ECRIN
(European Clinical Research Infrastructures Network)

Wolfgang Kuchinke
University of Duesseldorf (HHU) and ECRIN

EUDAT 1st User Forum
7 March 2012 - 8 March 2012, Barcelona

What is ECRIN?

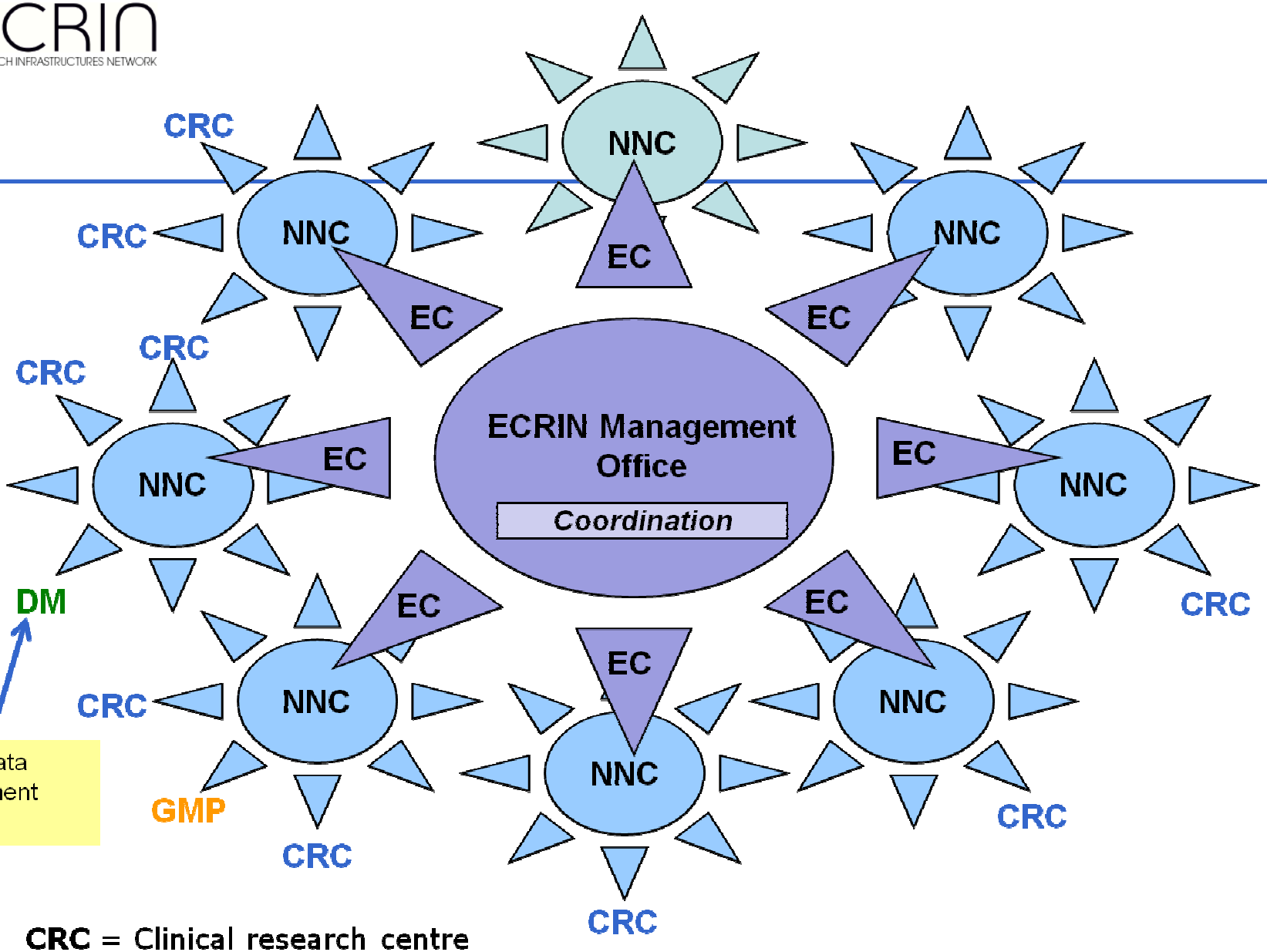
European Clinical Research Infrastructures Network

