What can investigators and trial coordination units expect from ECRIN?

KCE Trials Symposium- 12 October 2016

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

Christine Kubiak

Agenda

About ECRIN

How ECRIN supports trials?

International collaboration

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Context

Why ECRIN?

- Need for multinational trials
  - Greater access to patients, medical expertise and appropriate facilities
  - Higher methodological standards
  - Shared costs, tools and procedures
  - Potential for broad implementation of research outcomes
  - Avoidance of duplication of trials
- But several obstacles to multinational trials
  - Infrastructure interoperability, regulation, ethical review, insurance, contracts, management, cost models, funding, languages, etc.
- ECRIN as a solution
  - Provides support to sponsors in investigator-initiated trials
  - A pathway through Europe's fragmented health and legal systems

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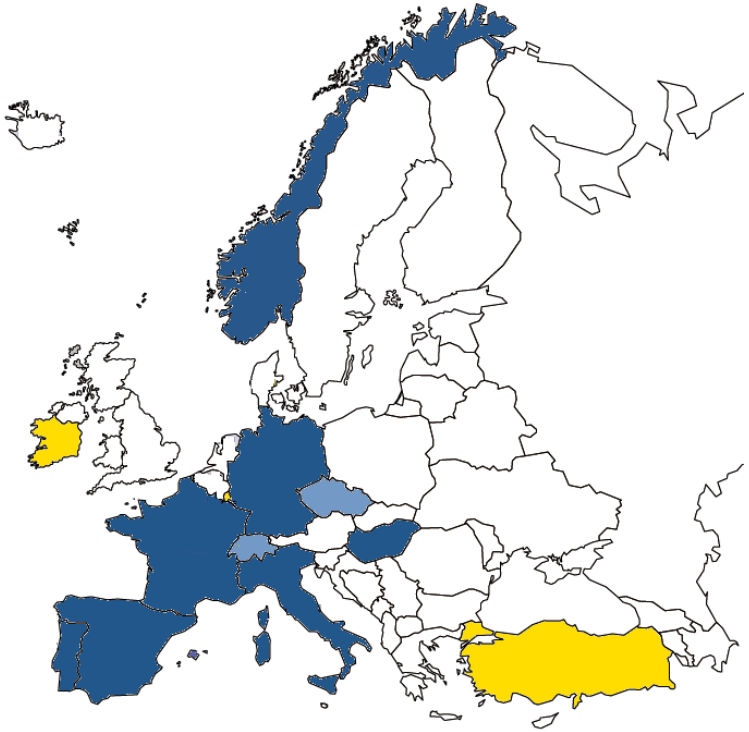
ECRIN

Overview

- A non-profit organisation with the legal status of European Research Infrastructure Consortium (ERIC)
- **Mission:** support the conduct of multinational clinical trials across Europe
- **Coordinated services from preparation to implementation**
- **9 Member and Observer Countries:** Czech Republic, France, Germany, Hungary, Italy, Norway, Portugal, Spain, Switzerland
  (additional countries about to join)



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History At A Glance

- **2004:** ECRIN created; began 1st project (EU Framework Program 6, FP6) on strategy development involving six countries
- **2006:** 2nd project (FP6) on tools development with 12 countries; listed on European Strategy Forum on Research Infrastructures (ESFRI) roadmap
- **2008:** 3rd project (FP7) with 14 countries to develop ECRIN's business plan and legal status
- **2012:** 4th project (FP7), ECRIN Integrating Activity (ECRIN-IA), with 23 countries to structure national scientific partners and build their capacity to manage multinational trials
- **2013:** Awarded ERIC status
- **2016:** Listed as an "ESFRI Landmark" on the updated ESFRI Roadmap

