InteropEHRate

EHR in people's hands across Europe

SHARING HEALTH DATA FOR RESEARCH: TECHNICAL PERSPECTIVE

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FINAL CONFERENCE

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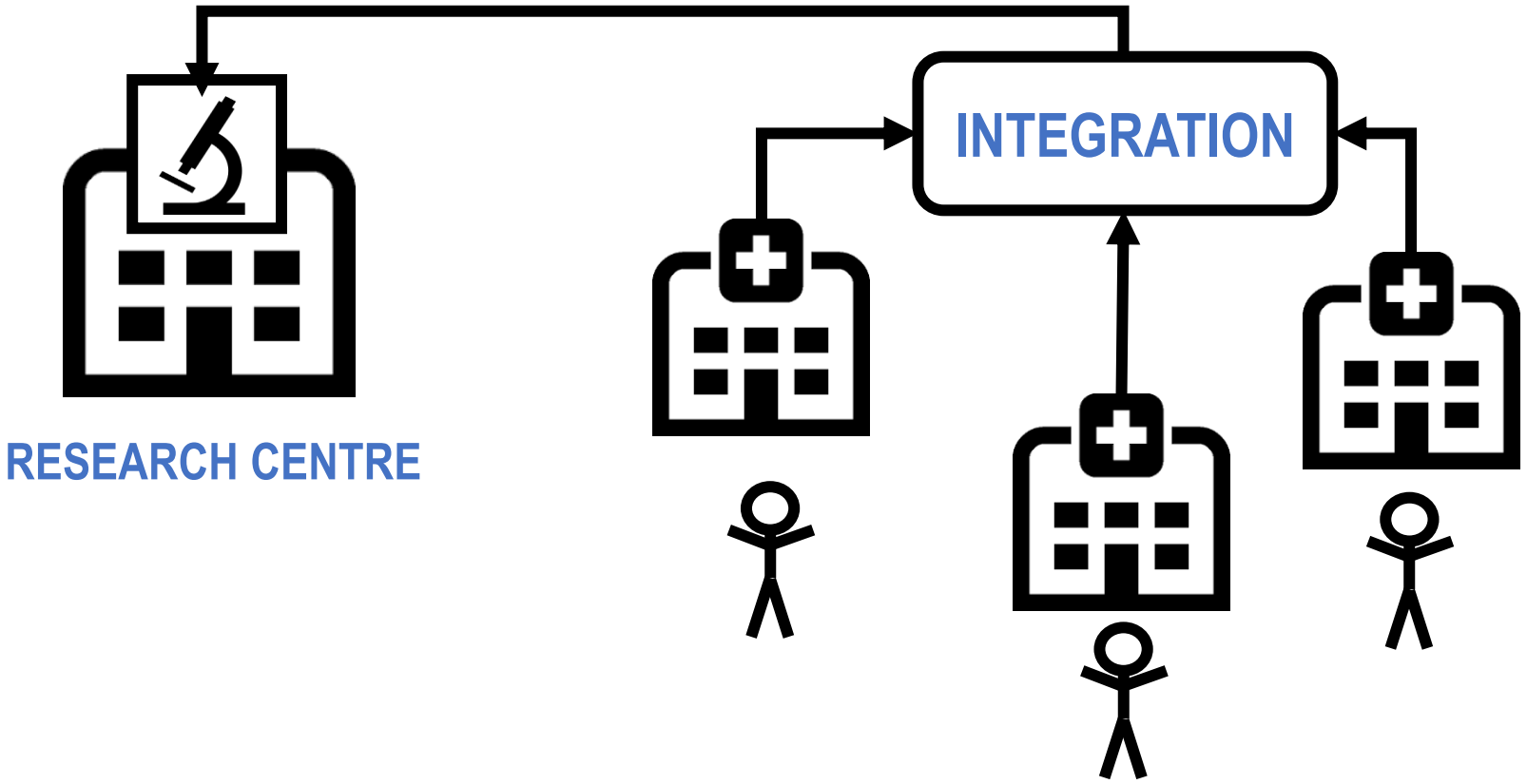
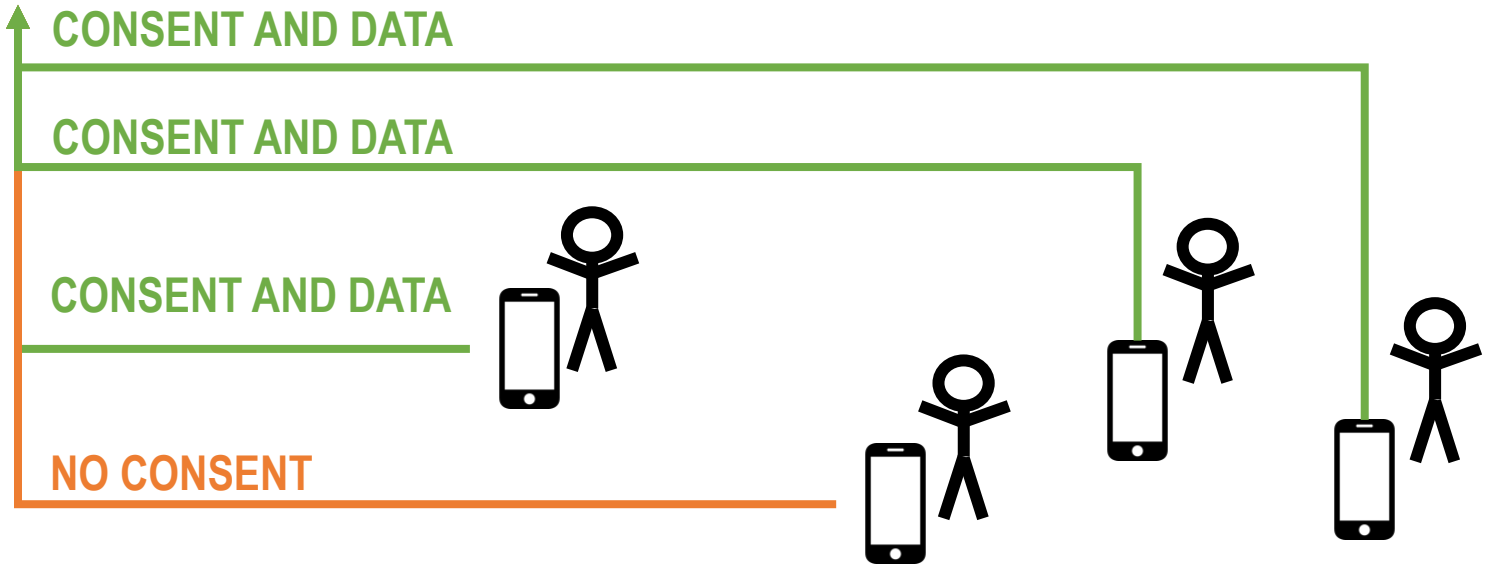
DATA SHARING FOR MEDICAL RESEARCH: STATE OF THE ART