- 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)

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURES NETWORK



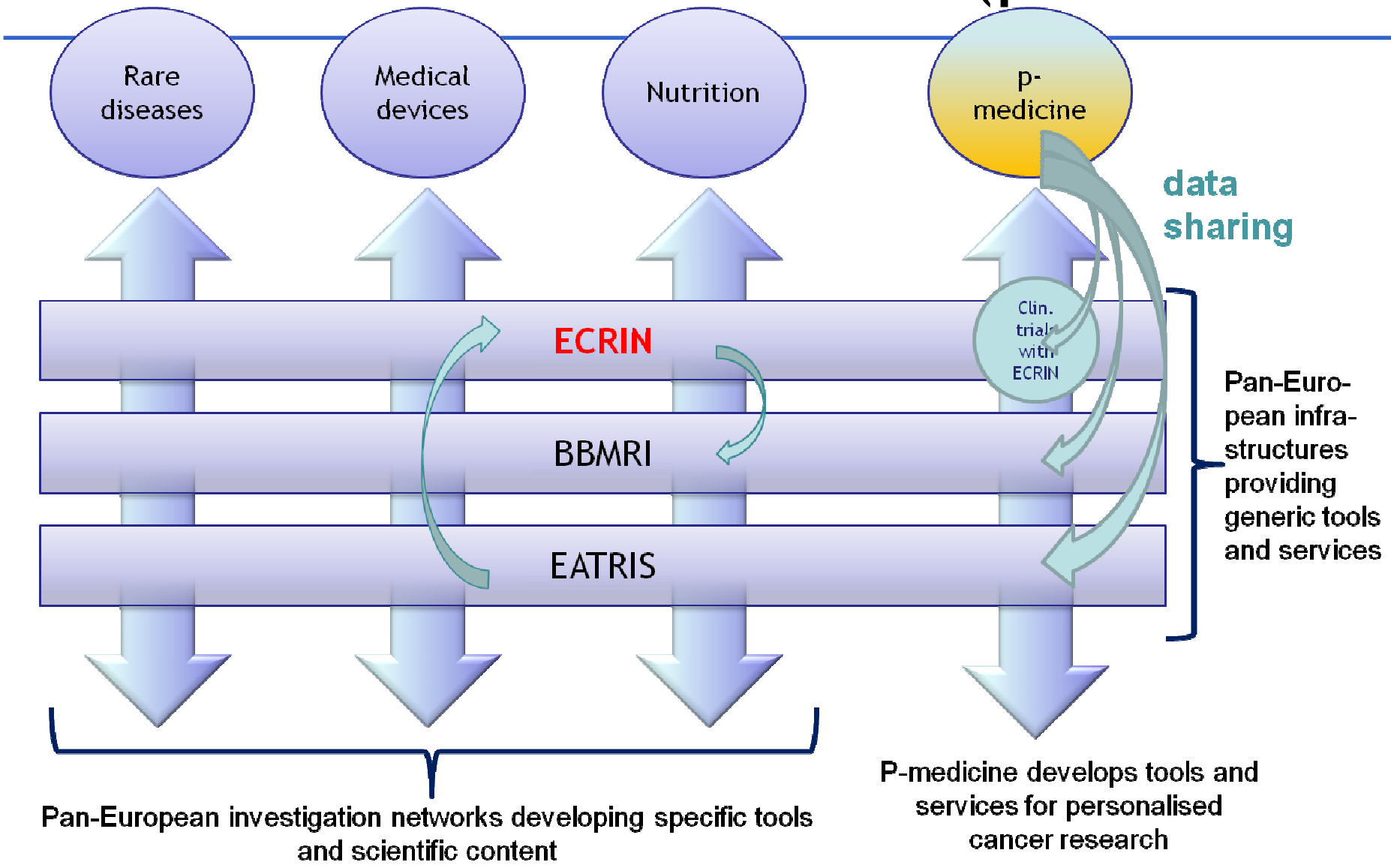
CRC = Clinical research centre
DM = Data centre
GMP = GMP facility for biotherapy

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 interoperabilty
  - 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, 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)

CDISC ODM (XML)

