USB Data Hub
Development of a governance and quality management system for exchange of patient related data for research purposes
a SPHN funded Infrastructure Development Project

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Use of Patient-related Health Data for Research

Current Situation:
Unstructured individual data requests to department heads, source system providers and IT-experts

Goal:
Structured, requests through a single point of contact

Under Development:
USB Data Hub for Personalized Health

Regulatory Framework:
Regulations that describe responsibilities and procedures associated with the set-up, conduct and closure of a Data Hub Organization as single point of contact to request research data
Concept of Data Governance at the USB

Data Hub Organization

- Data request
  - Evaluate request and check data availability

Data Hub Regulations

- Ethical Committee Regulations
  - Approval Ethics Committee
- Terms and Conditions of Data Transfer Agreement
  - Signed Contract

Data Provider

- Technical data retrieval

Data Integration Regulations

- Receive Data Delivery
- Receive Data Delivery
- Review and approve data for research delivery
- Review and approve data for research delivery

Researchers

- Plan study
- Data request

- Perform study
- Data delivery
- Data delivery
Data Governance at the USB and USZ

ELSI policy

Ethical Framework for Responsible Data Processing in the Swiss Personalized Health Network

(el. USB Data Hub Regulations for Personalized Health)

Processes describing:
- Structure
- Evaluation
- Documentation
- Data flow

Integration of further hospitals

ELSI = Ethical Legal and Social Implications (advisory group); USB = University Hospital Basel;
USZ = University Hospital Zurich; SOP = Standard Operation Procedure; PD = Process Description

= Infrastructure will be generated during funding period
Current Project Status

Work Package 1 (set-up):
✓ Kick-off meeting
✓ Define project team
✓ Meet with SPHN to identify expectations/requirements
  - Prepare detailed project plan
  - Generate a list of document to be developed

Work Package 2 (development):
  - Create process descriptions
  - Create regulations
  - Create SOPs
  - Create document templates

Work Package 3 (implementation):
  - Process mock run
  - Process audit
  - Pilot run
  - Generalisation