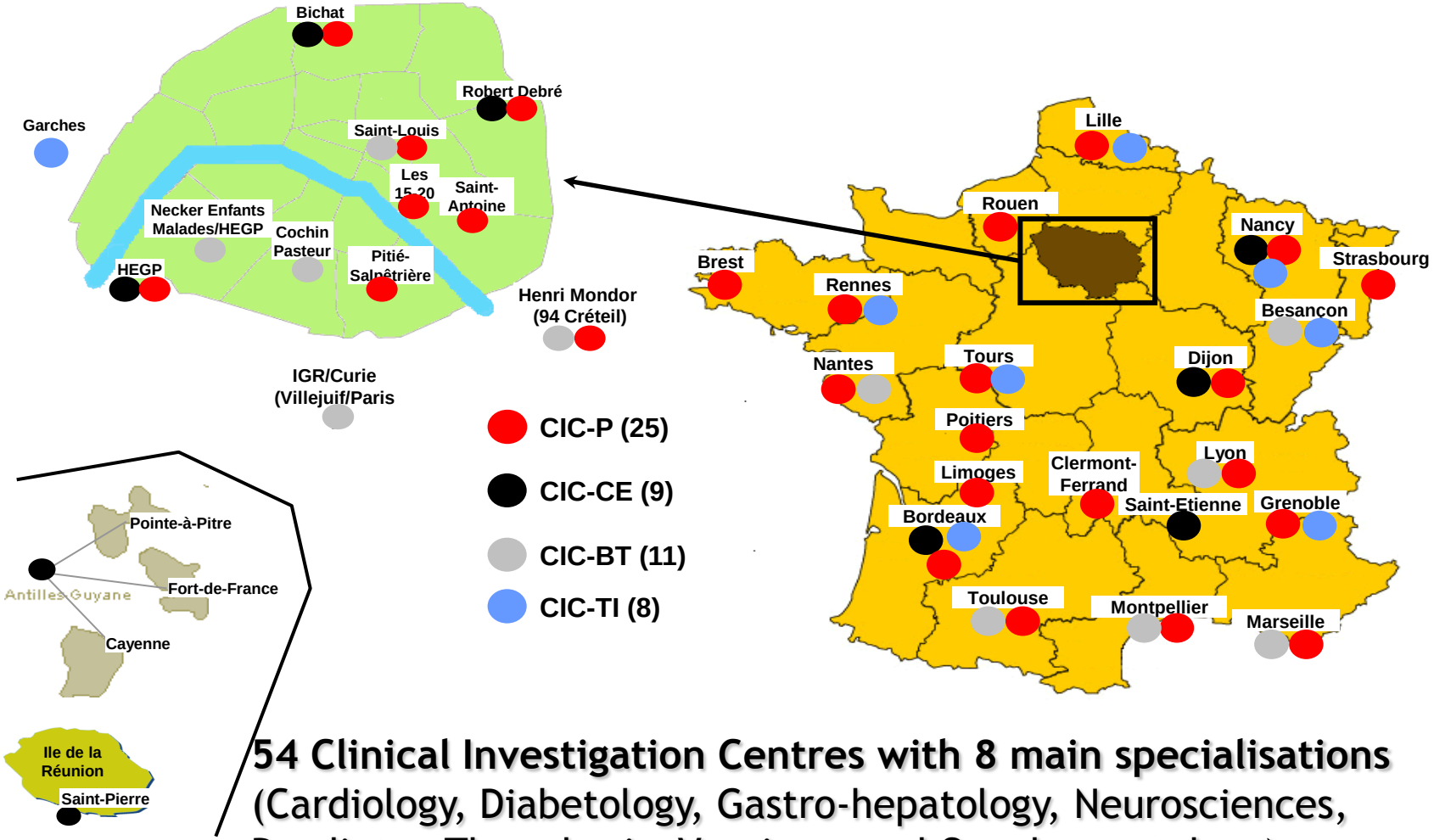
13 „Coordinating Centers“ for Clinical Trials
3 associated centres (Regensburg, LMU Munich,Hannover)

Central Office in Cologne

6 sites with an integrated pediatric module (PAED-Net):
Freiburg, Heidelberg, Cologne, Leipzig, Mainz, Münster