- **Top-down** approach;
- **prospective studies**: patients give paper-based consent;
- **retrospective studies**: patients give implicit prior consent to future studies;
- **data integration** across hospitals for research purposes.

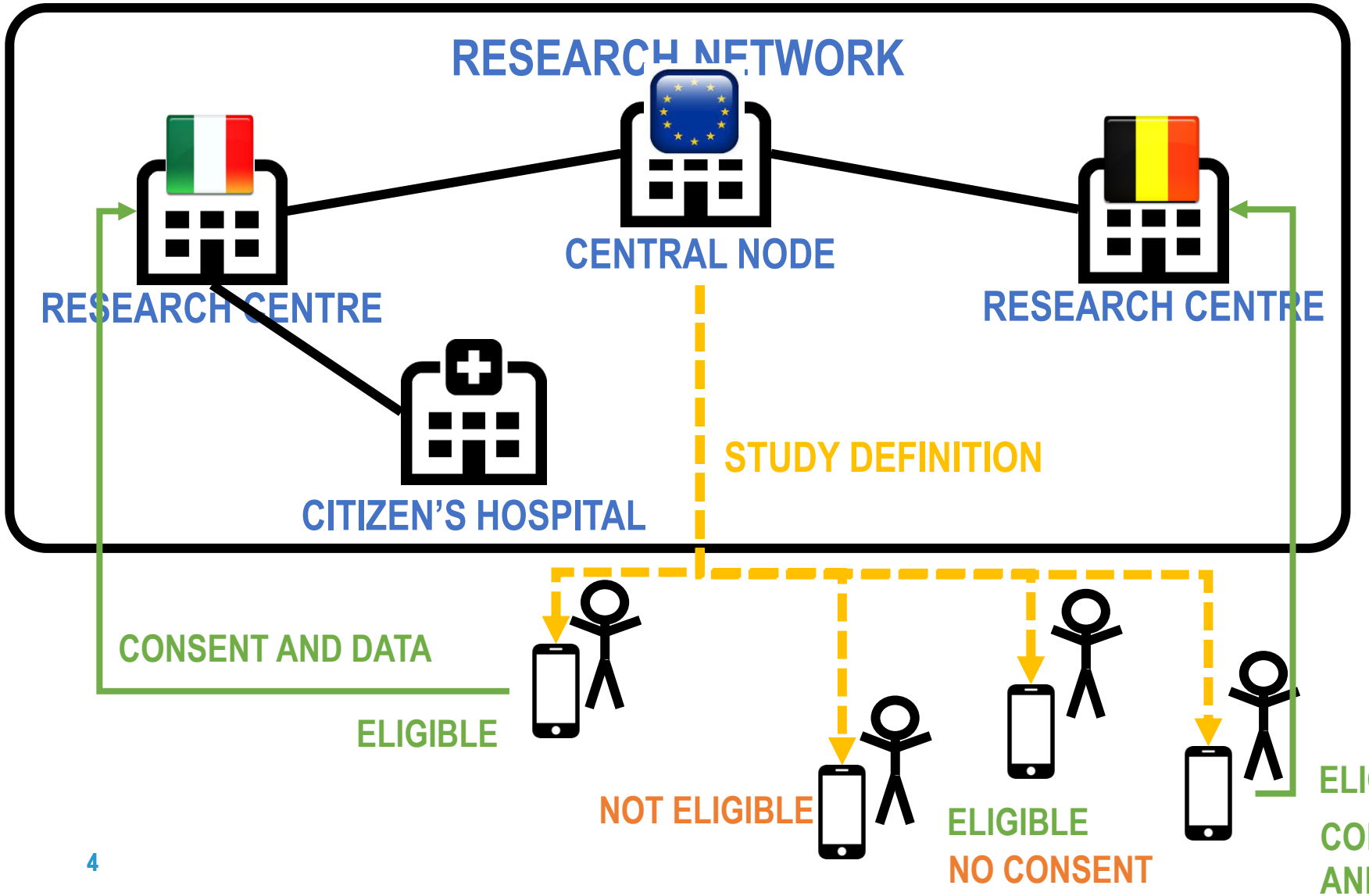
DATA SHARING FOR MEDICAL RESEARCH: INTEROPEHRATE

RESEARCH CENTRE



- **Bottom-up** approach;
- **electronic consent** for each study;
- **data already interoperable** on their phones;
- patients can be **anywhere**.

