



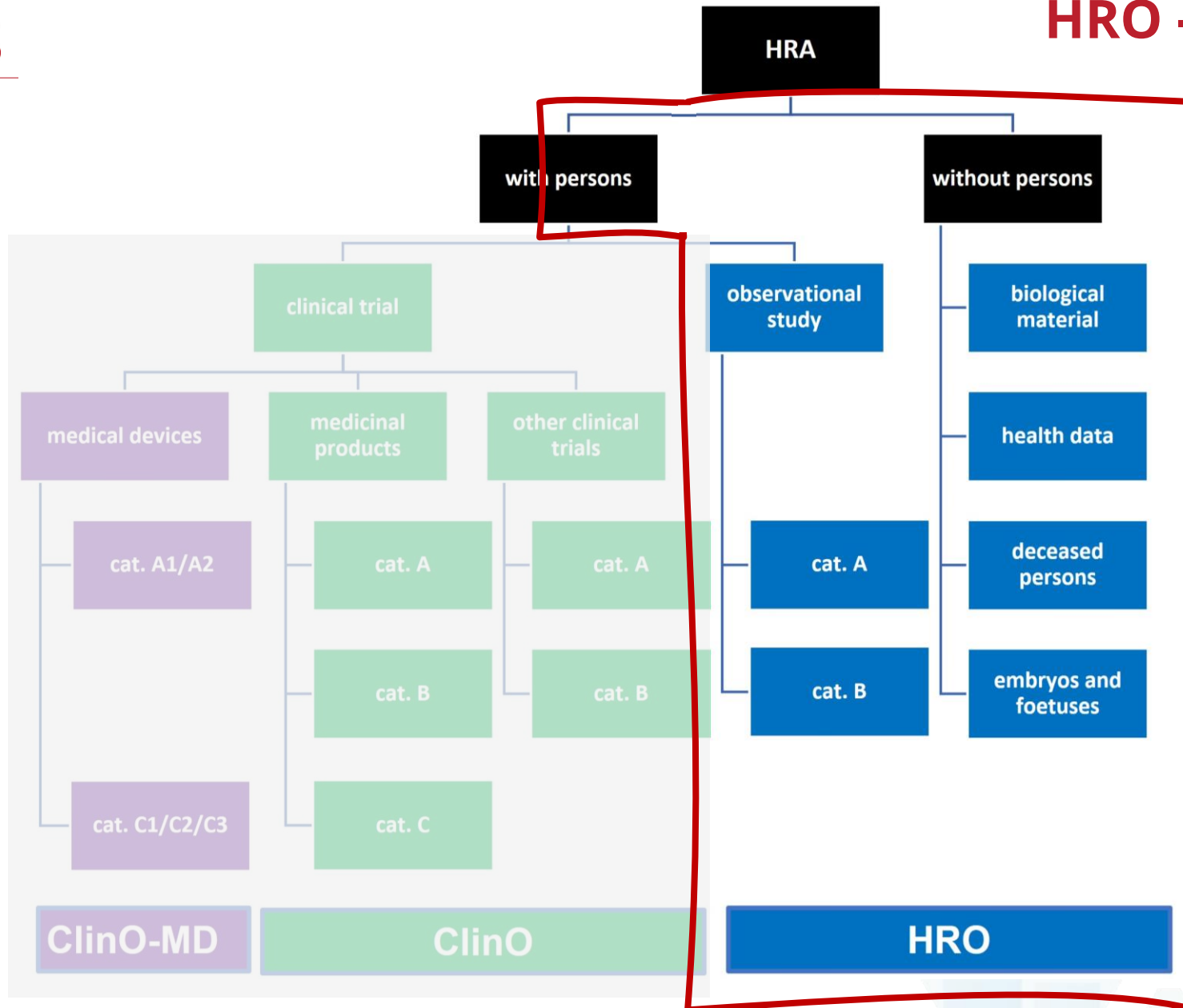
13 November | 12h00 - 13h00 | online seminar

Facts and pitfalls of observational studies

Data sharing and open research data – details for HRO projects

Data storage, data sharing, and contracts around data and samples – many researchers are not sure about what to handle how. This session highlights common practices, possibilities and must-knows, focusing on data storage and data sharing.

Registration and more information:
sctoplatforms.ch/HRO-training-series





SCTO
PLATFORMS

13 November | 12h00 - 13h00 | online seminar
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Dr. Julia Maurer

Team Lead Ethical, Legal and Social Implications; Lead SPHN ELSI Helpdesk, SPHN Data Coordination Center; SIB Swiss Institute of Bioinformatics

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HRO Lunch Session - Part I

Data sharing and open research data – details for HRO projects

Dr. Julia Maurer

Team Lead Ethical, Legal and Social Implications

Lead SPHN ELSI Helpdesk, SPHN Data Coordination Center

SIB Swiss Institute of Bioinformatics



Data sharing and open research data – details for HRO projects

Contractual and governance framework in the Swiss Personalized Health Initiative

Dr. Julia Maurer

Team Lead Ethical, Legal and Social Implications

Lead SPHN ELSI Helpdesk, SPHN Data Coordination Center

SIB Swiss Institute of Bioinformatics

SCTOplatforms, HRO lunch series, 13.November 2024

A project of

Total number of research projects submitted to ethics committees in 2023



https://kofam.ch/upload/gutachten_und_berichte/BA_G_Statistikbericht_2023.pdf

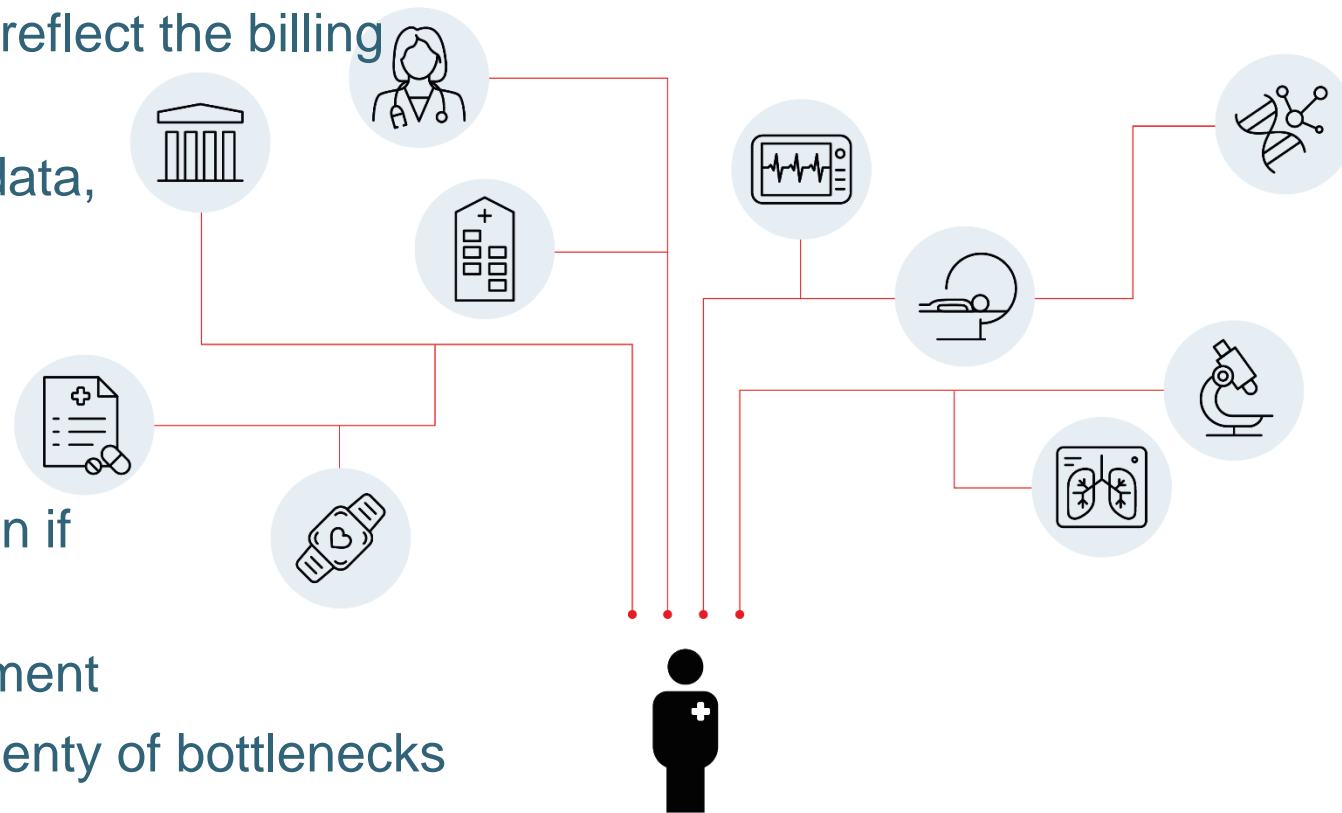
Type of research	Legal basis	n	% _{col}
Clinical trial	ClinO or ClinO-MD	516 ¹	21.1
Research involving persons, but not a clinical trial	HRO, Chapter 2	786 ²	32.1
Further use of health-related personal data and/or biological material	HRO, Chapter 3	1111	45.4
Research involving deceased persons	HRO, Chapter 4	30	1.2
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	2	0.1
Total number		2445	100