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BMS RIs
BIOLOGICAL AND MEDICAL SCIENCES RESEARCH INFRASTRUCTURES

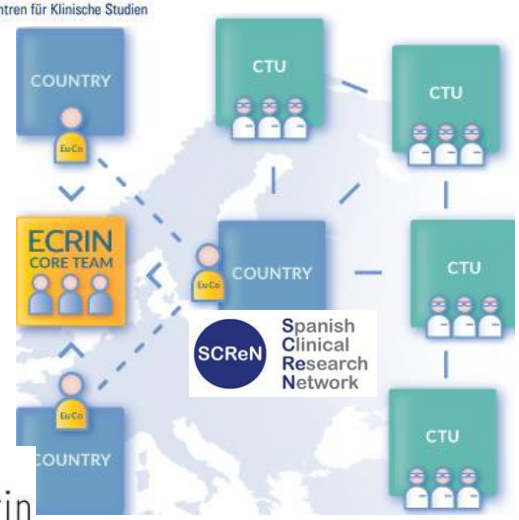
Platform covering the whole spectrum of research, discovery and development on health challenges : synergy and complementarity

Organisation: Distributed Infrastructure

Coordinating trials management provided by national partners

- **Core Team**
- **National Partners:** networks of clinical trial units (CTUs) able to manage trials in the country
- **National hub**
- **European Correspondents (EuCos):** hosted in national hubs (ECRIN staff)

KKS Netzwerk
Koordinierungszentren für Klinische Studien



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Fcrin
French Clinical Research Infrastructure Network

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Operational support to clinical trials

Coordinated Support from Preparation to Implementation

1 PREPARATION

ECRIN GIVES ADVICE AND INFORMATION ON:

- Funding sources and applications
- Investigation sites and patient recruitment
- Clinical trial units (location, services)
- Regulatory, ethical and insurance requirements
- Trial methodology
- Cost of trial management services

2 PROTOCOL REVIEW

ECRIN'S SCIENTIFIC BOARD AND EUROPEAN CORRESPONDENTS PROVIDE:

- Scientific and methodological evaluation of the full protocol
- Logistical assessment of project implementation plans

3 TRIAL MANAGEMENT

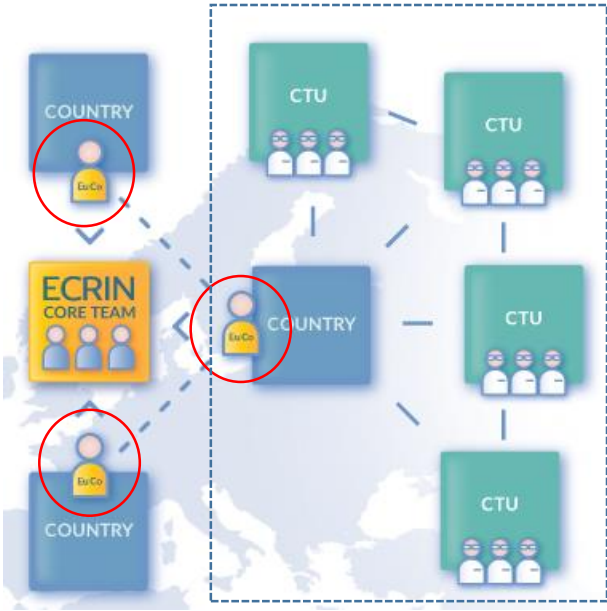
ECRIN COORDINATES AND SUPPORTS:

- Submissions to competent authorities and ethics committees
- Monitoring
- Adverse event reporting
- Data management
- Health product and biosample management

How it works?

European correspondents: Link Between ECRIN Core Team, National Scientific Partners, Countries, and Other Relevant Stakeholders

- Connected in a network
- Unique contact point for sponsors/coordinators
- Provide support during preparation and management of trials
- Oversee implementation of ECRIN's work (multinational trials, collaborative projects, tools development, partnership building, etc.) in their respective countries, managing the trial portfolio and coordinating with national partners



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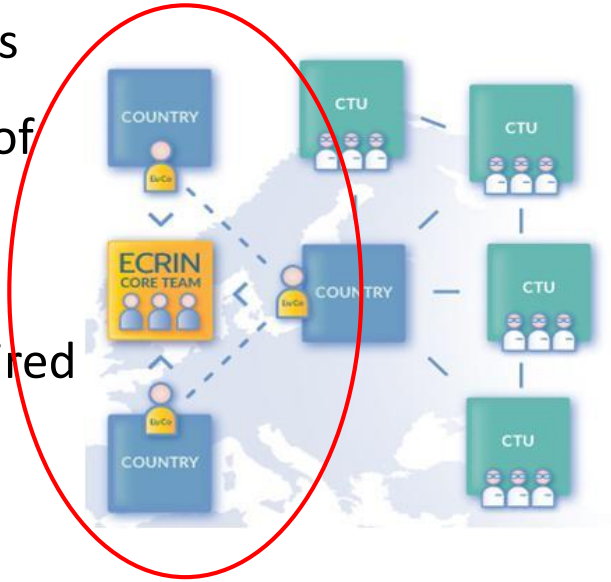
How it works?

