AlmaHealthDB

A reference architecture for biomedical research

Sabato Mellone

Dipartimento di Ingegneria dell'Energia Elettrica e dell'Informazione "Guglielmo Marconi"

AlmaHealthDB

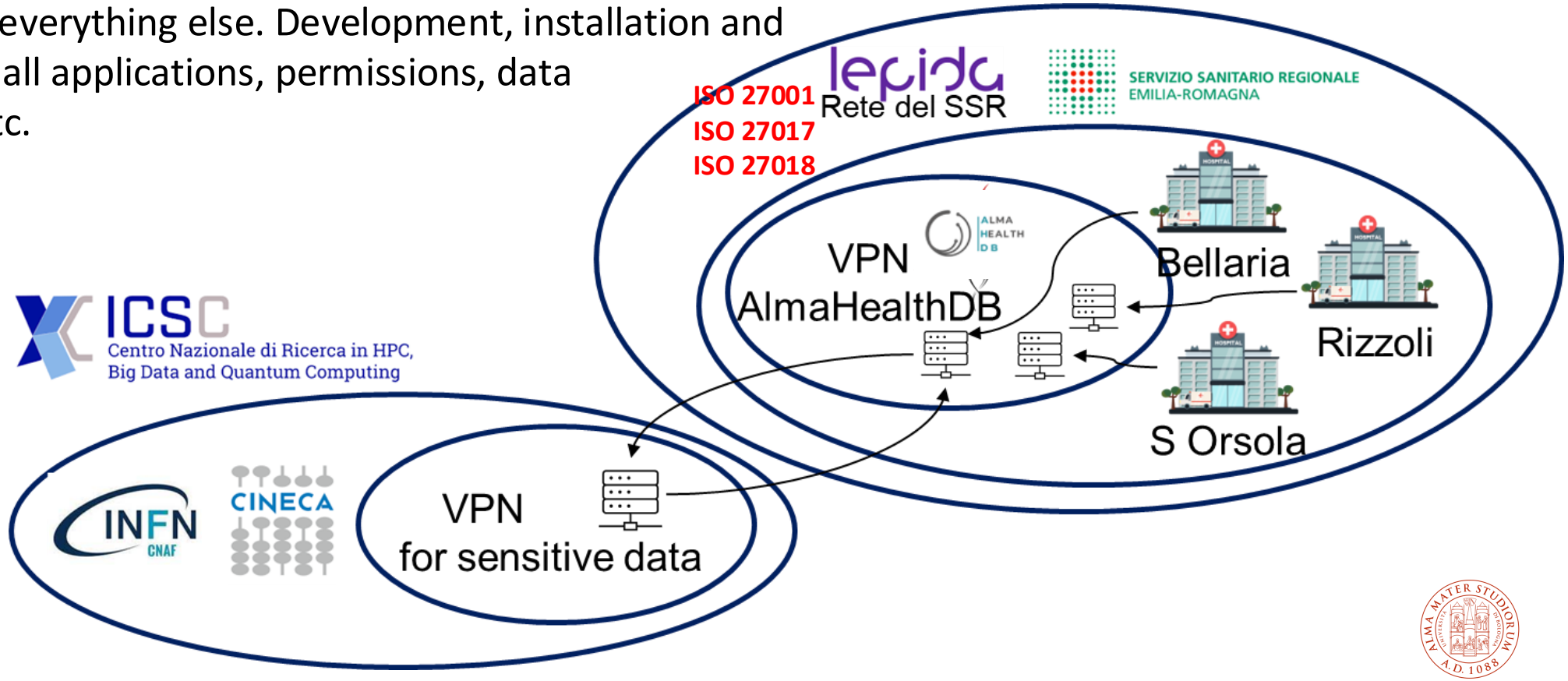
- **What:** IT and procedural enabling infrastructure.
- **Why:** Enable the use and reuse of clinical data for biomedical research purposes within the limits dictated by applicable laws.
- **Who:** the University of Bologna and the three research hospitals in Bologna: the Rizzoli Orthopaedic Institute, the Institute of Neurological Sciences (Bellaria), and the Bologna University Hospital (S. Orsola).
- **Where:** operates as a sub-network of the regional health service network on IT systems managed by Lepida, in-house of the Emilia Romagna Region.

Infrastructure

Roles and responsibilities:

- **LEPIDA: manages** network security (firewall), manages daily backups (15-day history), manages routine machine maintenance, disk encryption, disaster recovery.

- **AlmaHealthDB**: everything else. Development, installation and management of all applications, permissions, data management, etc.

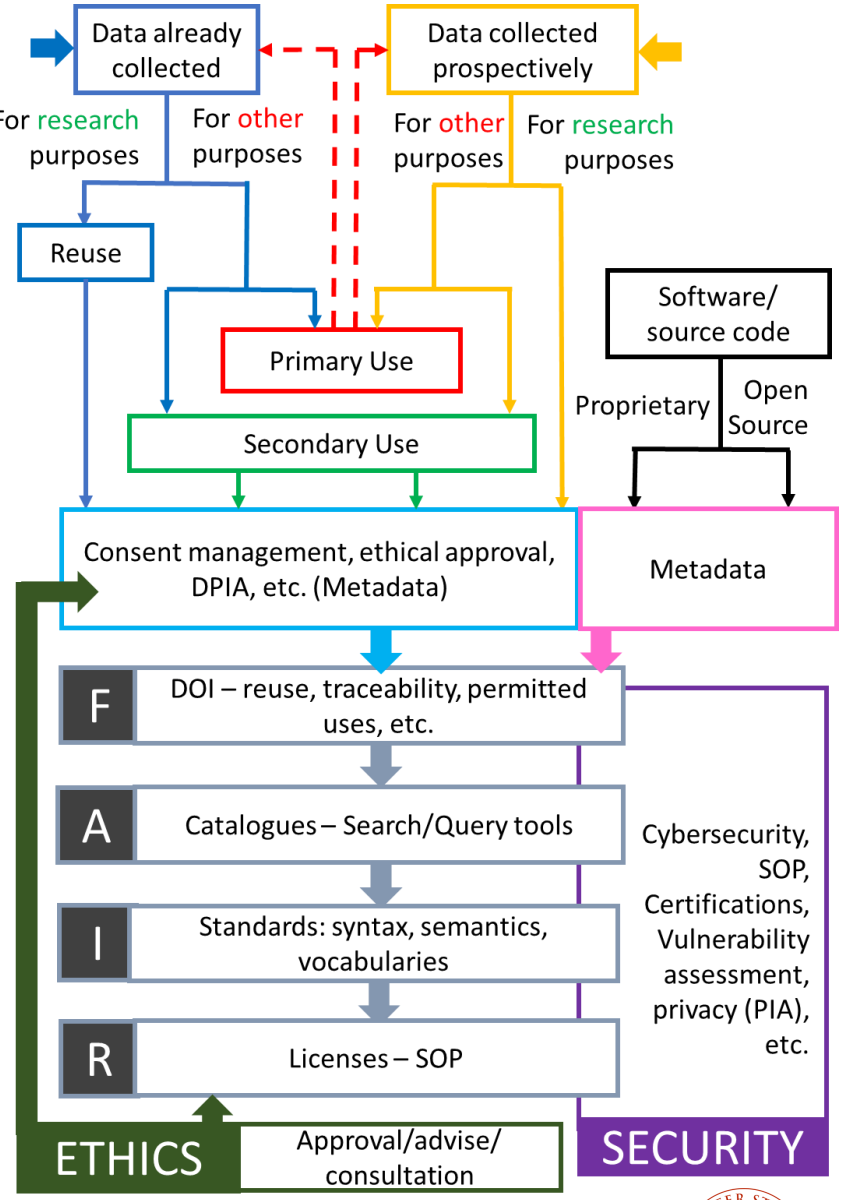