- 1 49 of these projects also include an application for further use of data/biological material.
- 2 190 of these projects also include an application for further use of data/biological material.

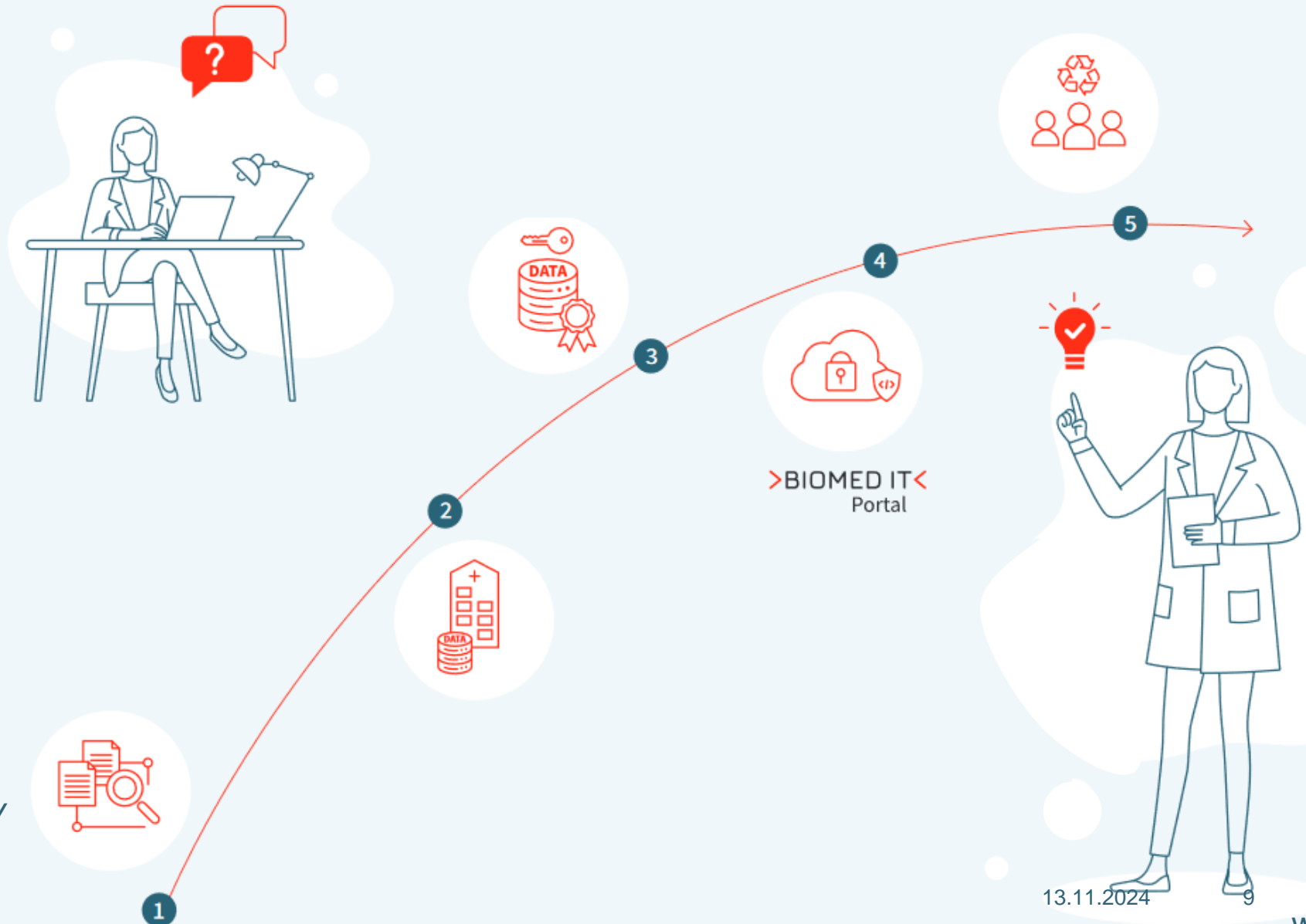
Purpose and need of further using data is significant!

Personalized Health (Research): The Challenges

- Real World Data captured for care, reflect the billing reality rather than the patient reality
- Lots of free text, lack of structured data, local or no standards
- Big Data analyses require a critical mass of data to be combined from various scattered sources
- Sensitive nature of health data (even if pseudo- or anonymized)
- Need of Trusted Research Environment
- Data ownership and governance: plenty of bottlenecks

