European Clinical Research Infrastructure Network (ECRIN) : operational services to the management of multinational clinical research

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International cooperation: industry-sponsored vs. academic trials

EU Commission funding

- 2004 ECRIN-RKP
- 2006 ECRIN-TWG
- 2008 ECRIN-PPI
- 2012 ECRIN-IA
- 2017 PedCRIN

National funding

- ECRIN-ERIC 2013
### ECRIN Members / Observers and national scientific partners

<table>
<thead>
<tr>
<th>Country</th>
<th>National hub</th>
<th>National CTU Network</th>
<th>Host Institution (linked third party)</th>
</tr>
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<tbody>
<tr>
<td>Czech Republic</td>
<td>Brno</td>
<td>CZECRIN</td>
<td>Masaryk University</td>
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<tr>
<td>Germany</td>
<td>Berlin</td>
<td>KKSN</td>
<td>KKSN Berlin</td>
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<tr>
<td>Spain</td>
<td>Barcelona</td>
<td>SCReN</td>
<td>ISCIII</td>
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<td>France</td>
<td>Toulouse</td>
<td>F-CRIN</td>
<td>INSERM</td>
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<td>Hungary</td>
<td>Pecs</td>
<td>HECRIN</td>
<td>University of Pecs</td>
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<td>Ireland</td>
<td>Dublin</td>
<td>CRCI</td>
<td>HRB</td>
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<td>Italy</td>
<td>Rome</td>
<td>ItaCRIN</td>
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<td>St Olaf Hospital</td>
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<td>Switzerland</td>
<td>Berne</td>
<td>SCTO</td>
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Distributed infrastructure, providing distributed services
ECRIN SUPPORT SERVICES

1. PREPARATION: ADVICE & INFORMATION
   - Trial design and methodology
   - Funding sources and costs
   - Investigation sites and patient recruitment
   - Task distribution for multinational trial management
   - Funding applications
   - Regulatory, ethical and insurance requirements

2. REVIEW: PROTOCOL & FEASIBILITY
   - Scientific and methodological evaluation of the protocol
   - Assessment of project implementation plans

3. IMPLEMENTATION: TRIAL MANAGEMENT
   - Project management and trial coordination
   - Clinical study authorisations (regulatory, ethical) and follow-up
     - Monitoring
     - Vigilance
     - Data management
     - Health product and biosample management
### Operational services, and tools for multinational trials

<table>
<thead>
<tr>
<th>ECRIN operational support</th>
<th>ECRIN tools</th>
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<tbody>
<tr>
<td>-&gt; Collaboration Committee</td>
<td>guidance on methodology / design</td>
</tr>
<tr>
<td>1 – Support to planning / design / funding</td>
<td>regulatory / ethics database (‘Campus’)</td>
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<tr>
<td>-&gt; Peer Review Committee</td>
<td>risk-based monitoring toolkit</td>
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<tr>
<td>2 – Protocol peer review, risk assessment</td>
<td>data centre certification</td>
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<tr>
<td>3 - ECRIN operational services</td>
<td>data sharing</td>
</tr>
<tr>
<td>➢ Distributed services</td>
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<tr>
<td>✔ regulatory-ethics approvals</td>
<td>✔ regulatory-ethics database (‘Campus’)</td>
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<tr>
<td>✔ study monitoring</td>
<td>✔ risk-based monitoring toolkit</td>
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<td>➢ Central services</td>
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<tr>
<td>✔ pharmacovigilance</td>
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<tr>
<td>✔ data management</td>
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ECRIN trial portfolio

> 50 trials, mean 6 countries per trial
Funding for multinational trials

- Instruct Ltd: 10
- CESSDA AS: 8
- INFRAFRONTIER GMBH: 16
- ELI-DC AISBL: 7
- ESS ERIC: 5
- ESS Neutron: 15
- JIV-ERIC: 4
- EATRIS ERIC: 30
- CLARIN ERIC: 8
- EMSO ERIC: 2
- CERIC-ERIC: 8
- SHARE ERIC: 5
- EURO-ARGO ERIC: 6
- ECRIN ERIC: 147
- DARIOH ERIC: 19
- ICOS ERIC: 8
- BBMRI-ERIC: 51
Partnership with medical specialty / investigation networks

EBRA
ECRAID
TRANSVAC
PedCRIN
c4c
EPTRI
EJP-RD
TB-Med
Digital revolution in clinical research
European Open Science Cloud, Health Research and Innovation Cloud

- Protocol design
- Site selection
  - patients?
  - investigator?
- Patient selection
- Informed consent
- Data from cohorts / registries
- Electronic health records
- Electronic data capture
- Data from national databases
- Data sharing for meta-analyses, re-analyses, secondary use

- Data reuse
- High-throughput –omics
- Imaging data
- Patient stratification studies
- Multimodal data management

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

International cooperation : CRIGH

- Clinical Research Initiative for Global Health
- Secretariat NIH + ECRIN (OECD and WHO partners)

6 projects
- Infrastructure and funding
- Global core competencies
- Research ethics
- Patient involvement
- Comparative effectiveness research
- Data management and data sharing

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