ECRIN, infrastructure for multinational clinical trials in Europe

Authentication and authorization infrastructure needs

www.ecrin.org

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ECRIN, infrastructure for multinational trials

- **Mission:** support the conduct of multinational clinical trials across Europe

- **Services:** operational services to sponsors in the management of multinational trials: regulatory and ethics, adverse event reporting, monitoring, data management etc.

- **e-services:** access to tools (ex. regulatory database)

- **Access** to individual patient data: CORBEL WP3.3
Operational support to clinical trials

Services at non-profit cost for the management of multinational trials

**Preparation**
- Advice & Consultancy
  - Funding advice
  - Regulatory & ethical requirements
  - CTU identification
  - Site mapping & participant recruitment
  - Insurance requirements
  - Costs
  - Methodology

**Validation**
- Full Protocol Evaluation
  - Scientific & methodological evaluation
  - Logistical assessment

**Conduct**
- Services
  - Interactions with competent authorities & ethics committees
  - Monitoring
  - Insurance support
  - Adverse event reporting
  - Data management
  - Support organising health product and biosample management
Capacity: Tools for multinational trials

ECRIN Provides and Maintains Tools to Facilitate Research and Trial Organisation (see www.ecrin.org)

- Quality assurance / SOPs
- Data centre certification
- Regulatory and ethical database
- Methodology guidelines

- Outcome measure database
- Risk-based monitoring toolbox
- Mapping of investigation sites
- Training
- Communication
Authentication and authorization infrastructure needs

- E-services? open / restricted access?
  - Mapping sites, CTUs, quality documents etc.

- Access to individual patient data
  - Requirement = eligibility criteria
  - CORBEL WP3.3
  - Challenge: anonymisation, personal data protection, etc
  - Procedure: group consensus
  - IT solution?
  - Controlled access