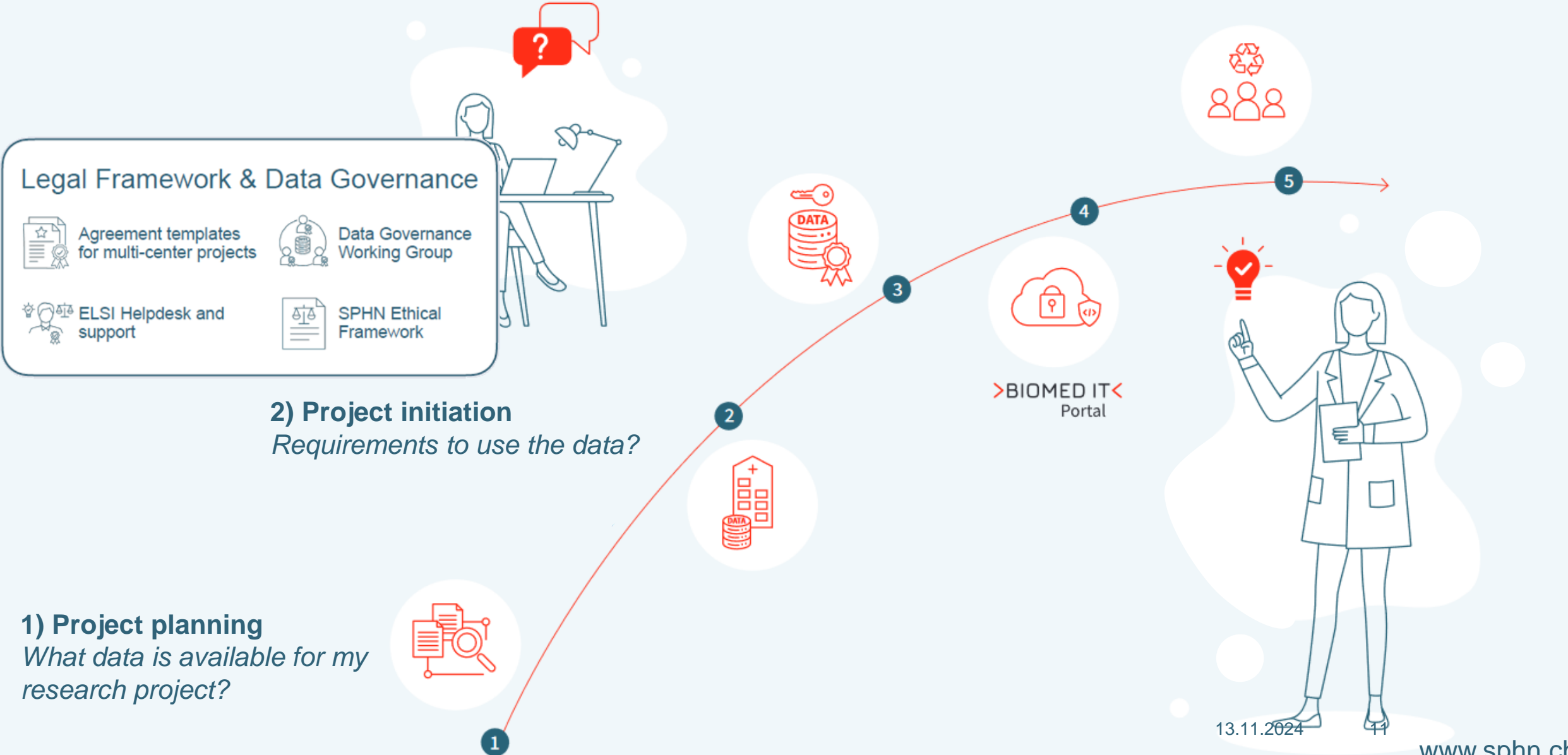


The SPHN value chain

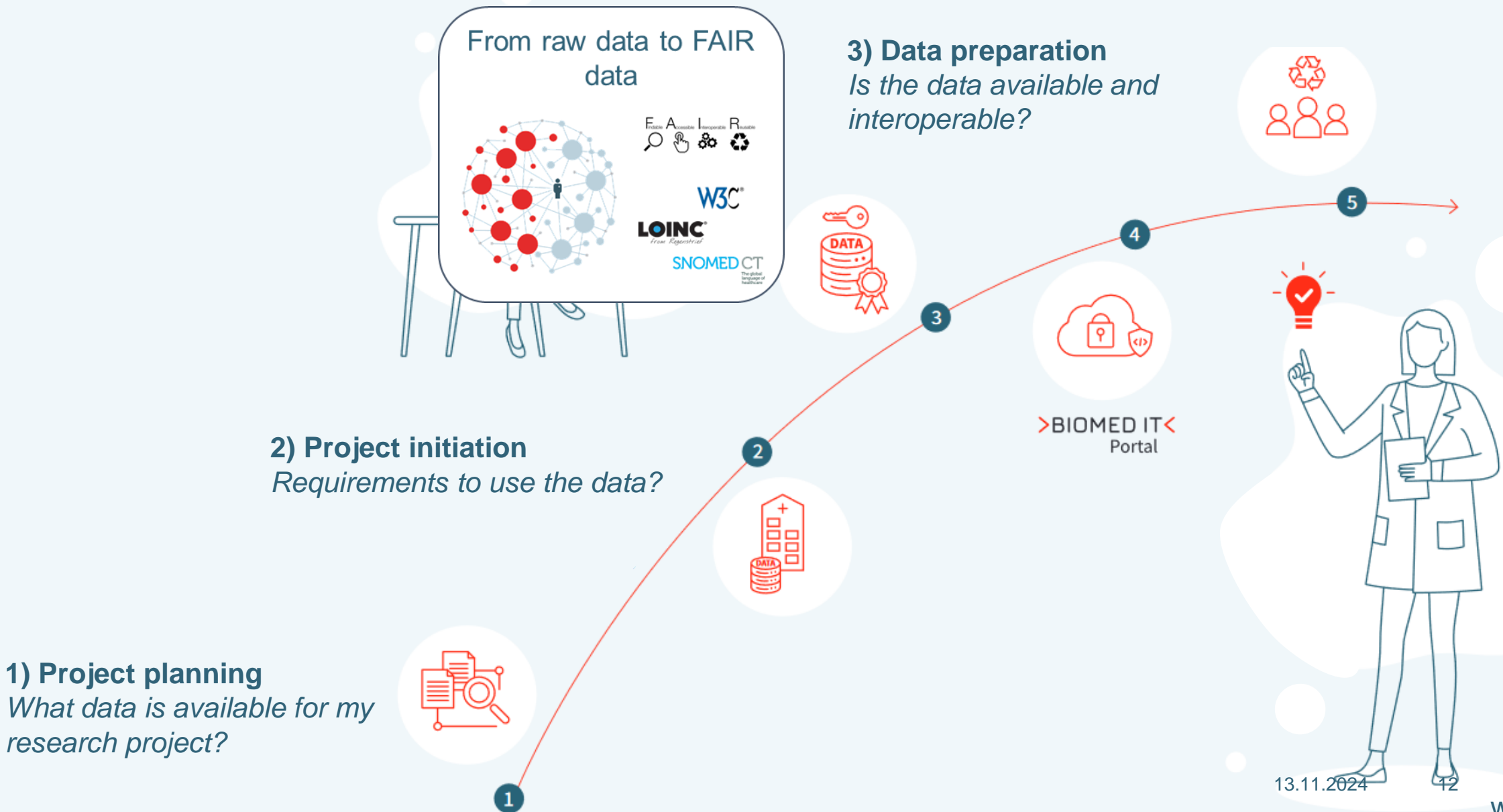


1) Project planning
What data is available for my research project?

The SPHN value chain



The SPHN value chain



The SPHN value chain

1) Project planning
What data is available for my research project?



1

2) Project initiation
Requirements to use the data?



2



3) Data preparation
Is the data available and interoperable?



3

>BIOMED IT<
Portal

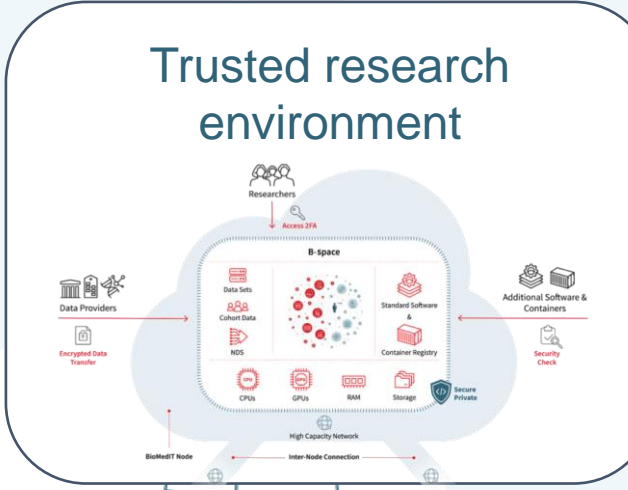
4) Data mobilization and analysis:
Where can I analyze sensitive data?



4



5



13.11.2024

13

The SPHN value chain

1) Project planning
What data is available for my research project?

SCTO platforms HRO lunch series, Dr. Julia Maurer



2) Project initiation
Requirements to use the data?



3) Data preparation
Is the data available and interoperable?



4) Data mobilization and analysis:
Where can I analyze sensitive data?



5) Data reuse
How can I make data accessible to other researchers?