Example trial

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Site

Visit

CRF form

Data item group

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

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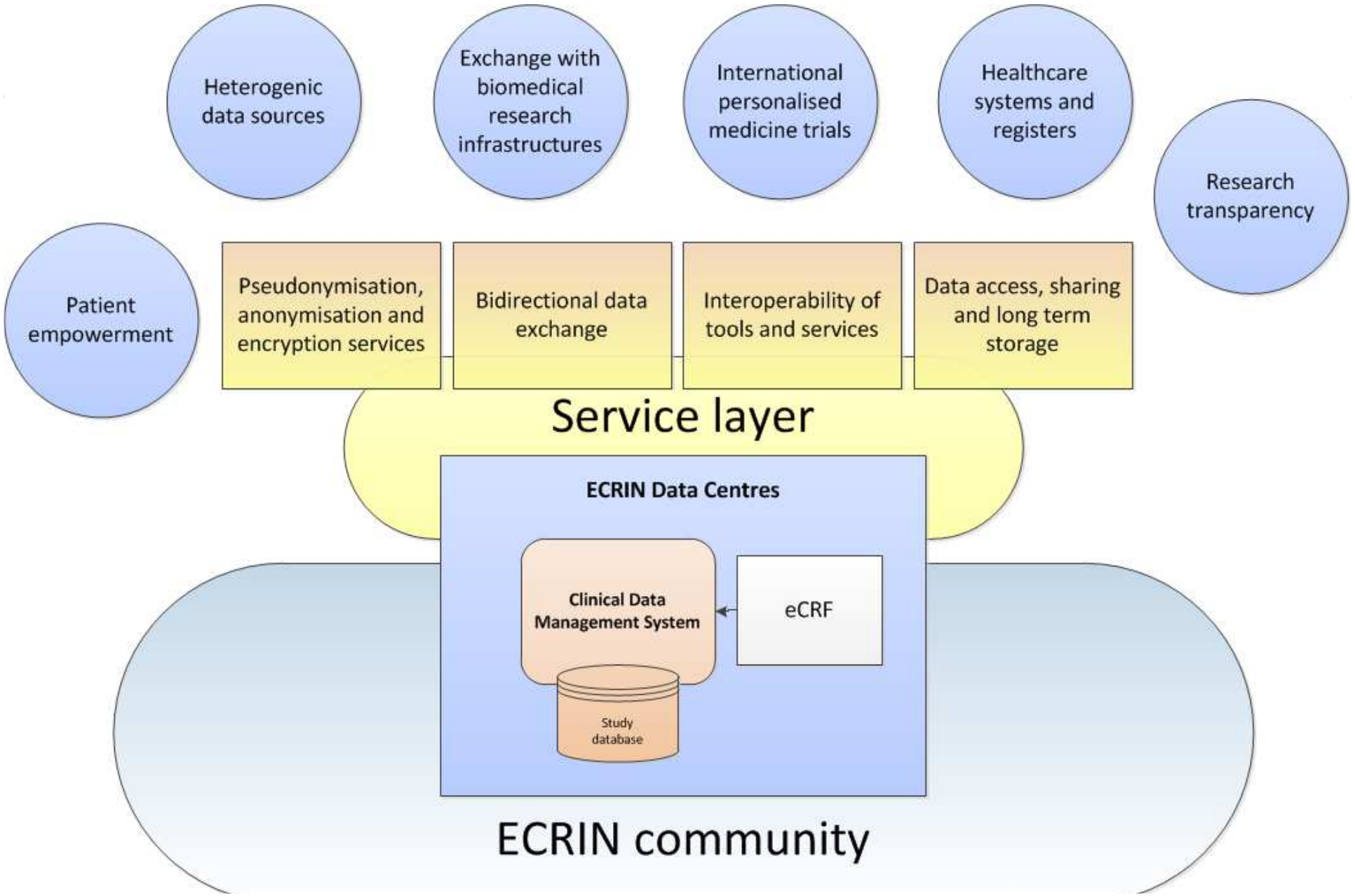

Contact

Wolfgang Kuchinke

ECRIN

KKS Duesseldorf, Heinrich-Heine University Duesseldorf,

Medical Faculty, Moorenstr. 5, 40225 Duesseldorf, Germany

kuchinke@med.uni-duesseldorf.de

www.transformproject.eu

www.p-medicine.eu/

www.ecrin.org