- Support investigators in the preparation of applications for multinational funding: input on logistical and operational components
- Provide guidance on logistical and operational aspects of the trial focusing on: regulatory and ethical aspects, insurance, contracting, trial monitoring, costs
- Provide guidance on the definition of the services required
- Provide assistance on applications for ECRIN scientific and methodological evaluations
- Coordinate logistical assessments (assess the availability/feasibility of services , identify CTUs, lead cost calculation for defined services)



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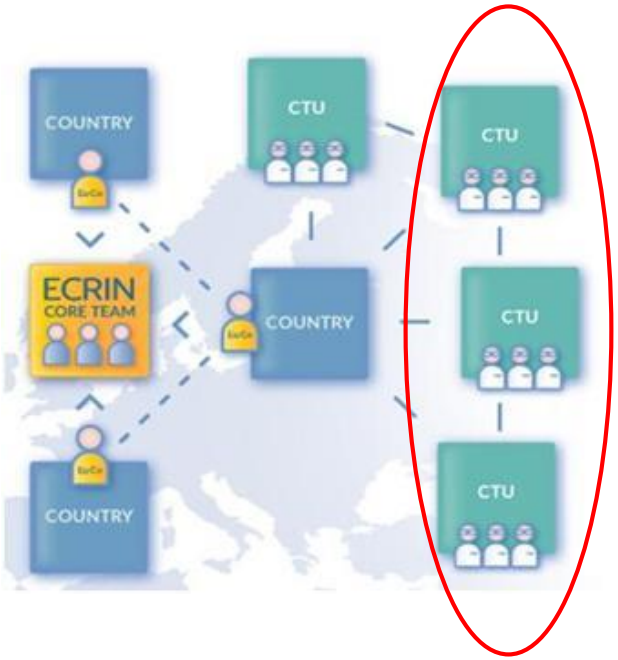
How it works?

3 TRIAL MANAGEMENT

- Organise communication between the sponsor, ECRIN and CTUs
- Coordinate the initiation and implementation of services performed by national partners
- Follow up on the provision of services by national partners according to the tasks, the timelines and the procedures of the trial and provide assistance in case of any issue



- Services provided by selected CTUs (national partners)

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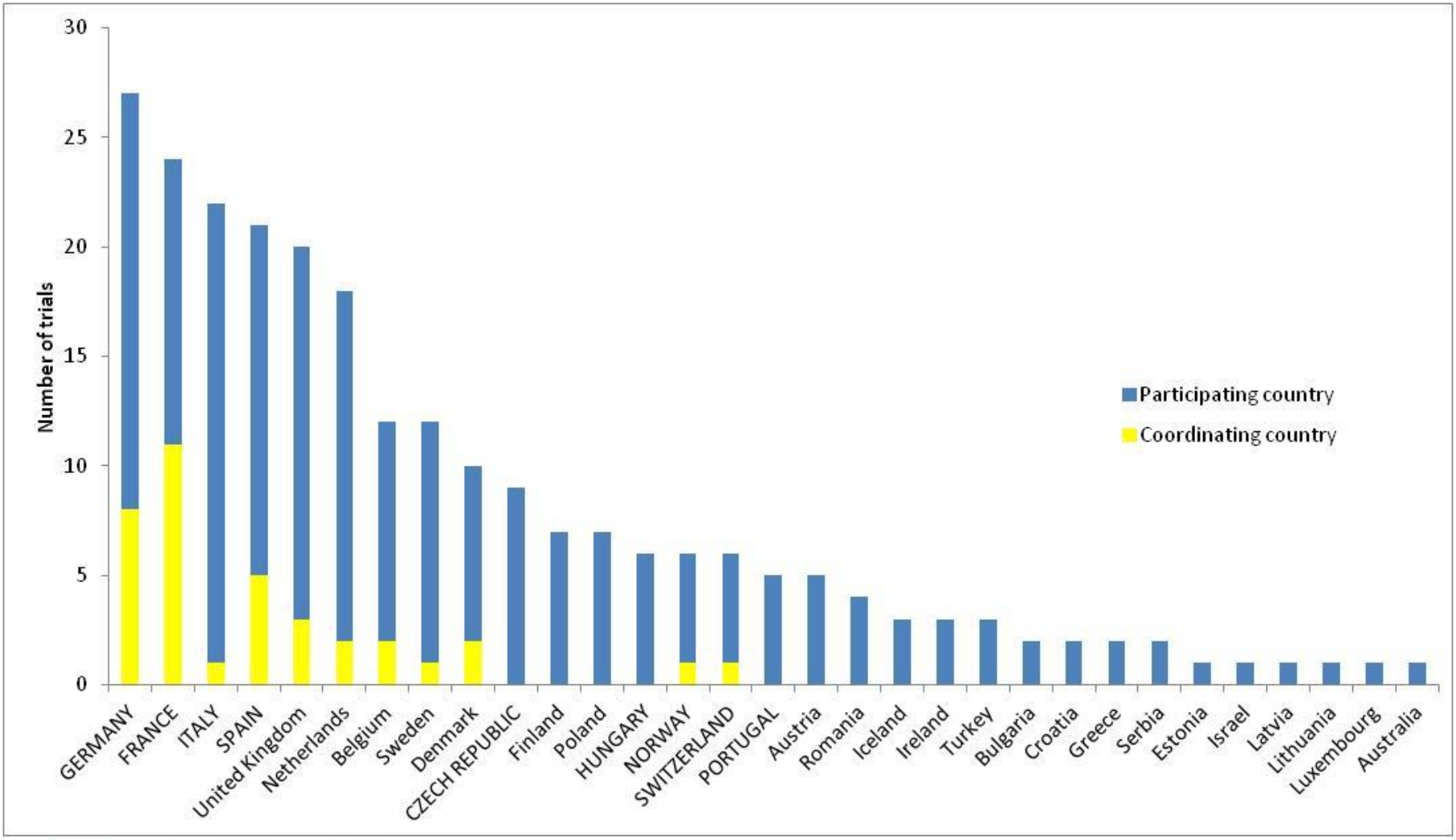
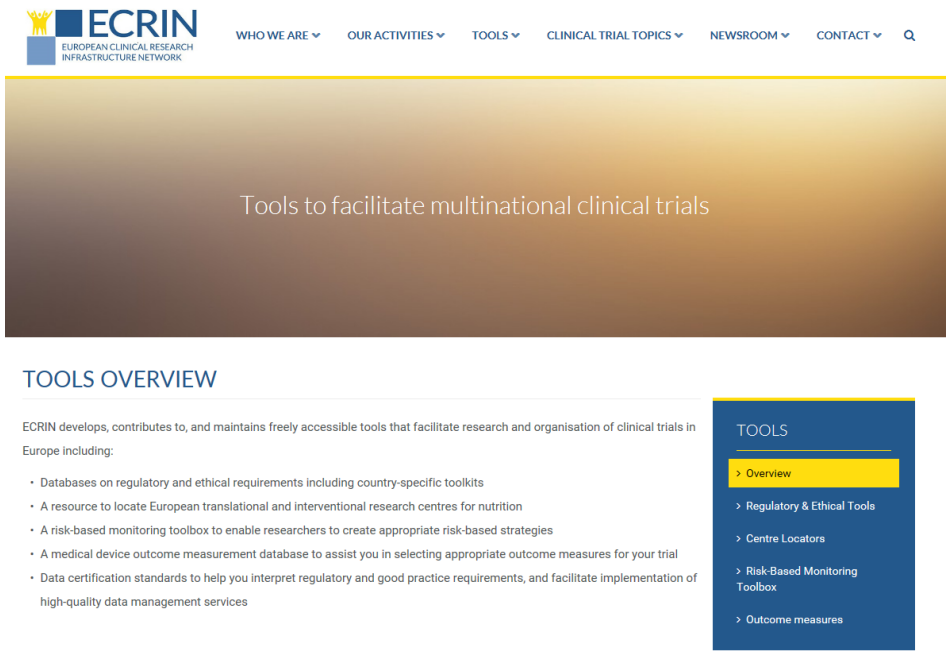
ECRIN trial portfolio

ECRIN is involved in information, advice and management services for 37 Trials (23 on-going or in preparation), with an average of 7 countries per trial



Tools to facilitate multinational trials



- **Regulatory and ethical database**
- **Quality management and data centre certification**
- **Risk based monitoring tool box**
- **Outcome measure data base**
- **Mapping of investigators sites**
- **Methodology guidelines**

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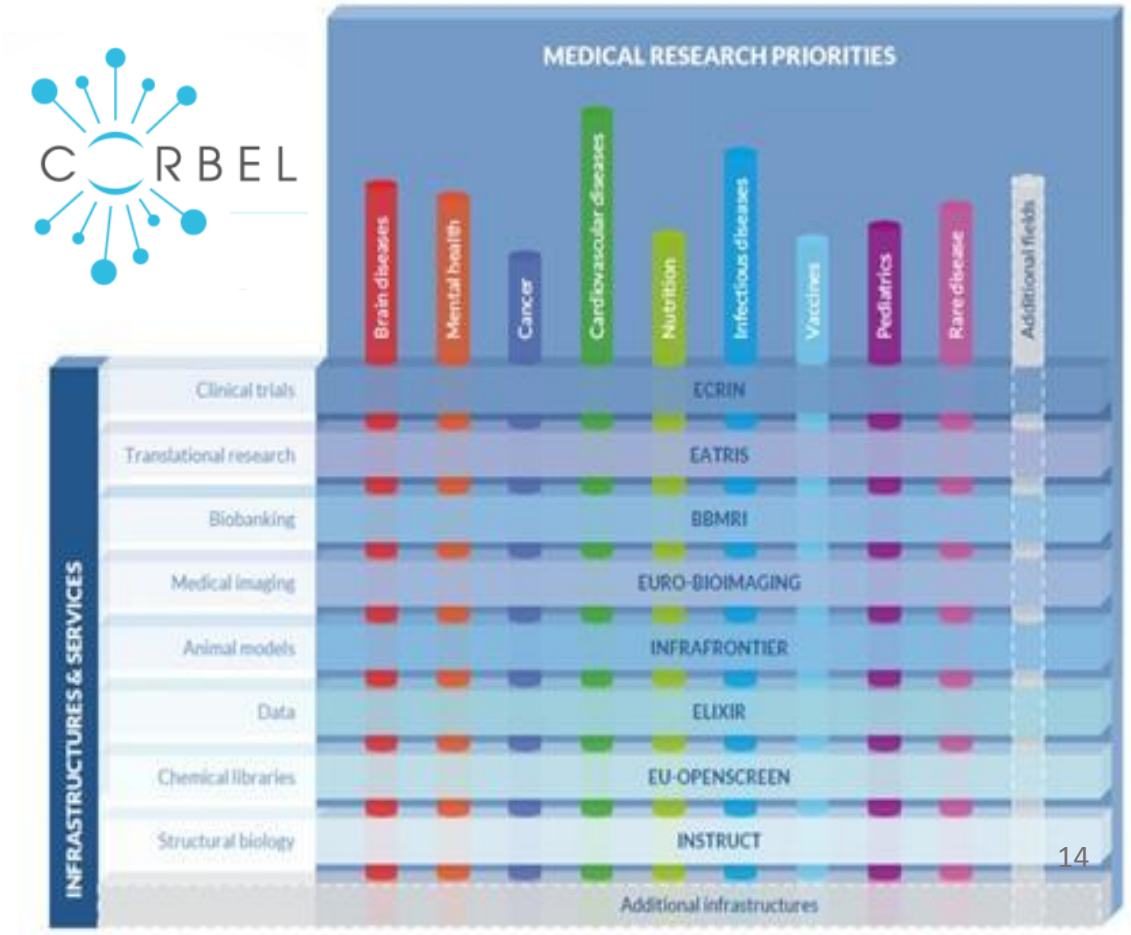
Partnership with medical research communities and medical research infrastructures

- Collaboration agreement with pan-European investigation networks (‘users')
- ECRIN-IA : structuring pan-European investigation communities (rare disease, medical device, nutrition)
- Coordinating ESFRI medical RIs & medical communities (Corbel WP3.1)



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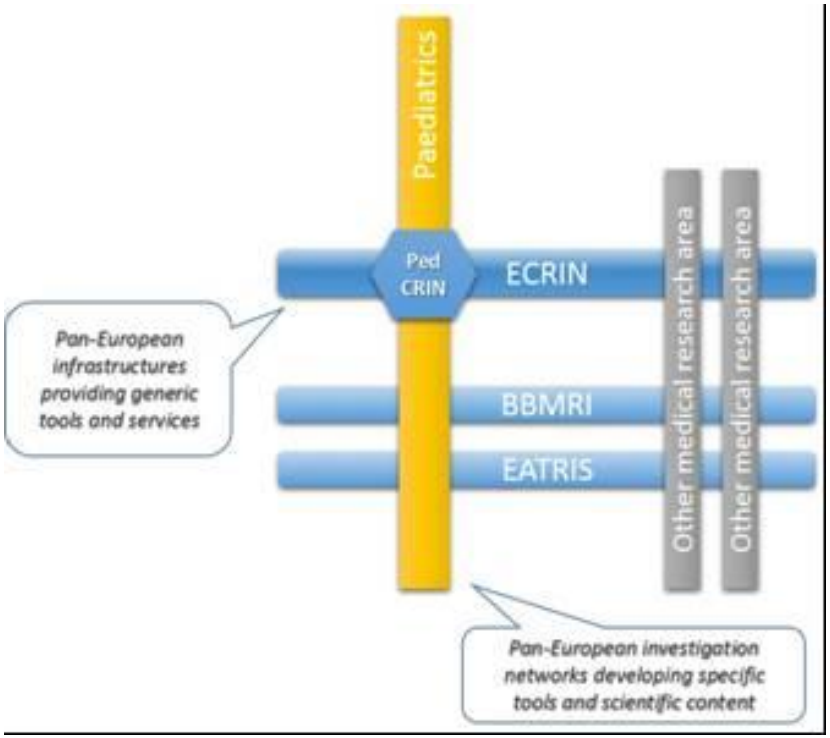
PEDCRIN project

Develop the management capacity for paediatric clinical trials

- **Develops specific tools**
  - Ethical and regulatory aspects
  - Outcome measures
  - Pharmacovigilance (adverse effects at various age groups)
  - Methodology for small sample size
  - Biosamples and analyses (small blood volumes)



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International partnerships

- Bilateral cooperation agreements
  - Therapeutic Innovation Australia
  - KoNECT Korea
  - National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH) (USA)
  - FIOCRUZ Brazil
  - FBRI, Japan
- Multilateral cooperation
  - CRIGH (follow-up OECD initiative)

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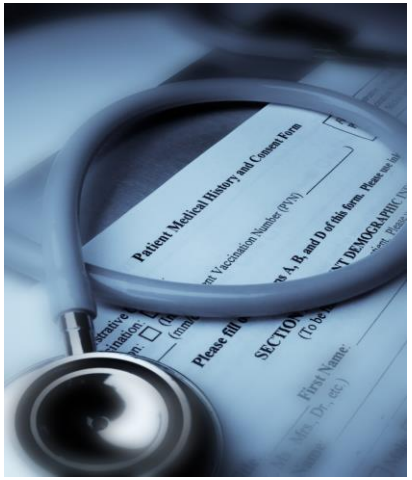
OECD Recommendation on the Governance of Clinical Trials



OECD

OECD Follow-up initiative : CRIGH

Clinical Research Initiative for Global Health

- Consortium broader than OECD countries (Ebola crisis !)
- Multilateral cooperation on
  - Infrastructure and funding
  - Global core competencies
  - Research ethics
  - Patient involvement
  - Comparative effectiveness research
  - Regulatory awareness
- OECD and WHO as partners
- Secretariat NIH + ECRIN
- Kick-off meeting 12&13th October 2016

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Thank you!

Any questions?

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