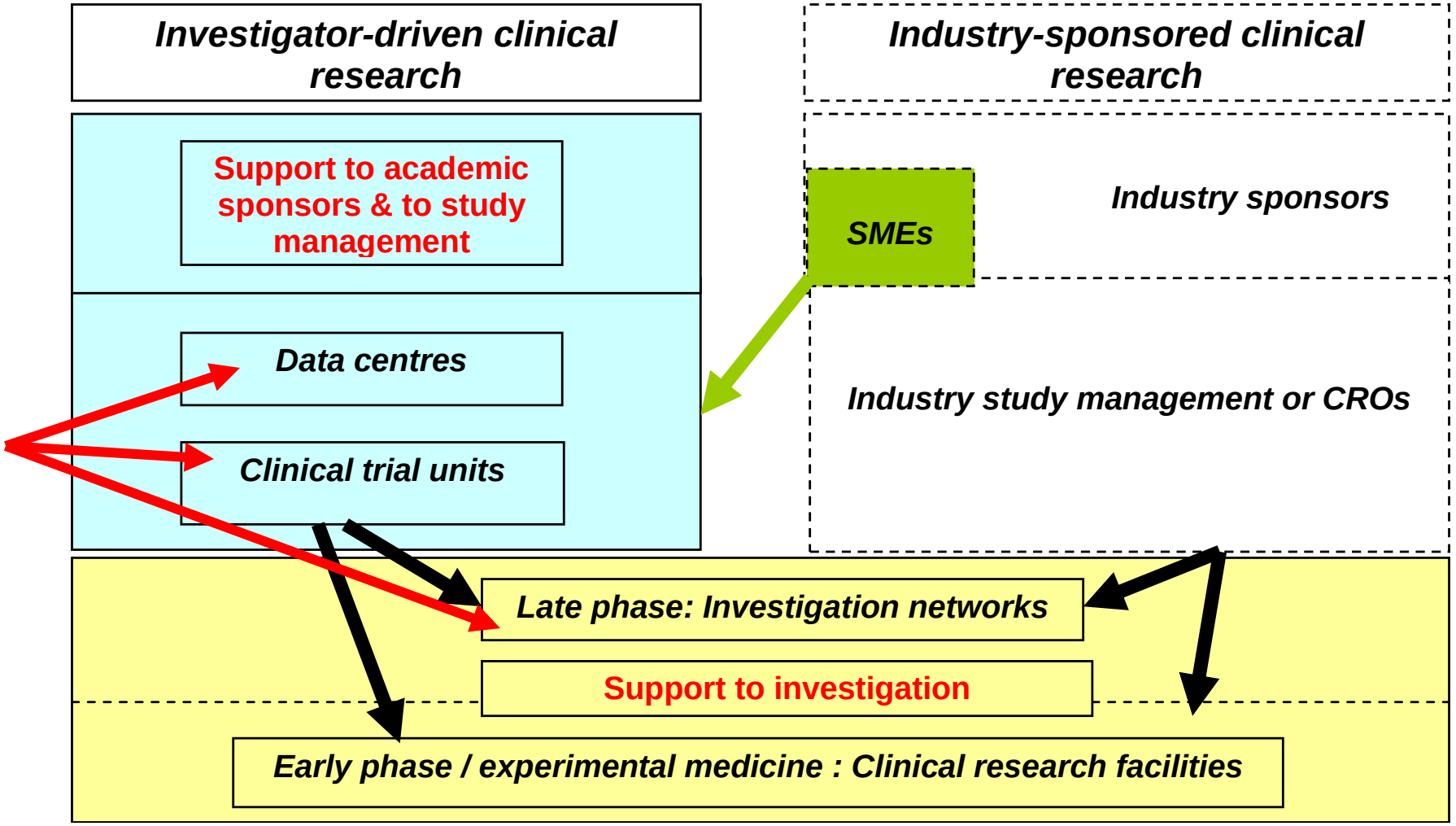
Permanent cooperation partner:
Surgical network (CHIR Net) represented by:
Study centre of the German Surgical Society