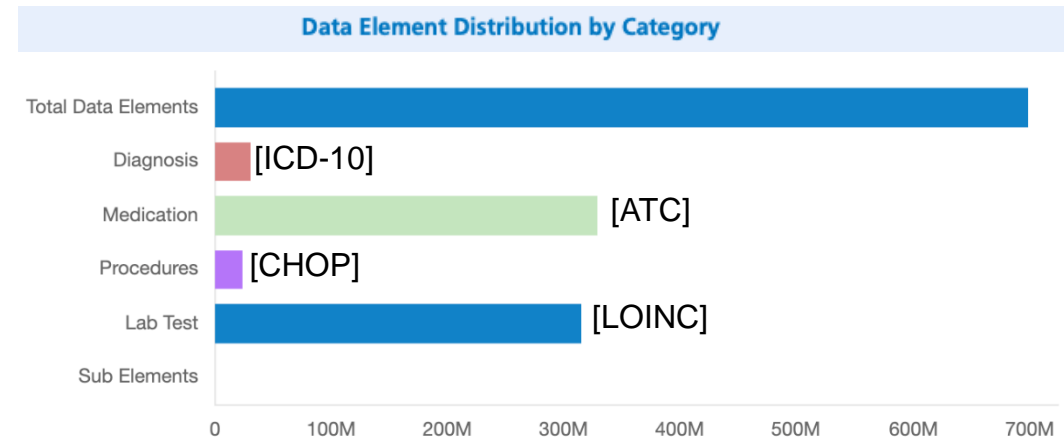
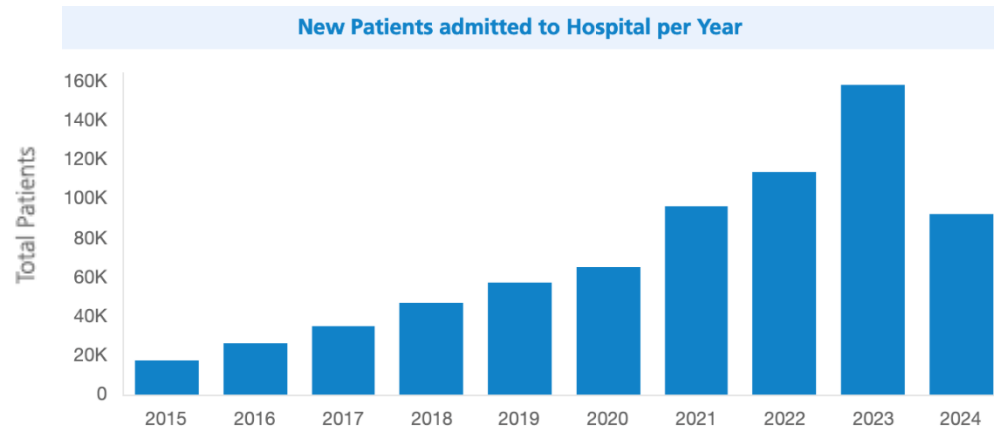
SPHN Schema Scope - SPHN Metadata catalogue

Open access strategy?

From Health Data Discoverability...

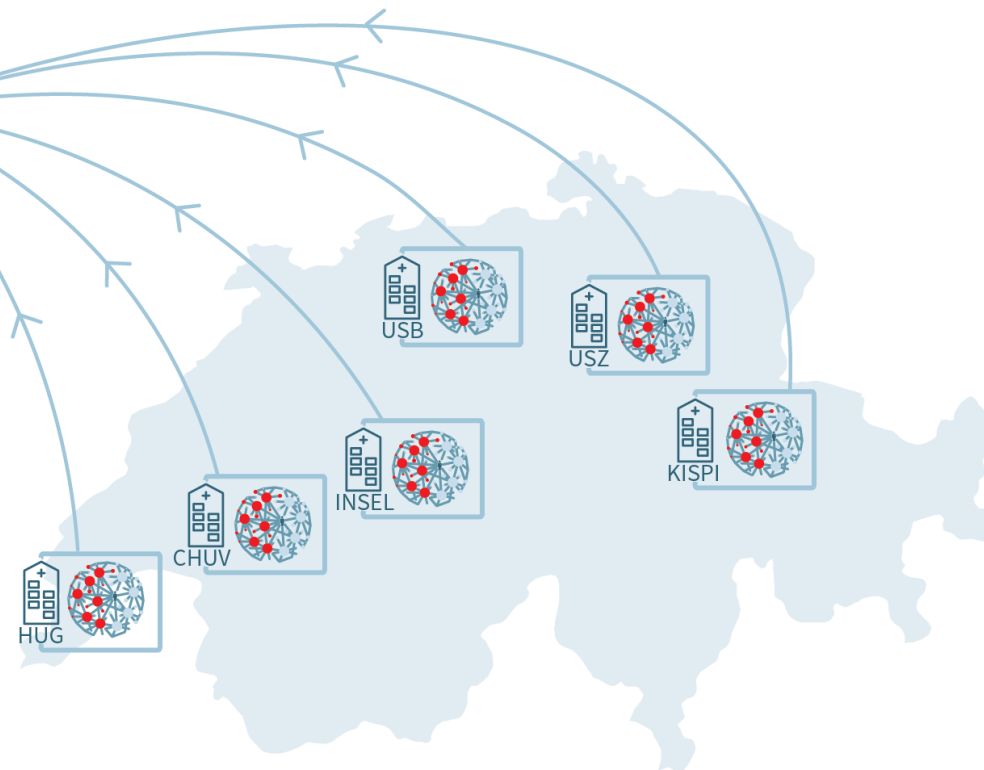
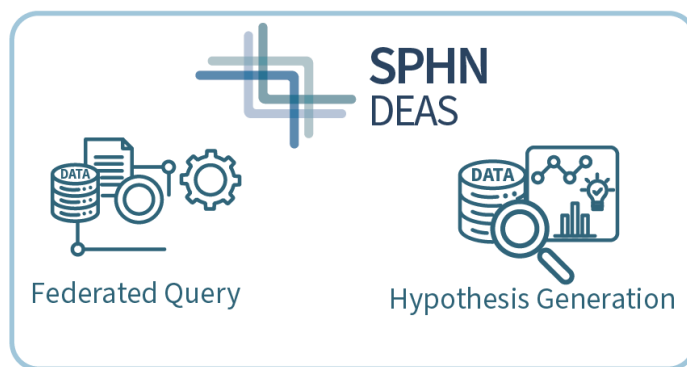
Federated Query System

- > **710'000 patients** (general consent), 5 hospitals
- > **699'000'000 data elements**: *Demographics, Diagnoses, Procedures, Medication, Laboratory tests and values*



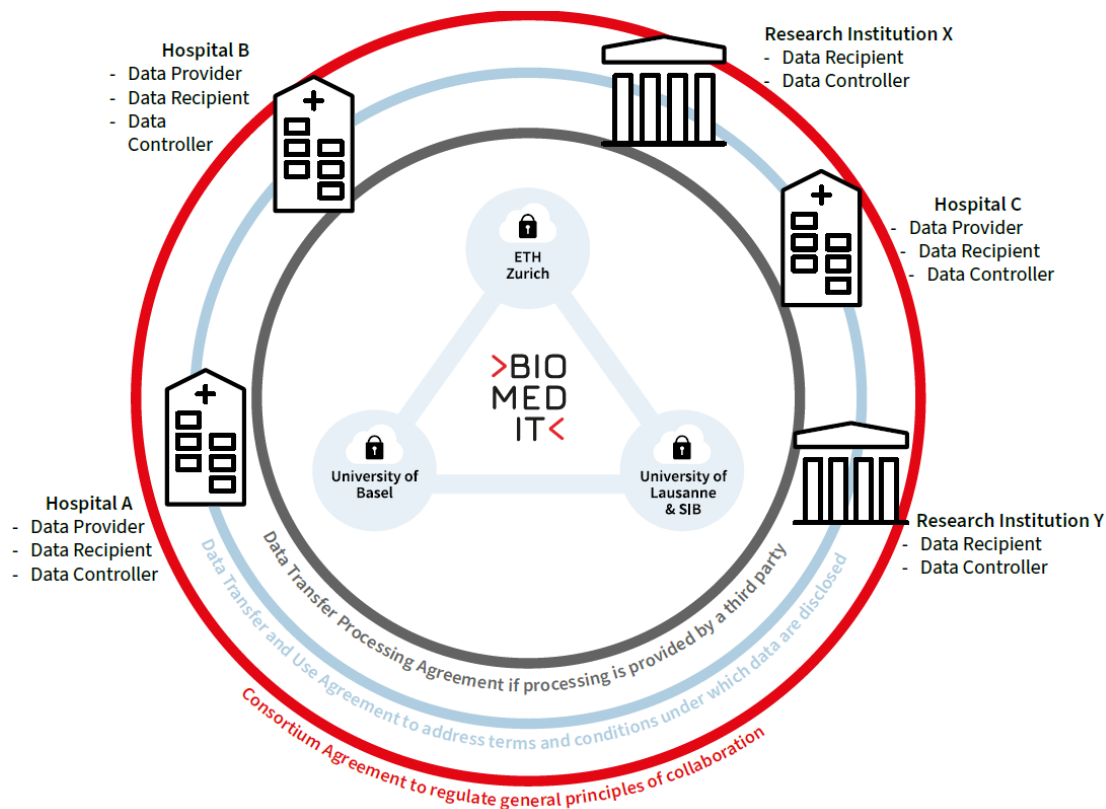
... to Federated Data Exploration

Data Exploration & Analysis System (2025)



