ECRIN
(European Clinical Research Infrastructures Network)

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What is ECRIN?

European Clinical Research Infrastructures Network

• Based on the connection of coordinating centres for national networks of clinical research centres and clinical trials units

• Pan-European, distributed infrastructure providing integrated services to multi-national clinical research in the EU

• Clinical trials services are coordinated by the ECRIN European correspondents and provided by national ECRIN partners
Objectives of ECRIN

• **Integration** of EU clinical research capacity
  - support to investigators
  - support to sponsors in multinational studies
  - unlocking latent potential: scientific, patients, ...

• **Harmonisation** of tools, training and practice
  - improved quality, credibility, transparency
  - ECRIN Data Centre Certification Program
  - requirements of GCP-compliant data management in multinational clinical trials

• **Harmonisation** of legislative systems (new EU Directive)
Objectives of ECRIN IA

• Expansion of ECRIN partnership and development in following areas
  - expanding the network and strengthening its national partners
  - supporting cross-border connection of investigation networks
  - further developing data management and monitoring

• Support of research structures in Europe that will act as strategic partners for a wide range of pan-European projects

• Transnational access: rare diseases, nutritional research, medical device trials

• Taking advantage of the ECRIN organisation, know-how, competences, procedures
Personalised medicine clinical trials with ECRIN (p-medicine)

- Rare diseases
- Medical devices
- Nutrition
- p-medicine

ECRIN

BBMRI

EATRIS

Pan-European investigation networks developing specific tools and scientific content

P-medicine develops tools and services for personalised cancer research

Data sharing

Pan-European infrastructures providing generic tools and services
Data management needs

- **Data management tools**
  - ICH-GCP compliance
  - EU regulatory context (Dir 2001/20/EC and 2005/28/EC)
  - Other (CDISC standard / interchange / guidelines)

- **Electronic Data Capture, electronic documents**
  - e-Case Report Forms (eCRF), e-Trial Master File (eTMF)
  - Electronic signatures (digital, biometric..)
  - Traceability of changes, query management
  - Long-term archiving (15 years)
  - Adaptation to multinational studies

- **Registration of clinical trials, Repository for clinical trial data** (raw data, anonymized)
Advanced data management needs

- Data exchange and interoperability
  - Bidirectional exchange of data with other biomedical research infrastructures, biobanks, genetic data, structural biology data, imaging data, toxicity data, safety data, animal model data

- Import of simulation data
  - Systems biology, VPH (oncobuilder)

- Interoperability of tools and services

- Exchange of data with the healthcare system
  - Data anonymization, pseudonymisation, aggregation, encryption
Data management problems

• Development and maintenance of an appropriate **data management environment** is a challenge for academic clinical trial units
• **Complexities** of running a IT / data management centre are underestimated
• Considerable **heterogeneity** in the use of different software products
• **Deficits** in **quality of data management** (e.g. computer system validation, data management audits)
Need for additional services

- Collaboration with research initiatives and other e-infrastructure
- Resulting enhanced need for data access and data sharing, data integration
- This increases the problems for data management in clinical trials
- Therefore a need for additional tools and services
Organisation of data in ECRIN community

- Central position of **clinical trial data base**
  - including electronic data capture, safety database, query generation, ...), electronic **Case Report Form (eCRF)**, GCP, pseudonymisation with the study participant ID

- **Data and documents** are stored centrally at the leading investigator site (TMF), and locally at all sites (ISF)

- **CRF paradigm** for clinical trial metadata

- Creation and certification of **ECRIN Data Centres**, support of European international trials

- **Cooperation** of ECRIN with the EU FP7 projects TRANSFoRm, p-medicine, EHR4CR and BioMedBridges, and disease networks
  - necessity of exchange data with care data registers, genetic and cancer databases, biobank databases (data privacy)
Example trial

From: cdisc.org
Wishes for a common layer of service

- Support of data exchange for international clinical trials
- Support of GCP clinical trials by ECRIN data centres (data services should be maintained by an ECRIN data centre, services must be validated for GCP and regulatory compliance)
- Independence of short software life cycles
- Support of clinical trials workflow (including safety reporting, data querying, remote monitoring, medicine logistics, electronic archiving,...)
- Easy to use by investigators in different European sites, easy to use by investigators from different research backgrounds
- Enabling the access and information exchange between care data registers, genetic databases, biobanks databases and imaging databases
- Support of data privacy and confidentiality in clinical trials
- Support of data standards like CDISC
Wishes for a common layer of service

- Support of efforts towards more transparency
  - Services implemented with means for protection of personal data
  - Adding to efforts to establish trial registries (e.g. www.clinicaltrials.gov) and data results repositories
    - Disclosure of the recruitment performance of sites
    - Disclosure of the full protocol with amendments
  - Access of the scientific community to the raw, anonymised data through an appropriate repository

- Supporting patient empowerment
Contact

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