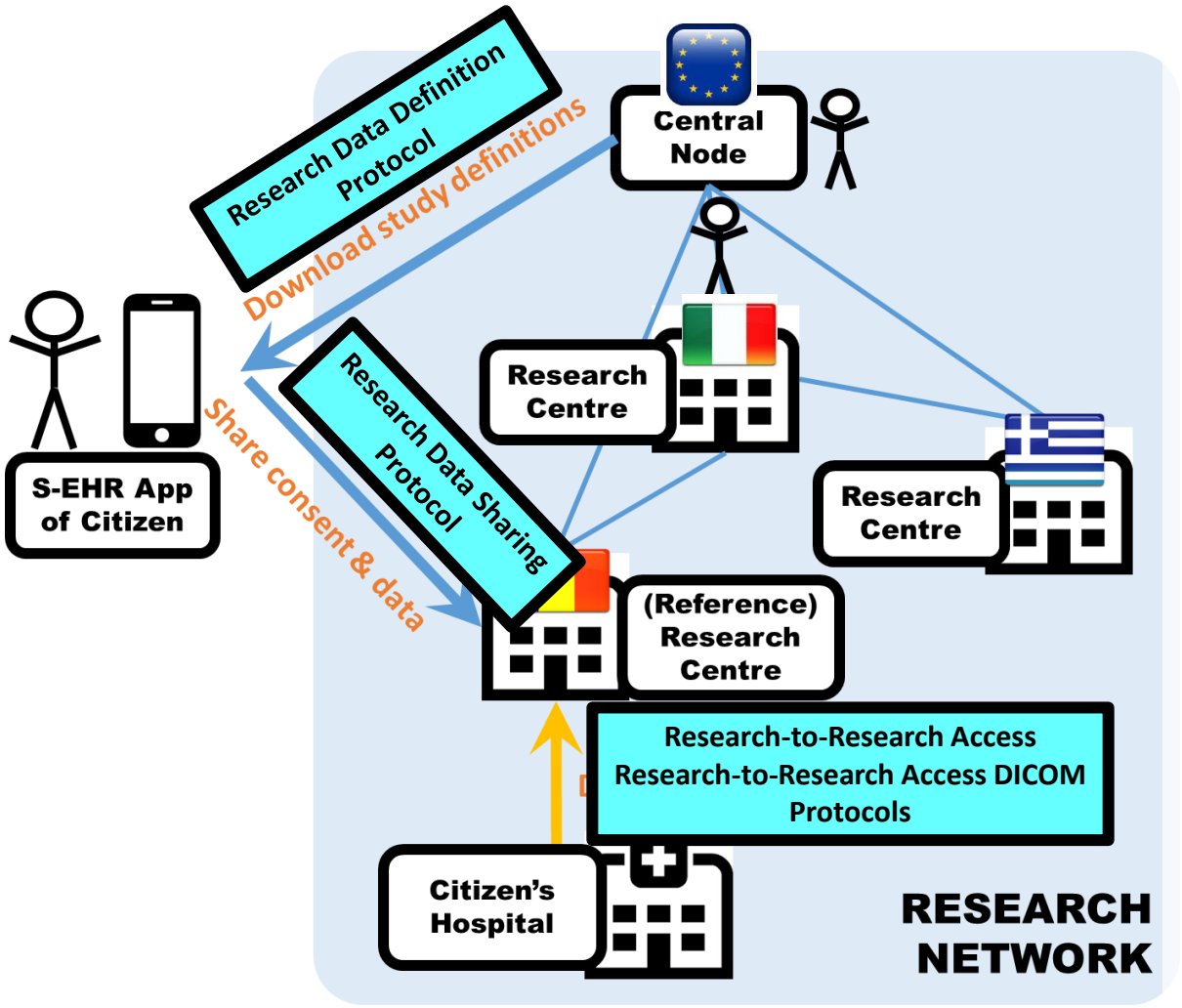
RESEARCH NETWORK



MAIN STEPS

1. Automated download of research definition and privacy-preserving **in-phone evaluation** of enrolment criteria;
2. **secure and automated transmission** of pseudonymised data and questionnaire answers;
3. **anonymous content retrieval from patient's hospital** if data not present on phone.

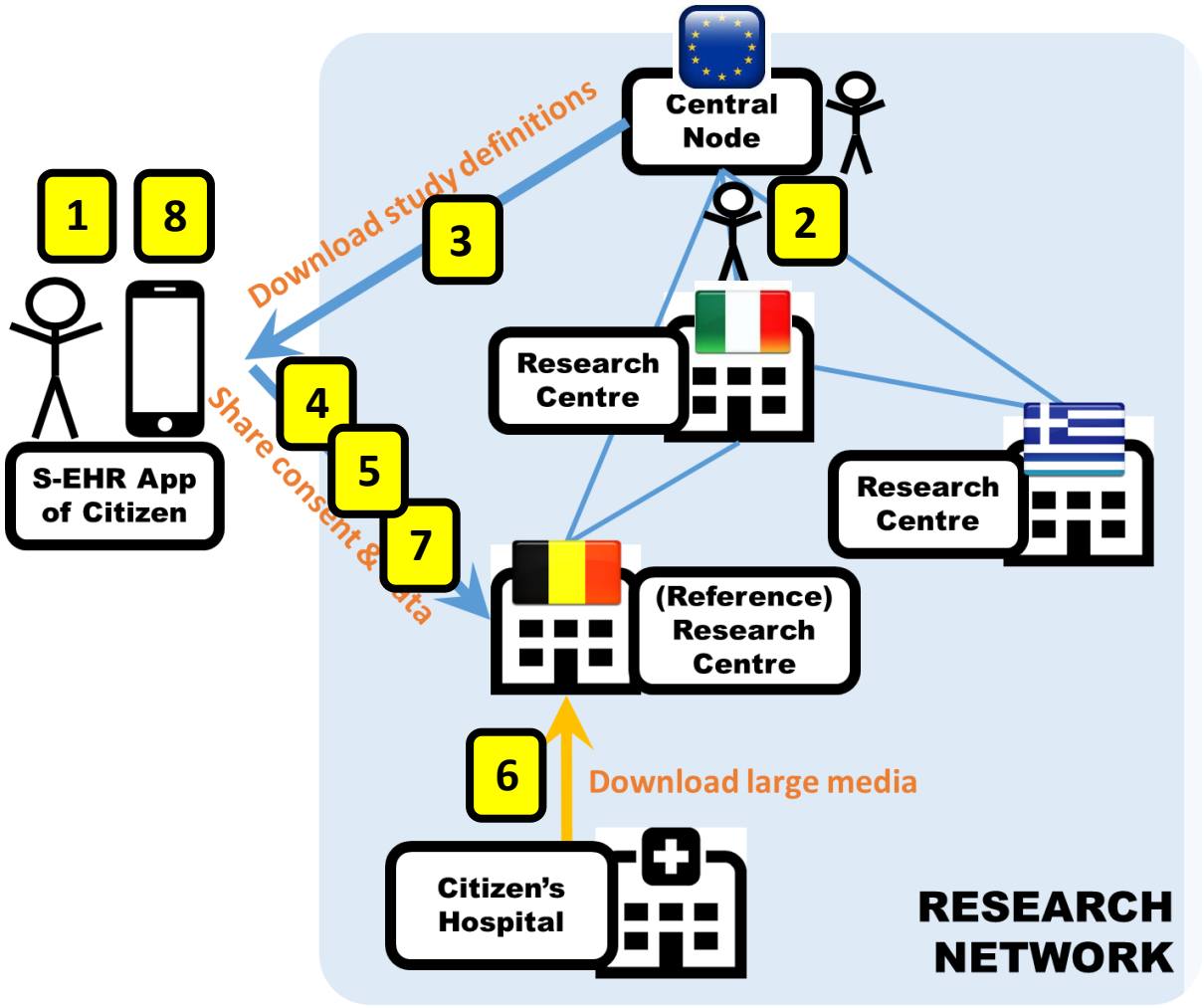
COMMUNICATION PROTOCOLS SPECIFIED



Four citizen-centric communication protocols:

- **RDD (Research Data Definition):** transfer of Research Definition Documents from the Central Node to the Citizen;
- **RDS (Research Data Sharing):** transfer of consent and pseudonymised health data and research questionnaire answers from the Citizen to the Research Centre;
- **R2R-Access (Research-to-Research Access):** transfer of large documents, not present on the phone, directly from the Citizen's hospital to his/her Research Centre;
- **R2R-Access-DICOM (Research-to-Research Access DICOM):** extension of the above for the transfer of DICOM media files, for compatibility with existing DICOM protocols.

RESEARCH DATA SHARING PROCESS



IEHR specifications are focused on citizen-centric operations.

Research management inside the network is only partially covered.

1. **OPT-IN** to receiving notifications about future studies by the **Citizen**;
2. **PUBLISHING** of a new study by the **PI of the study** and the **Central Node Administrator**;
3. **SILENT ELIGIBILITY CHECK** on the **Citizen**'s phone;
4. **ENROLMENT** into a new study by the **Citizen**;
5. **AUTOMATED DATA RETRIEVAL** from the **Citizen**'s phone;
6. **LARGE DATA RETRIEVAL** from the **Citizen**'s hospital;
7. **WITHDRAWAL** from a study by the **Citizen**;
8. **OPT-OUT** from future studies by the **Citizen**.

TECHNOLOGICAL CHALLENGES AND INNOVATIONS

PILOT

- **RDD (Research Data Definition):**
  - **Central Node portal** for the management of research studies;

DEMO IMPLEMENTATION

  - **formal and multilingual description of research studies** for automation: Research Definition Document (RDD);
  - **digitally signed transmission of the RDD** to avoid malicious data collection.
- **RDS (Research Data Sharing):**
  - **fully automated, silent, and privacy-preserving check of inclusion criteria** on the Citizen's phone, in order not to bother non-eligible citizens;
  - **consent digitally signed** by the Citizen in order to avoid paper-based participation;
  - **automated in-phone data query** made possible through prior data conversion to a cross-border interoperable format;
  - **automated in-phone data pseudonymisation** to preserve the anonymity of patients;
  - **transmission of data provenance** in order to prove the origin of each data value;
  - **secure data transfer** (encrypted and digitally signed) to the RC, in order to avoid malicious access.

REFERENCE IMPLEMENTATION

- **R2R-Access (Research-to-Research Access) + DICOM:**
  - **automated retrieval of large media** from the Citizen's hospital, based on his/her prior consent;
  - on-the-fly anonymisation of media files.

OPEN SPECIFICATIONS

PILOT IMPLEMENTATION

Research Data Sharing Feature	Main Tech. Partners	Pilot implementation scope
Central Node research management portal	University of Trento	**Upload, validation, and publishing of RDD documents**
Formal description of research studies	Fraunhofer Institute	**Fully specified based as an open FHIR extension and used in the pilot**
Digitally signed transmission of the RDD	UBITECH	**Fully implemented**
Fully automated, silent, and privacy-preserving check of inclusion criteria	Andaman7, University of Piraeus	**Implemented for a subset of possible (simple) criteria**
Patient consent digitally signed	UBITECH	**Counter-signing by research centre not implemented**
Automated in-phone data query	Andaman7, University of Piraeus	**Implemented for a subset of possible (simple) queries**
Automated in-phone data pseudonymisation	BYTE	**Implemented only for structured data, pseudonym reversal not implemented**
Secure data transfer	UBITECH	**Fully implemented**
Transfer of large images directly from hospital	—	**Implemented through the phone instead**
Data reception and storage at Research Centres	University of Trento	**Only data storage and simple retrieval APIs**

RESEARCH PILOT EXECUTION