- Full SPHN Dataset (>165 clinical parameters)
- All patients with General Consent since 2018 from 6 hospitals
- Value distribution and survival curves of patient cohorts
- Fully privacy preserving, powered by **TUNE INSIGHT**

SPHN Legal Framework for data sharing with multiple parties



SPHN Semantic Interoperability Framework

Ontologies and standards

SNOMED CT
 The global language of healthcare

LOINC
 From Regenstrief

ICD-10

Schweizerische
 Operationsklassifikation (CHOP)
 Systematisches Verzeichnis - Version 2021

WHO Collaborating Centre for
 Drug Statistics Methodology

UCUM
 The Sequence Ontology

[...]

SPHN Concepts: Semantic definition of modular building blocks

SPHN Concept:	Meaning binding SNOMED CT
Allergy	418038007 Propensity to adverse reactions to substance (finding)
• reaction type	Defined allowed valuesets value set binding to SNOMED CT 419199007 Allergy to substance (finding); 782197009 Intolerance to substance (finding); 261665006 Unknown (qualifier value)
• substance category	
• substance	Defined standards SNOMED CT, ATC, other
• code	
• generic name	
• quantity	
• severity	
• identification datetime	
• last reaction datetime	

SPHN RDF Schema: Exchange format for highly interconnected data

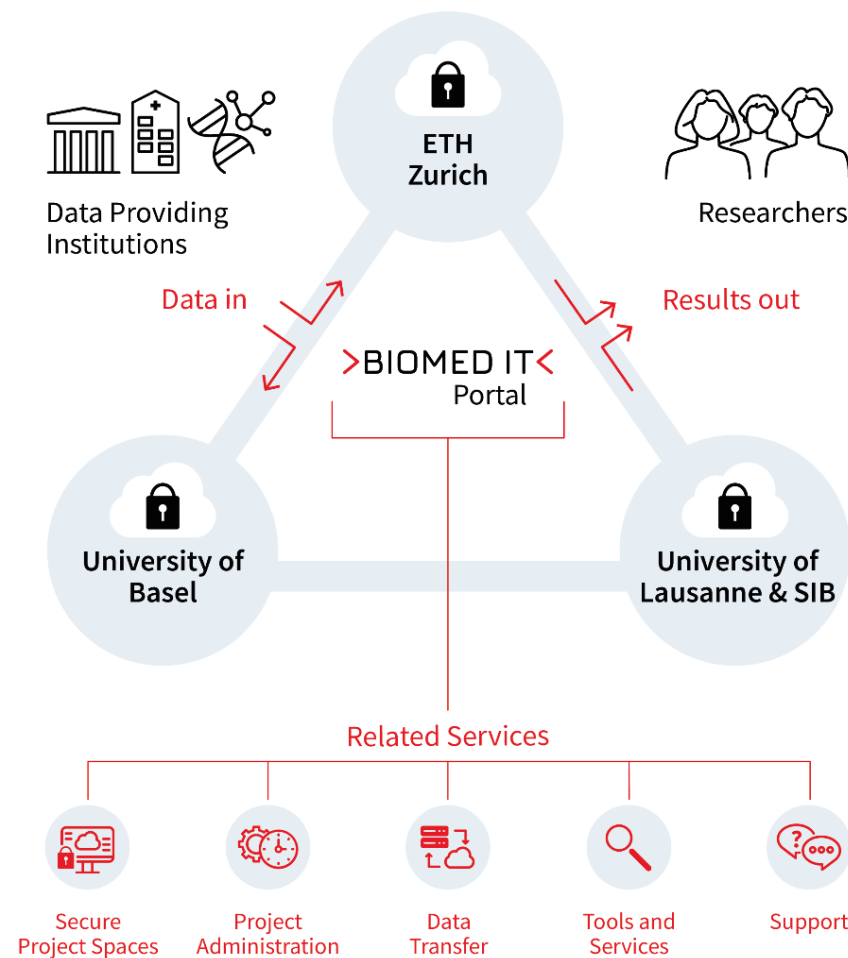
Re-use or use case specific transformation

- Data catalogues and query systems
- Data delivery to research projects
- Shared platforms, databases, repositories

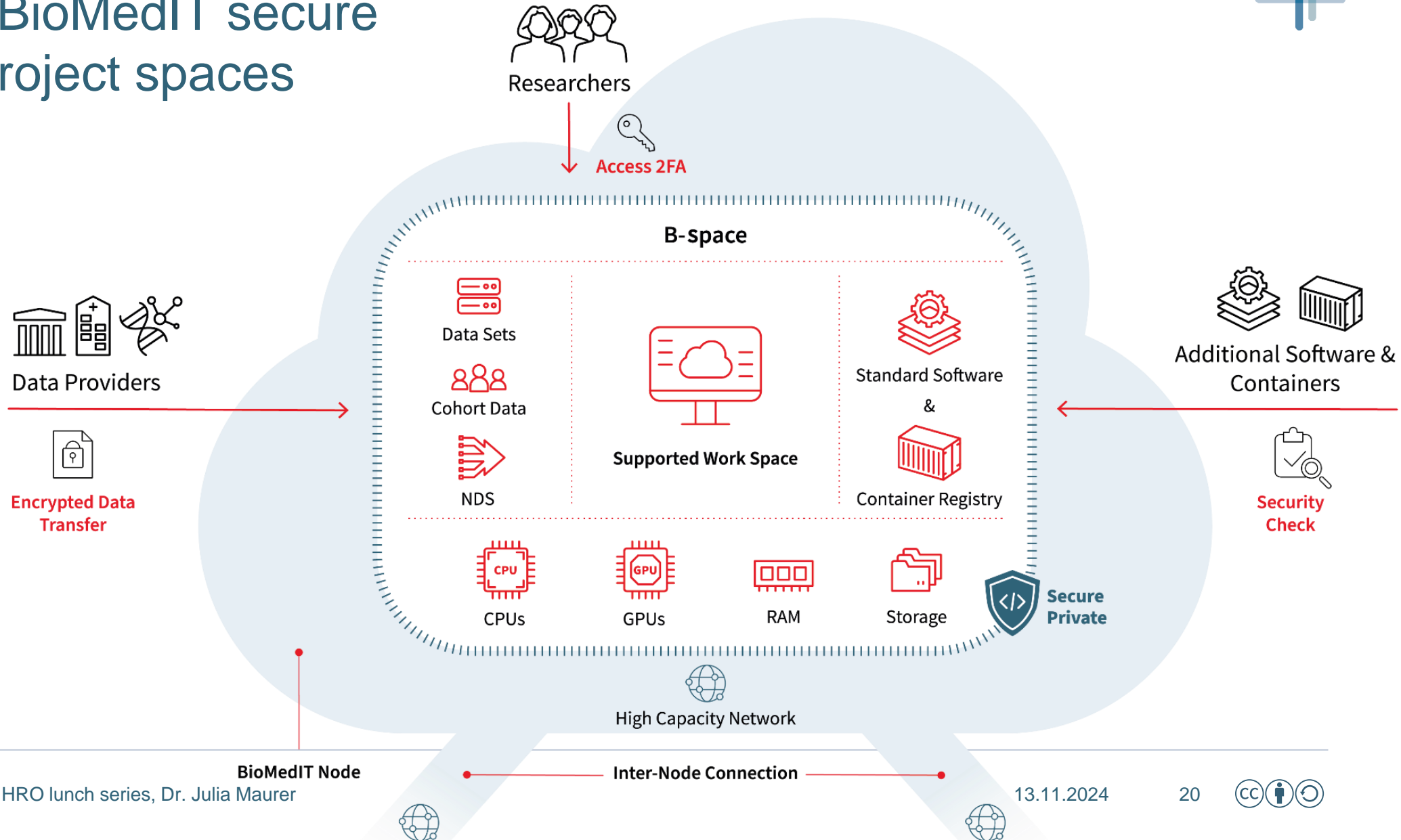
F indable A ccessible I nteroperable R eusable

BioMedIT Network - Trusted research environment

- 3 physical nodes (ETHZ, Unibas, Unil) that provide IT support for scientific research
- Secure cloud and HPC offerings
- Central [IT service] management (SIB)
- BioMedIT portal as a central access point with various tools and services
- Security by design: Common “Information Security Policy” (Swiss standard)
- Secure mobilization, processing and storage of sensitive research data
- End-to-end encrypted data transfers



B-spaces: BioMedIT secure research project spaces

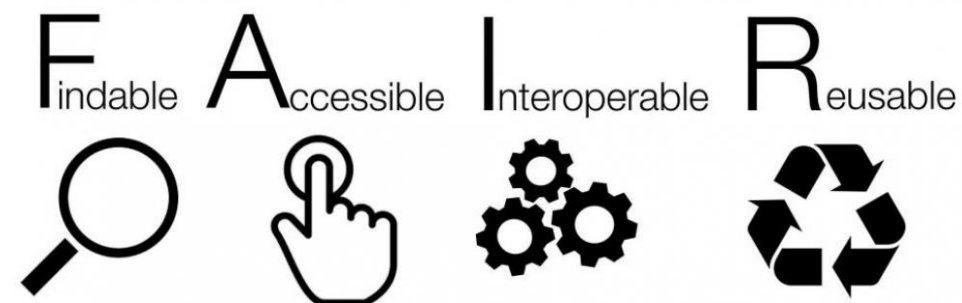


Sensitive data can never be OPEN!

But they can be FAIR

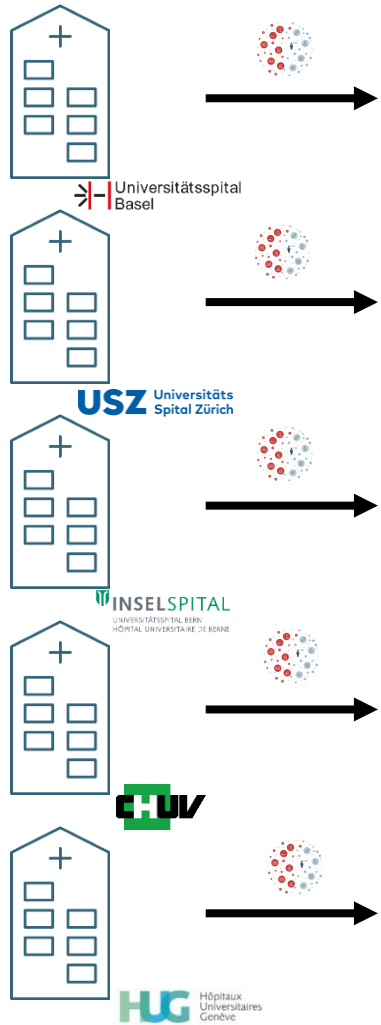
- The FAIR principles enable efficient and effective data sharing, discovery, and collaboration in health research and innovation
 - Findable: (Meta)data findable for humans and computers
 - Accessible: Once found, know how data can be accessed
 - Interoperability: Data needs to work with applications and workflows for analysis, processing and storage
 - Reusable: Optimize data reuse via comprehensive, well-described metadata

- **The FAIRification of data is time-consuming and cost-intensive**

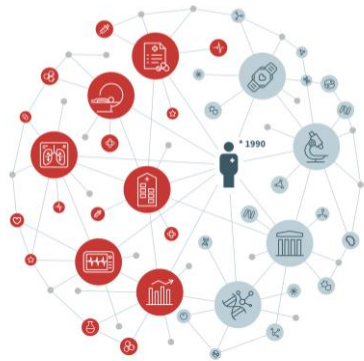


Wilkinson, M. et al. The FAIR Guiding Principles for scientific data management and stewardship. Sci Data 3, 160018 (2016). <https://doi.org/10.1038/sdata.2016.18>

SPHN National Data Streams



B-Space per project
Secure data processing
Triplestore and terminology server



>BIOMED IT<

Project-specific infrastructure development,
data management and data-driven research

IICU

Personalized, data-driven prediction and assessment of infection-related outcomes in Swiss ICUs (IICU)

Main PIs: Prof. Dr. Adrian Egli (UZH) & Prof. Dr. Catherine Jutzeler (ETHZ)

Duration: 01.09.2022 - 31.08.2025 (36 months)
Award: CHF 5 Mio

[Lay summary](#) | [More information](#)

SPO-NDS

Swiss Personalized Oncology National Data Stream (SPO-NDS)

Main PIs: Prof. Dr. Olivier Michelin (CHUV) & Prof. Dr. Bernd Bodenmiller (ETHZ)

Duration: 01.09.2022 - 31.08.2025 (36 months)
Award: CHF 5 Mio

[Lay summary](#) | [More information](#)

SwissPed Health

Pediatric personalized research network Switzerland (SwissPedHealth) – a Joint Pediatric National Data Stream

Main PIs: Prof. Dr. Luregn Schlapbach (University Children's Hospital Zurich) & Prof. Dr. Julia Vogt (ETHZ)

Duration: 01.09.2022 - 31.08.2025 (36 months)
Award: CHF 5 Mio

[Lay summary](#) | [More information](#)

LUCID

LUCID, Low Value of Care in Hospitalized Patients, a National Data Stream on Quality of Care in Swiss university hospitals

Main PIs: Dr. Marie Méan (CHUV) & Dr. Guillaume Obozinski (EPFL)

Duration: 01.09.2022 - 31.08.2025 (36 months)
Award: CHF 5 Mio

[Lay summary](#) | [More information](#)

>BIOMED IT<

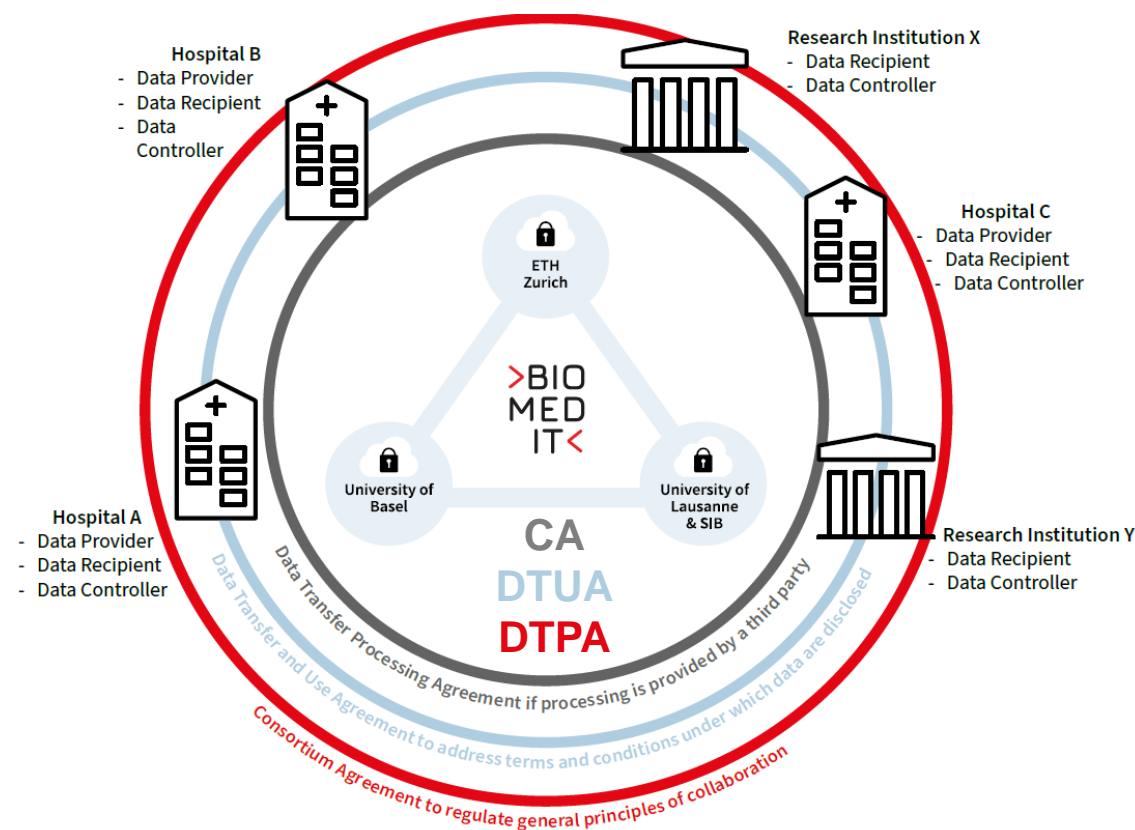
Strategic Focus Area
Personalized Health and Related Technologies

Reuse of personal datasets to create public value

Open access strategy?

SPHN contractual framework for using health data in mutli-center projects

- Data Governance (incl consent management) remains with data providing institutions (local Data Governance Boards)
- Roles of parties: data provider, data recipient, data controller, data processor
- SPHN-DCC «ELSI-Helpdesk» offers support → dcc@sib.swiss



Legal regulations and guidelines for using RWD

Switzerland:

- **Federal Data Protection Act (FADP) and cantonal data protection acts**
- Research and medical secrecy (Swiss Criminal Code)
- **Human Research Act (HRA) and its ordinance**
- Human Genetic Testing Act (HGTA)
- Health Insurance Act (Krankenversicherungsgesetz, KVG)
- Cancer Registration Act (CRA)

Soft law/guidelines

- WMA Declaration of Taipei
- International Ethical Guidelines for Health-related Research Involving Humans
- Recommendations for the establishment and operation of registries
- Swiss Personalized Health Network (SPHN) guidelines

Why to set up an agreement? Which aspects have to be covered contractually?

Project specific aspects

- Responsibilities (including Governance)
- Financing/Remuneration
- Publications
- Intellectual Property and other rights on results

Data protection aspects

- Responsibilities
- Lawfulness and fairness
- **Purpose limitation**
- **Minimization**
- Transparency
- Accuracy
- **Security**
- Accountability
- Possible access and re-use

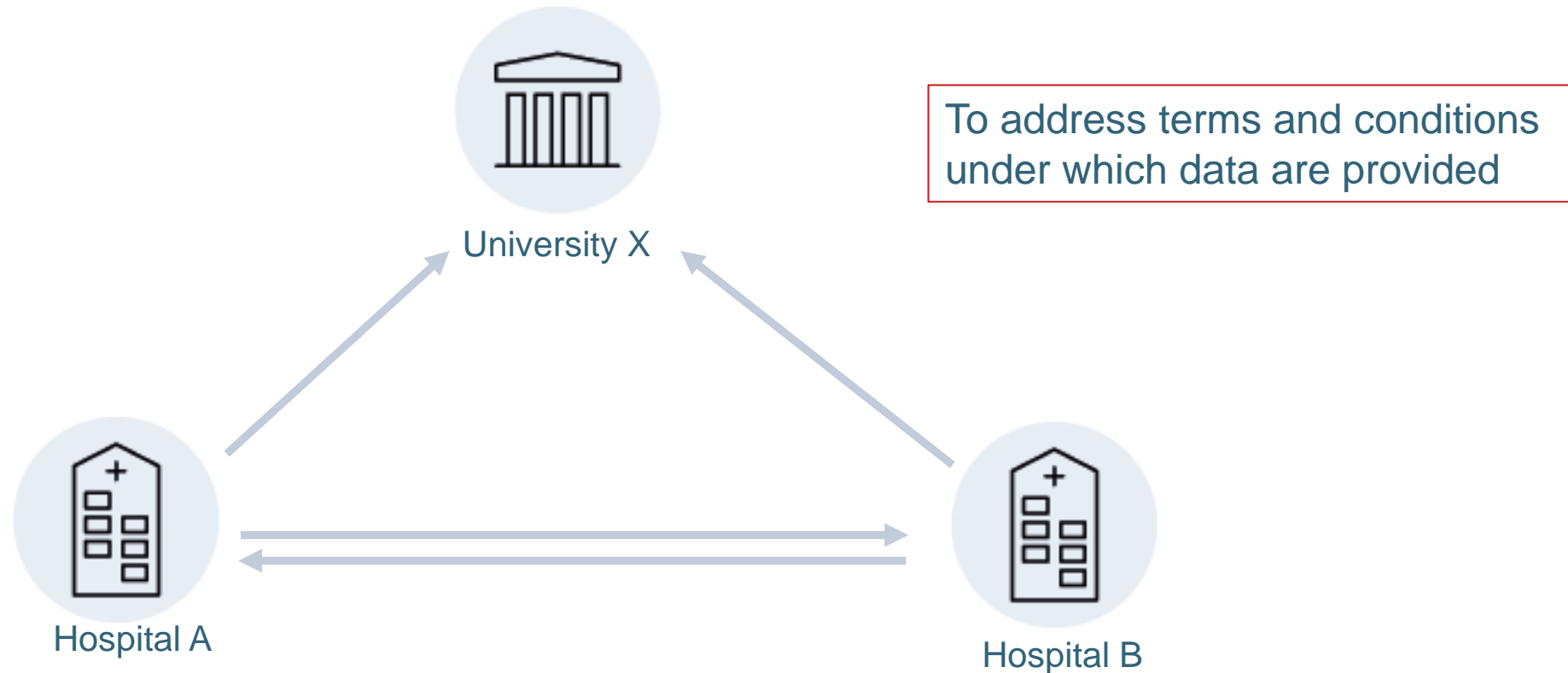
A general **Consortium Agreement** between the different stakeholders...

To address :



- ✗ principle of collaboration
- ✗ principle of data usage
- ✗ governance
- ✗ financial aspects
- ✗ confidentiality
- ✗ intellectual property
- ✗ publications...

...with a **Data Transfer and Use Agreement** as an annex to the Consortium Agreement



Key elements of Data Transfer and Use Agreement

The Data Transfer and Use Agreement (DTUA) is the main written control on how sensitive health data is transferred, processed and exploited in SPHN and BioMedIT.

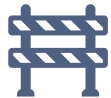
Elements to be addressed in a data transfer and use agreement



Security measures



No attempt at re-identification



Limitation of the data processing purpose (no use for purposes other than research)



Data subject rights: right of access to data...

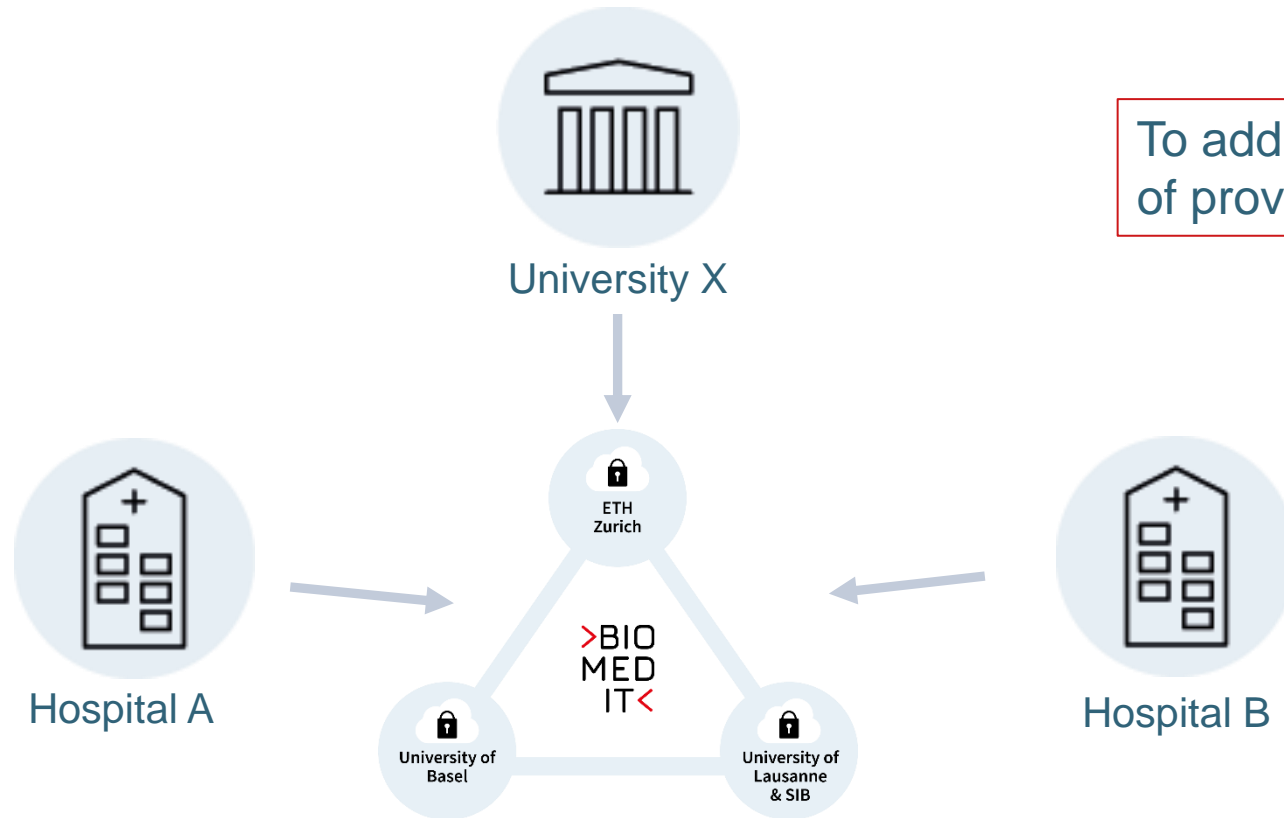


Applicable rules to international data transfers



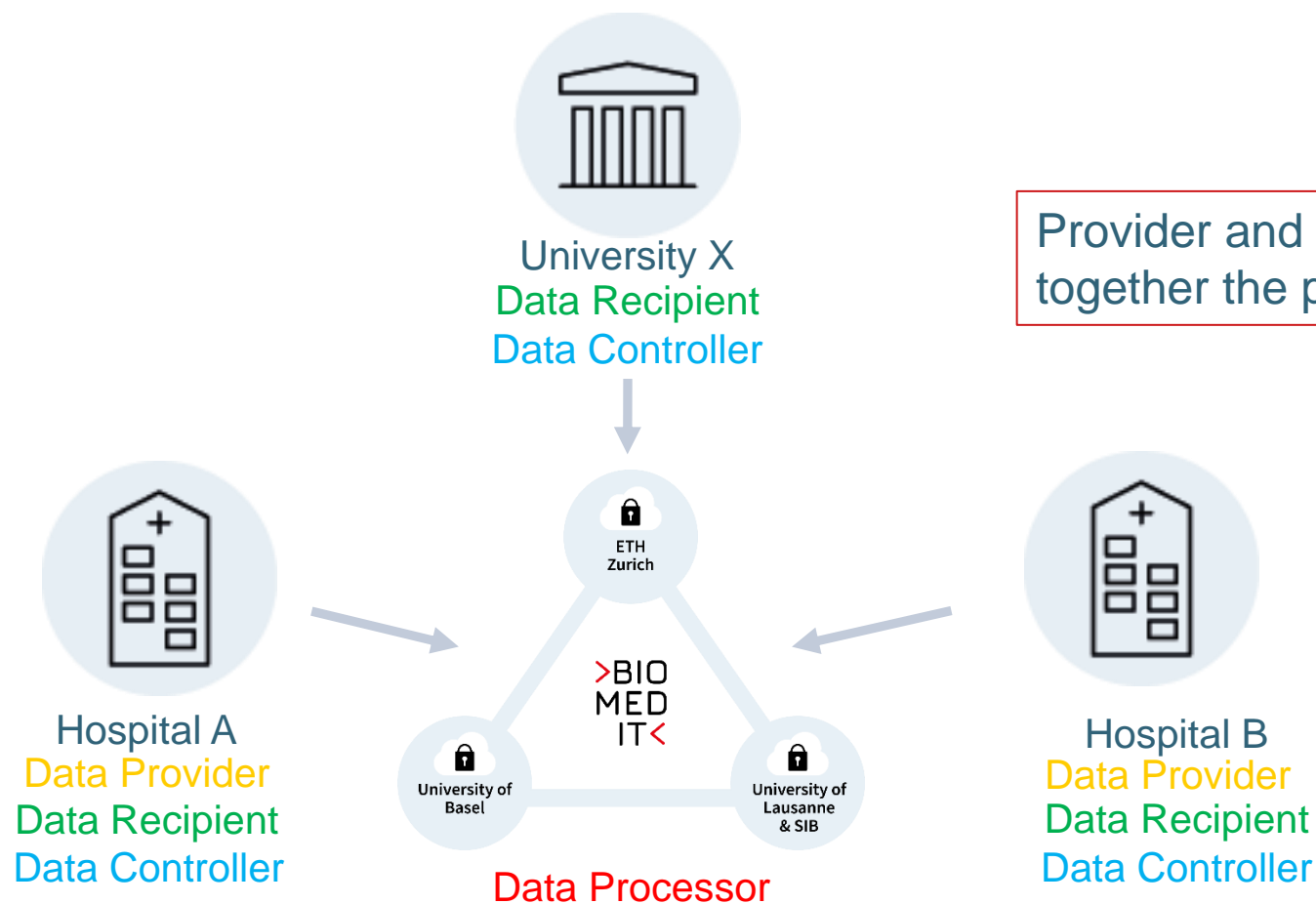
Liability for non-compliance

...and if processing of data is provided as service by a third party (BioMedIT network), a **Data Transfer and Processing Agreement** is needed



To address terms and conditions of provided services

Who **discloses** (data provider) and **accesses** (data recipient) data and **controls** data (data controller). Where are data **processed**?



SPHN legal agreements templates

Overview of available legal agreement templates and their contents

The three types of agreement can be included in a single agreement (e.g.: CA+DTUA+CA; see templates below). When the parties enter into a CA for the purpose of exchanging data and wish to use a subcontractor for data processing the CA integrates a DTUA and DTPA.

- + Consortium Agreement (CA)
- + Consortium Agreement + DTUA + DTPA (multi node)
- + Consortium Agreement + DTUA + DTPA (single node)

- + DTUA + DTPA (multi node)
- + DTUA + DTPA (single node)

- + DTPA (multi node)
- + DTPA (single node)

- + DTUA without an external processor

sphn.ch/dtua

What are the bottlenecks to health data sharing in Switzerland? An interview study

Kelly E. Ormond^a, Sabine Bavamian^b, