
ECRIN (European Clinical Research Infrastructures Network)

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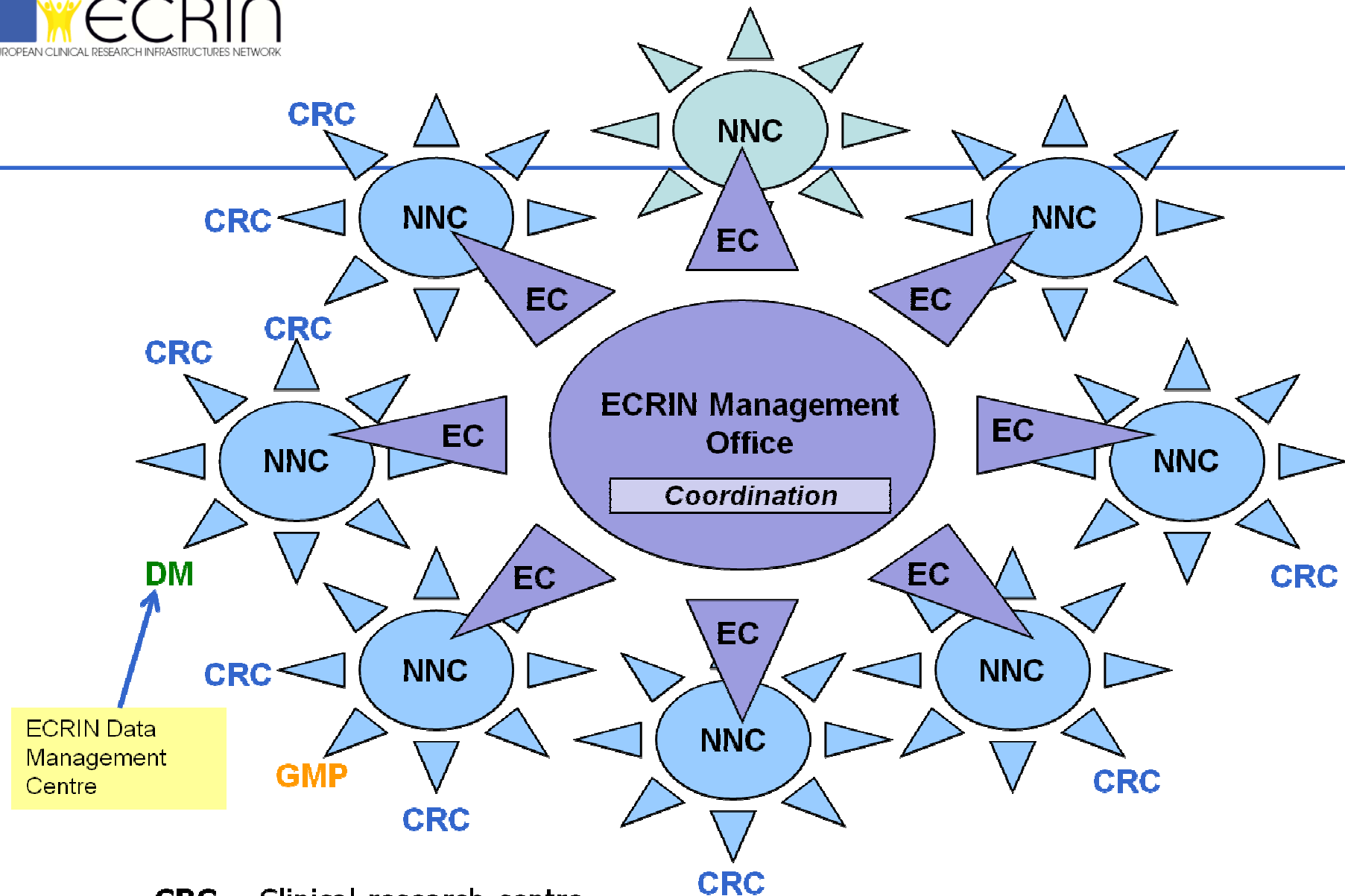
What is ECRIN?

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)



CRC = Clinical research centre

DM = Data centre

GMP = GMP facility for biotherapy

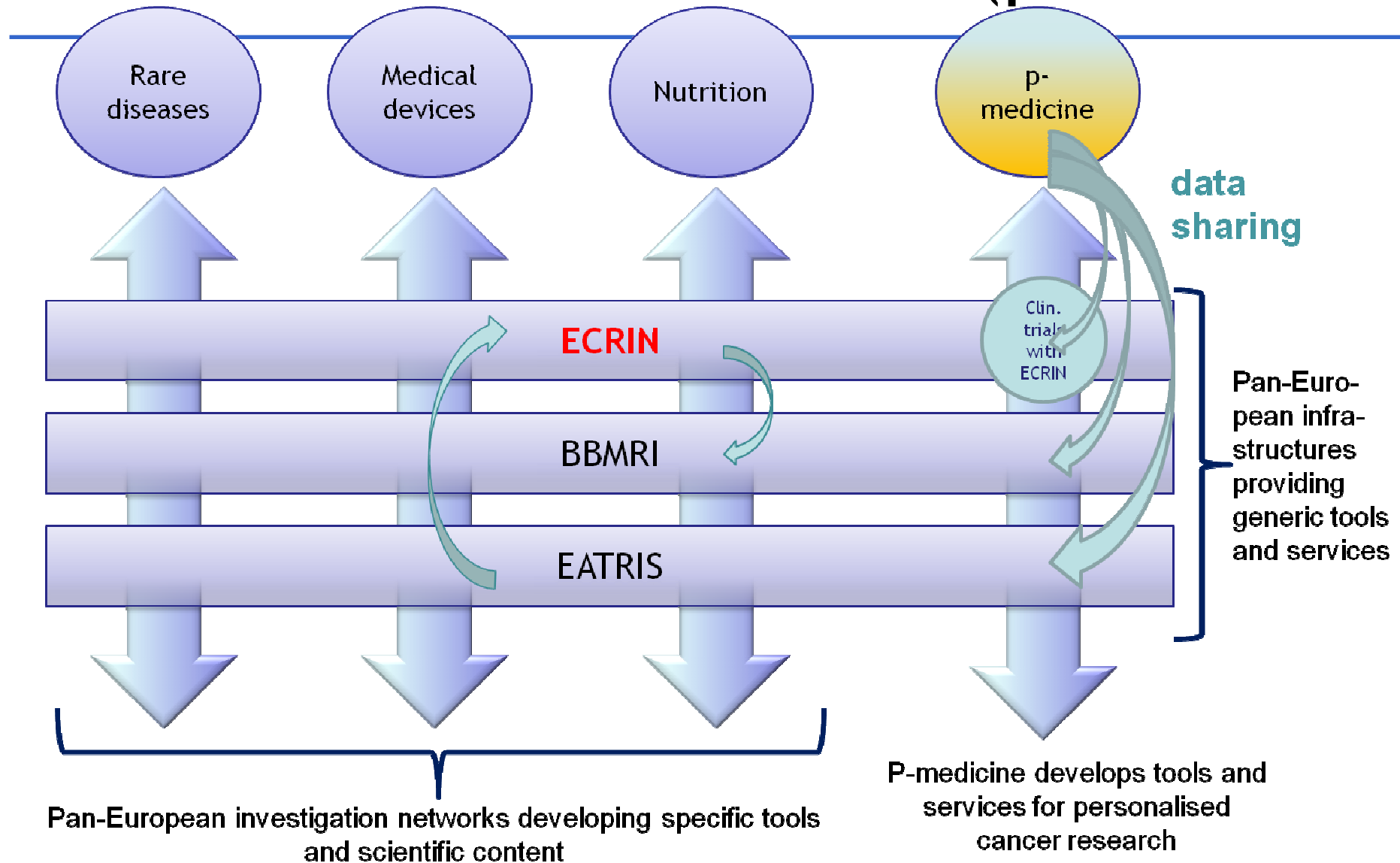
EC = European Correspondent

NNC = National Network Coordination

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)



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**
 - Interoperability between Clinical Data Management Systems, Document Management Systems, Biobank Access Systems, Laboratory Information System, Safety Systems
- Exchange of data with the **healthcare system**
 - Data anonymization, pseudonymisation, aggregation,

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)

CDISC ODM (XML)

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+ <SubjectData SubjectKey="{
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Site

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- <SubjectData SubjectKey="{  
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Visit