France



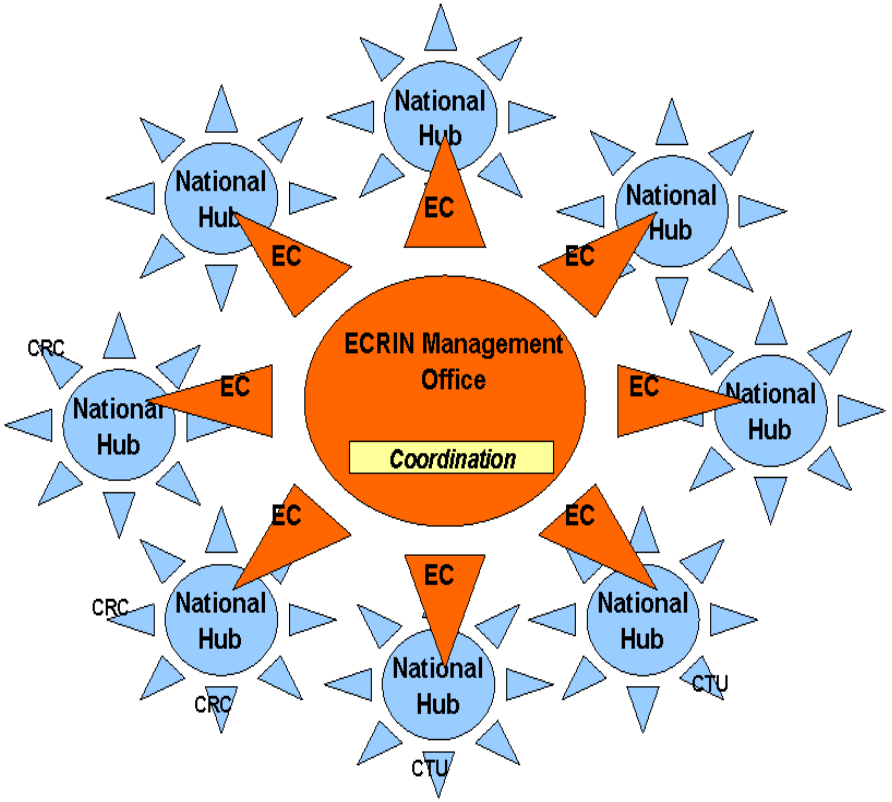
54 Clinical Investigation Centres with 8 main specialisations
(Cardiology, Diabetology, Gastro-hepatology, Neurosciences, Paediatry, Thrombosis, Vaccines, and Oncohaematology)

French partner : F-CRIN, supported by the infrastructure call of 'investissements d'avenir'



Network of European Correspondents

- Key contact point
- Act as a local relay in ECRIN activities
  - structuring
  - support
- Organisation and management of the pilot projects within the national coordination and in particular
  - maintaining updated knowledge
  - providing information and consulting
  - providing tools and documents for the set-up and management of multinational studies
  - coordinating the support and services



CRC= Clinical research centre
CTU= Clinical trial unit
EC= European Correspondent

transnational team

Core set of information and consultancy

during the preparation of the clinical research project

- Adaptation of protocol to local context
- Information on regulatory and ethical requirements
- Information on clinical trial sites and participant recruitment
- Information on clinical trials units
- Information on insurance
- Information on cost evaluation and funding opportunities
- Information on contracting

Core set of services

provided *during the conduct* of the project, after evaluation by the *Scientific Board*

- Submission to, and interaction with, competent authorities and ethics committees
- Support with insurance contracting
- Adverse event reporting
- Monitoring
- Data management
- Investigational medicinal product management

ECRIN data centres: certification process

Call for applications to become a pilot centre for the ECRIN Data Centre Certification Program

As part of the further development of the European Clinical Research Infrastructures Network (ECRIN), applications are invited from clinical trials units within the national networks linked to ECRIN, to become a pilot centre for certification as an ECRIN data centre, and to assist in evaluating the certification process.

First call issued on

1st June 2011

www.ecrin.org

Data Centre Certification Program

Application document to become an ECRIN Data Centre (Pilot)

Please complete this questionnaire and declaration and send it, with any associated documents, to ECRIN (the address is provided at the end of this document) by the **31st August 2011**.