Legal basis for processing

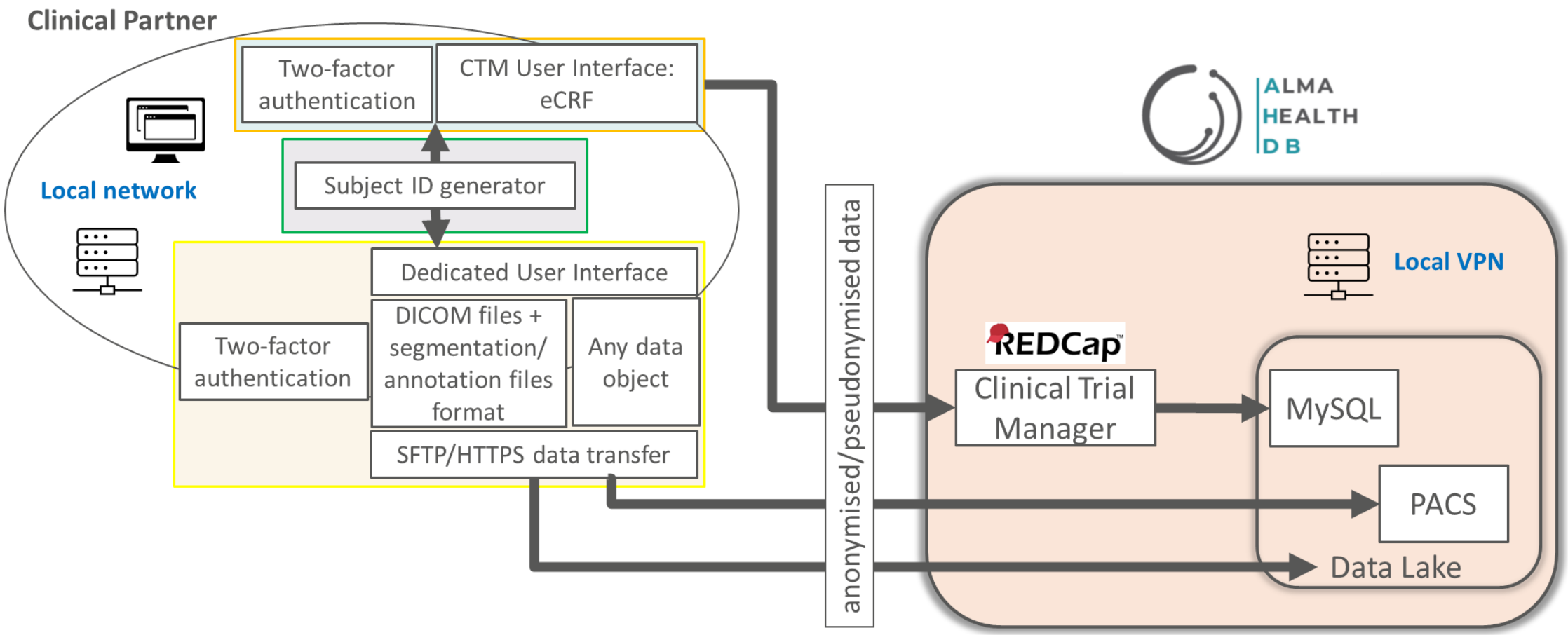
- **Retrospective and Prospective Studies with Informed Consent**
- **Retrospective Studies without Informed Consent**: Allowed only for IRCCS on topics related to their recognized scientific area (Article 110-bis, paragraph 4 of Legislative Decree 196/2003)
- **Legislation Under Review**: Data Act, Data Governance Act, AI Act, EHDS, etc.

Infrastructure

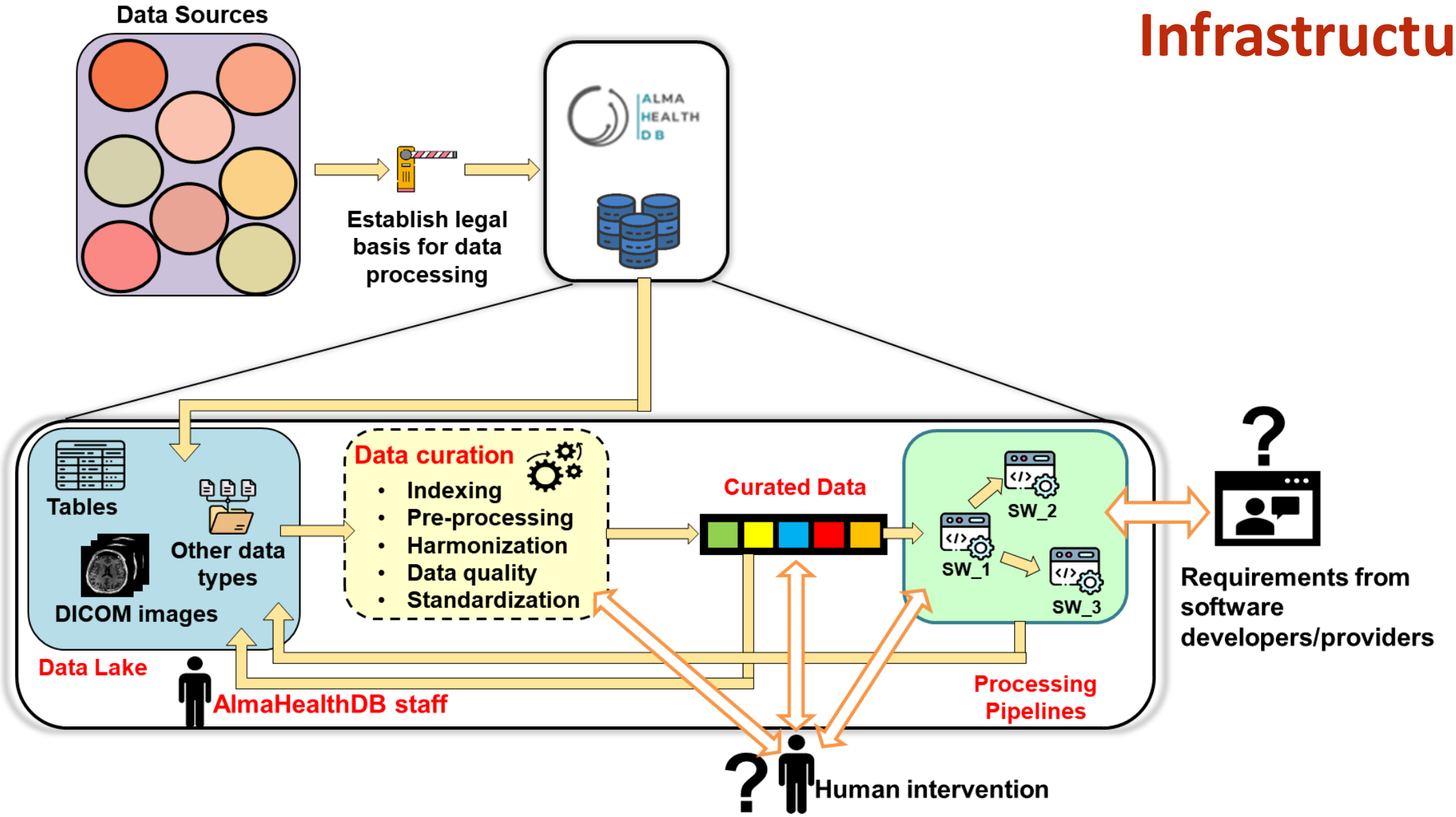
- Organizational measures: governing bodies and DPOs of the three research hospitals in Bologna and UNIBO approved a series of Standardized Operating Procedures (SOP) governing the management of the infrastructure.
- A technical-legal permanent table oversee the management of the infrastructure and SOP application. Input data undergoes an assessment process which establishes its origin, permitted uses, the presence of valid consents and authorizations, and conditions for processing. Outcomes of this assessment process are coded into a set of standardized metadata that is associated with the input data.



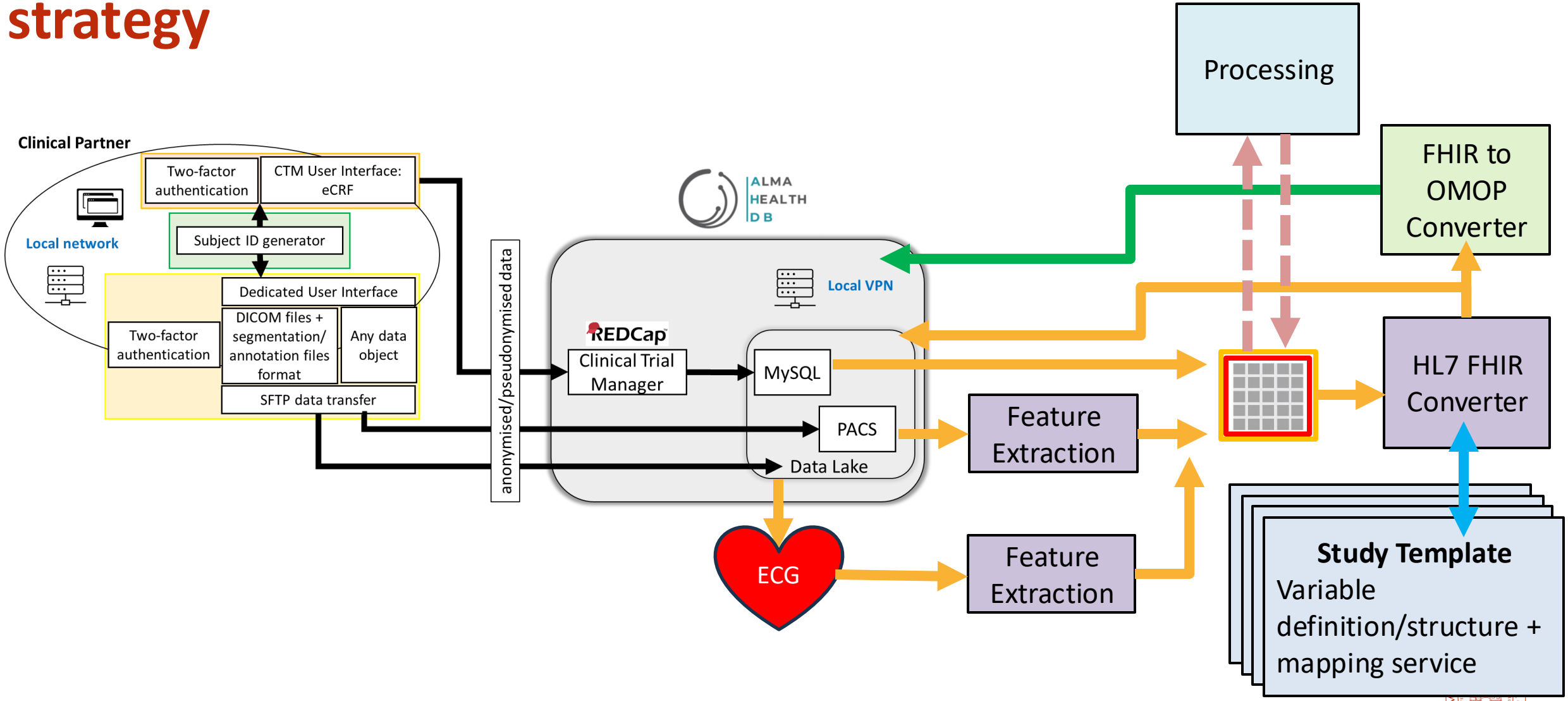
Data Ingestion



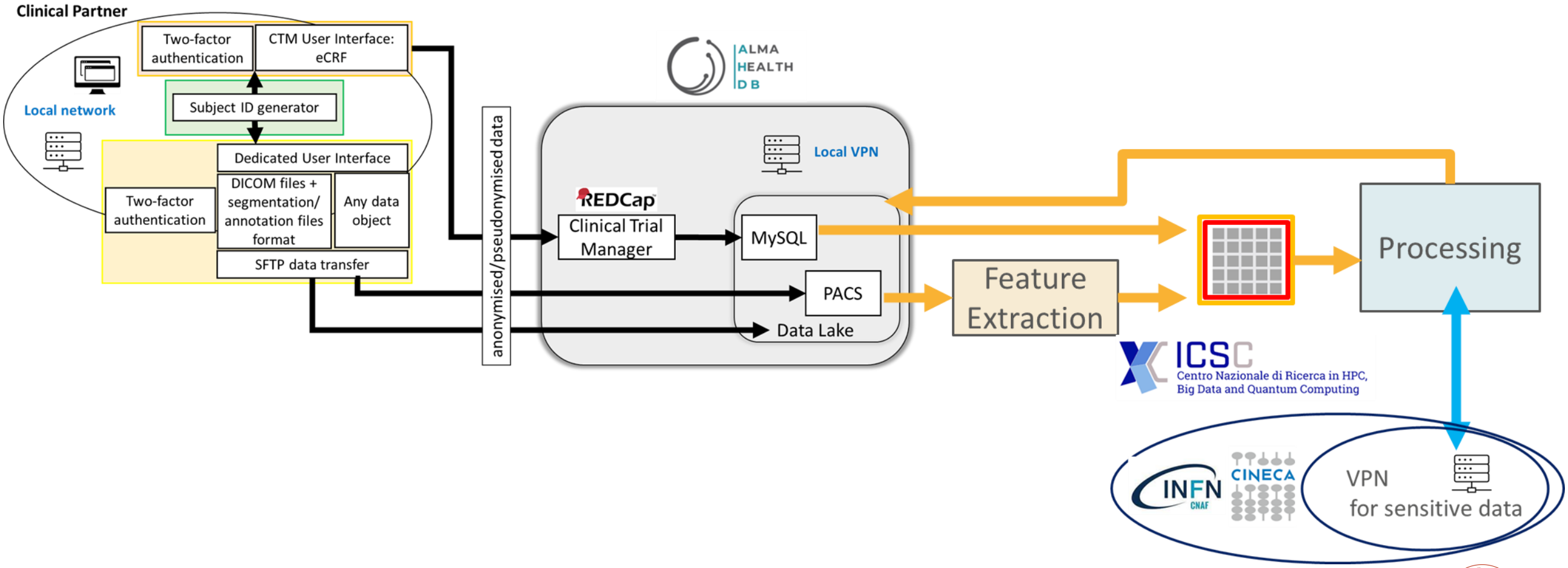
Infrastructure



The AlmaHealthDB interoperability strategy



External computational resources



Expertise

- The AlmaHealthDB team comprises multidisciplinary experts with backgrounds in computer science, biomedical engineering, information engineering, data curation, law, and ethics.
- Their mission is to support health research and innovation by unlocking the potential of health data.

Services

- Writing of the Data Management Plan
- Carry out the Data Protection Impact Assessment (DPIA)
- Authorization and management of external user access for multicentre studies
- Automatic extraction of clinical data from primary hospital systems
- Creation of secure big data analytics environments and processing pipelines
- Integration with the Clinical Trial Manager (REDCap)
- Integration with mobile health technologies (wearables, apps)
- Automated statistical processing procedures for continuous monitoring of studies
- Data export in standard data formats such as HL7 FHIR and OMOP CDM
- Access to supercomputing resources.

Ongoing projects

HORIZON RIA projects

METASTRA

https://www.metastraproject.eu/

CPW
CANCER PREVENTION at WORK

https://cancerpreventionatwork.eu/

BIOTOOL-CHF

https://www.biotool-chf.eu/

National PNC/PNRR projects

ICSC
Centro Nazionale di Ricerca in HPC, Big Data and Quantum Computing

https://www.supercomputing-icsc.it/en/icsc-home/

DARE
DIGITAL LIFELONG PREVENTION

https://www.fondazionedare.it/it/

HEAL ITALIA

https://www.healitalia.eu/

Conclusions

- AlmaHealthDB's reference architecture is designed to support medical research while safeguarding patient privacy, which is particularly crucial in pediatric applications and even more so when considering rare diseases.

- By adhering to strict data governance protocols and state of the art technologies, AlmaHealthDB provides a secure and efficient platform for pediatric research.

ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA

Sabato Mellone

Dipartimento di Ingegneria dell'Energia Elettrica e dell'Informazione
"Guglielmo Marconi«

Email: sabato.mellone@unibo.it