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- <StudyEventData StudyEventOID="SE.VISIT0">
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- <FormData FormOID="FORM.DEMOG">
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CRF form

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- <ItemGroupData ItemGroupOID="IG.DEMOG" ItemGroupRepeatKey="1">
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Data item group

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- <AuditRecord>
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</FormData>
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Data items

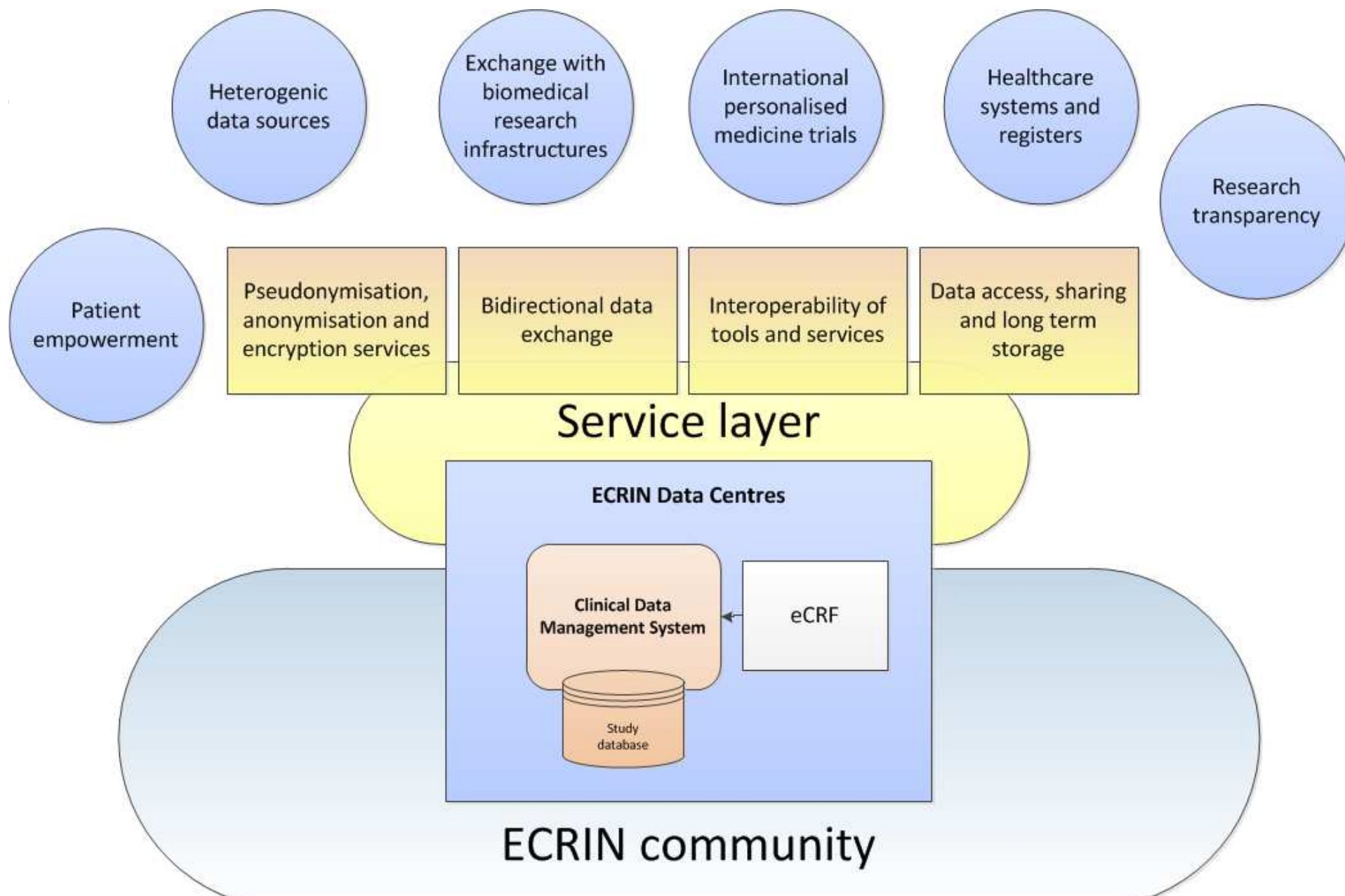
From: cdisc.org

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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