A. Questionnaire

1. General Information

1.1. Name of centre or unit

1.2. ECRIN Scientific Partner Organisation *(e.g. national network)*

1.3. Centre web site

1.4a. Head of centre or unit

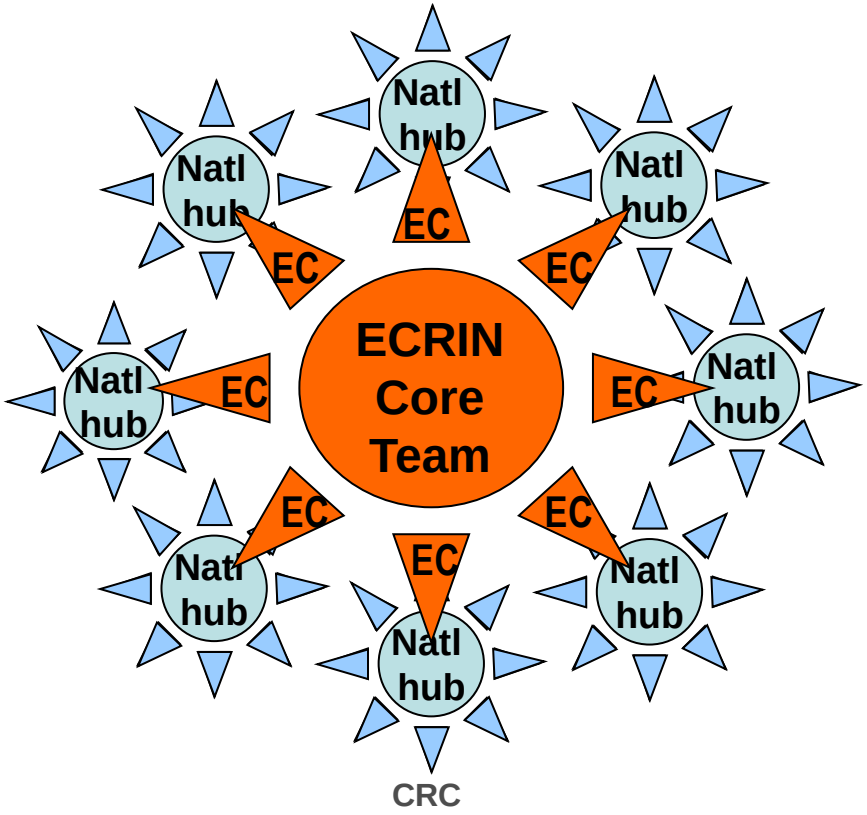
Name

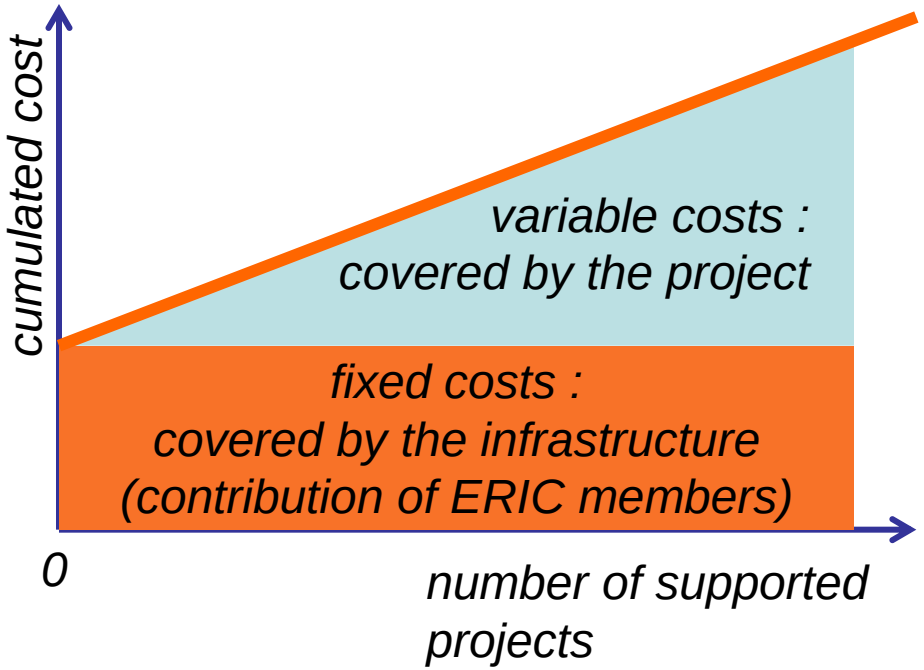
Address

ECRIN-ERIC business model

For non-economic activities
- plus limited economic activities (max 10-20%)

Infrastructure -> fixed costs
Project -> variable costs



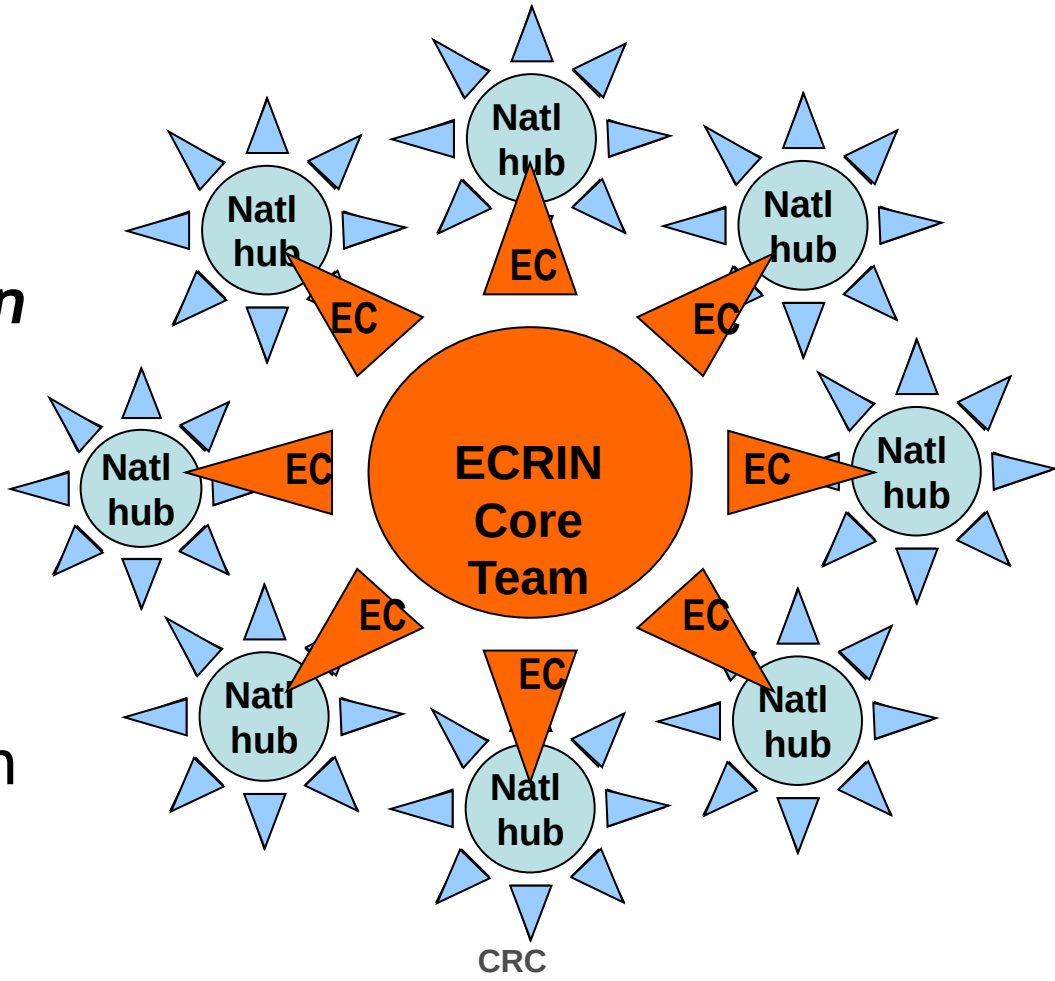


ERIC status
members = national ministries

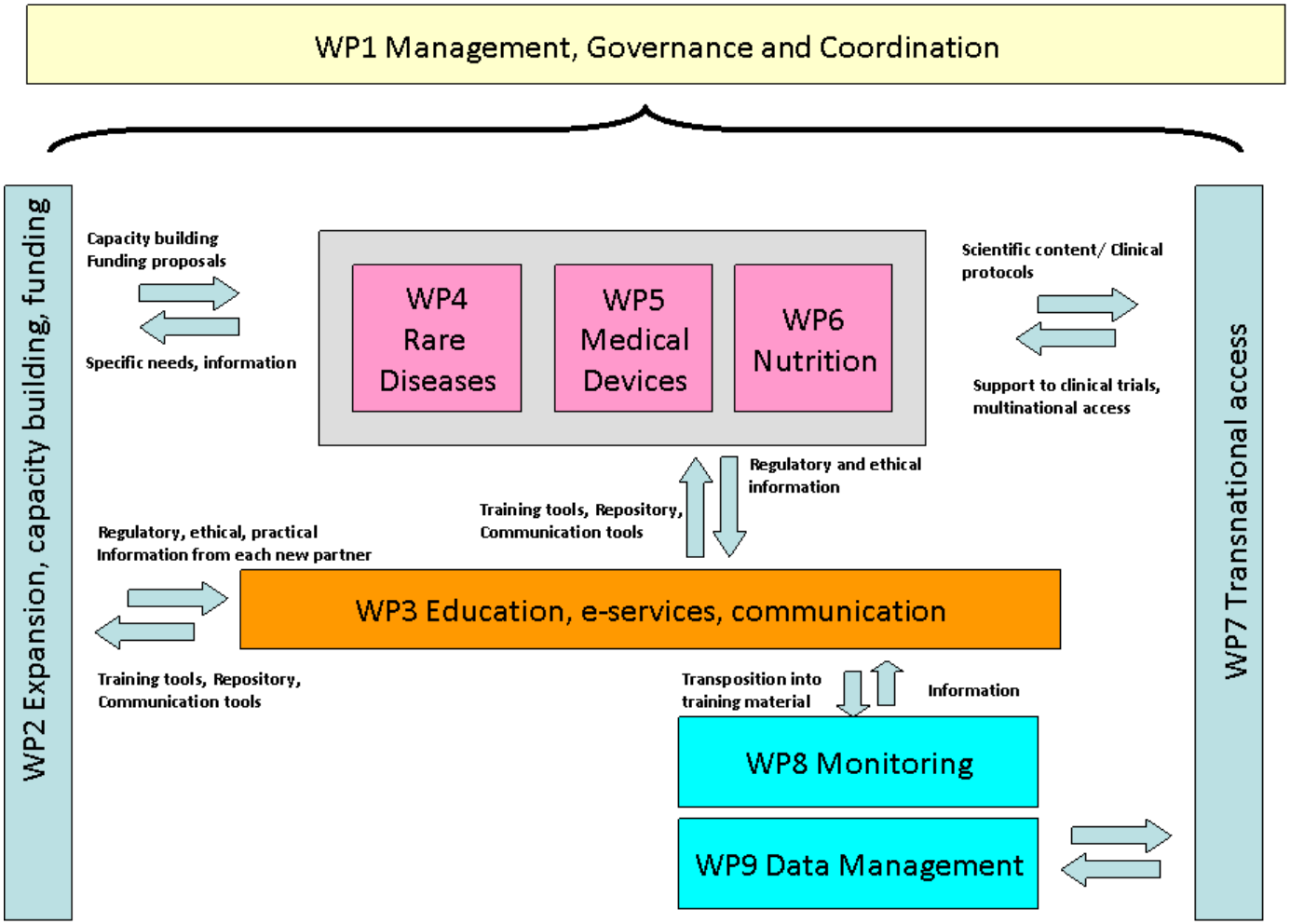
- ECRIN ERIC team
- national networks

Consortium agreements on

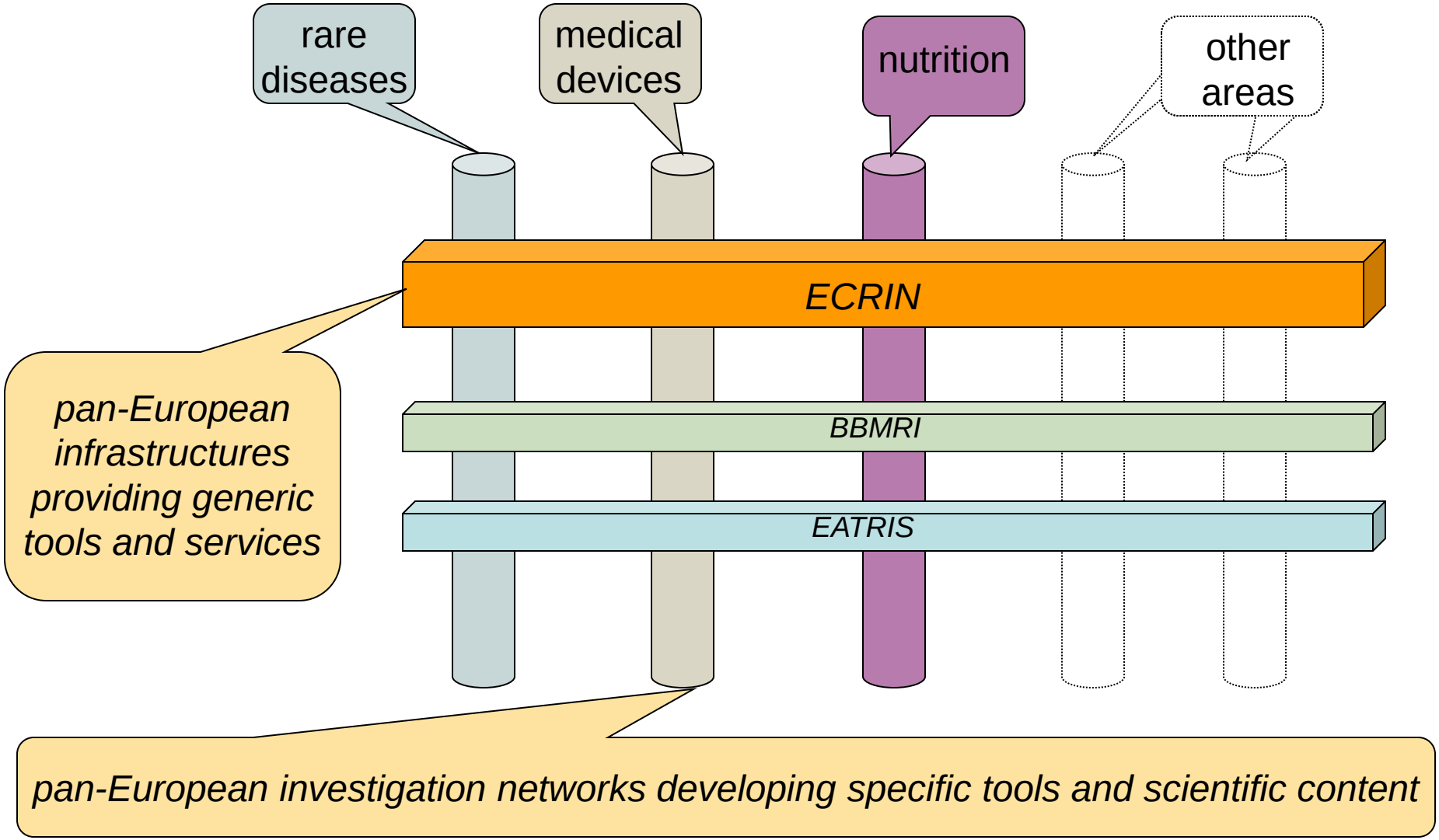
- Provision of services
- QA
- costs
- functional links between EuCo and hub



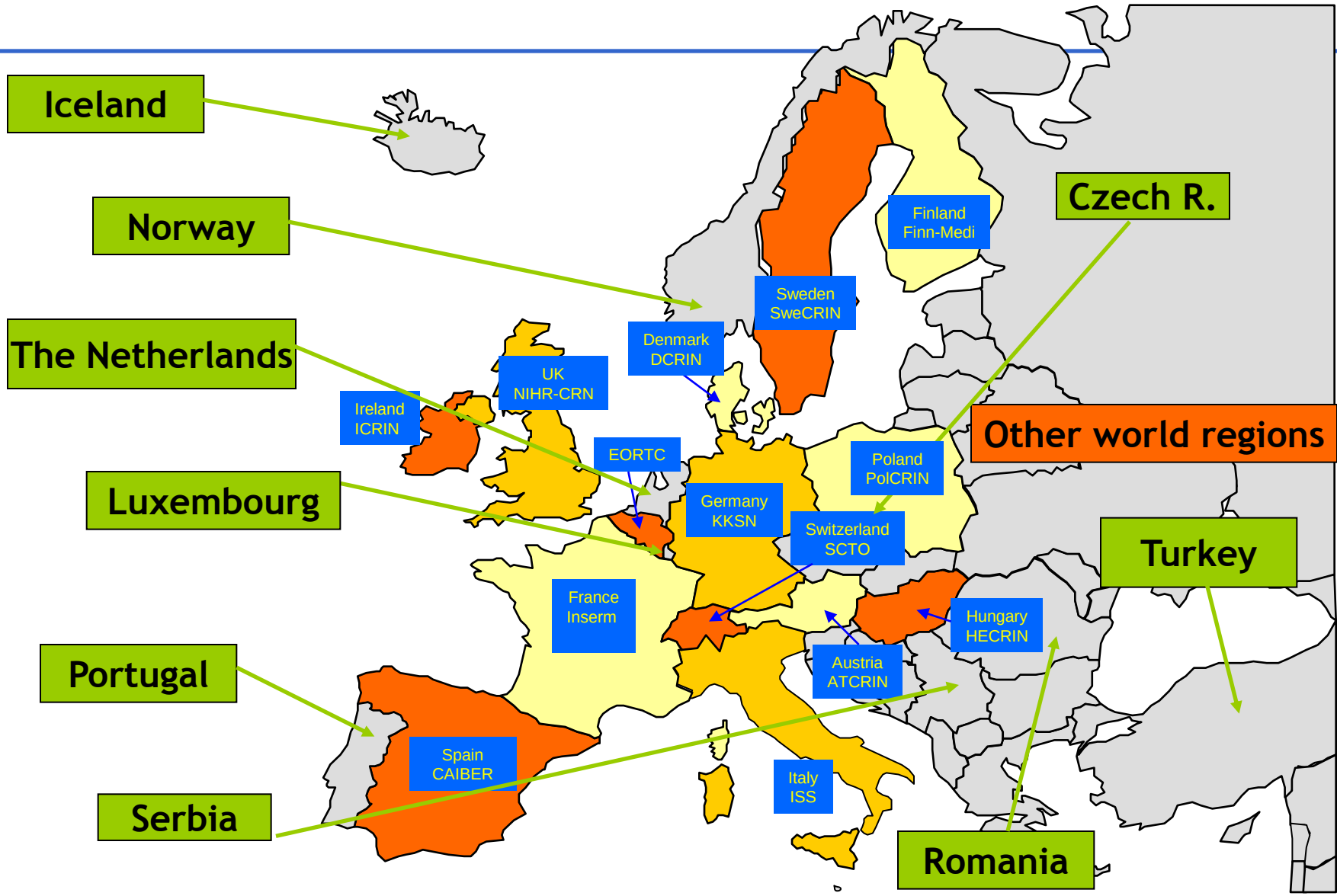
ECRIN-IA: structuring pan-European investigation networks



Pan-European structuring of biomedical research



ECRIN network and expansion



Funding to multinational trials

- **FP7 HEALTH.2011**
  - *Regenerative medicine clinical trials.*
  - *Investigator-driven clinical trials for childhood-onset neurodegenerative diseases.*
  - *Investigator-driven clinical trials for therapeutic interventions in the elderly populations.*
  - *Investigator-driven clinical trials of off-patent antibiotics.*
  - *Investigator-driven, treatment trials for rare cancers.*
  - *Investigator-driven clinical trials for the management of cardiovascular diseases.*
  - *Investigator-driven clinical trials to reduce diabetes complications.*
- **Other funding mechanisms ?**
  - Innovative Medicines Initiative
  - ERA-net ?
  - Joint programming ?
  - ECRIN-IA ‘transnational access‘ 3M€

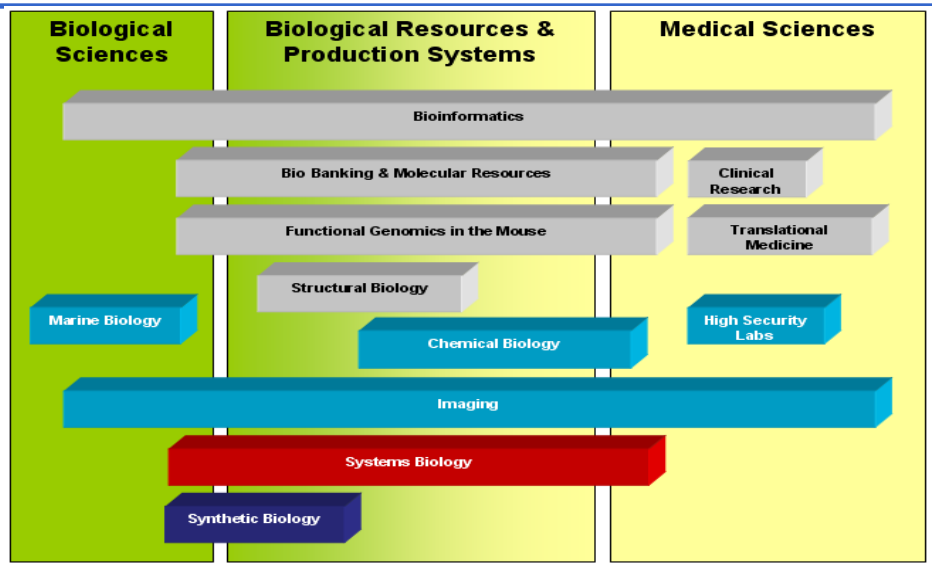
Involvement in training : European Medicines Research Training Network

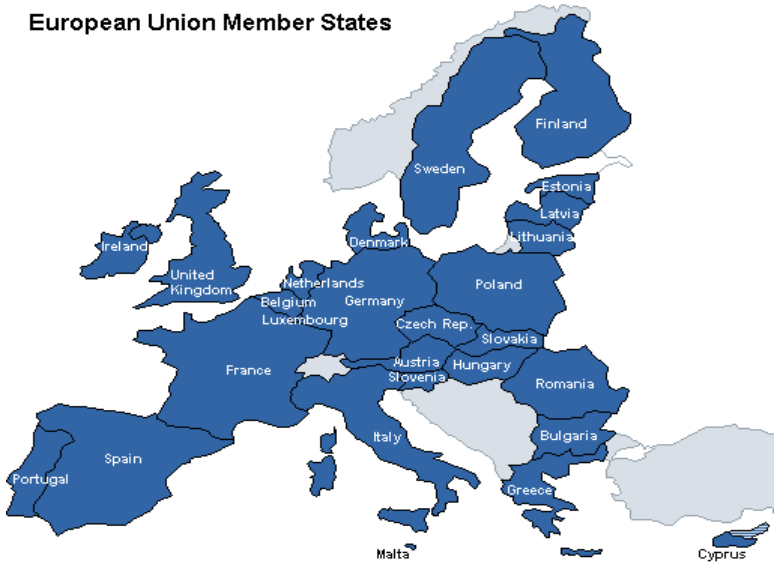
European education platform covering the whole life-cycle of medicines research, from basic science through clinical development

www.emtrain.eu

EMTRAIN develops a strategy and tools to train R&D professionals, bridging gaps between

- disciplines
- countries
- industry and academia





Impact on legislation : towards the revision of the 2001/20/EC Directive

- 2006 : Consultation on guidance « specific modalities for non-commercial trials »
  - different requirements depending on the sponsor ?
  - or different requirements depending on the risk ?

  Non-commercial sponsors: 12% phase I, 43% phase II, 73% phase IV

- FP7 ICREL project (2008): increased burden and costs
  www.efgcp.be/icrel

- ESF-EMRC Forward Looks on investigator-driven clinical trials (2008-2009) : risk-based approach, single clinical trial application

- Roadmap Initiative for Clinical Research in Europe (2009-2010)

- OECD GSF 'Working Group to Facilitate International Cooperation in Non-Commercial Clinical Trials'

Communication with patients and citizens, transparency in clinical research

- Promote public awareness of the challenges raised by clinical research
- Promote transparency
  - registration of trials protocols
  - reporting of clinical trials results
  - open access to raw, anonymised trials data
- Training of patients associations to clinical trials methodology
- Involvement of patients associations in protocol design

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Thank you !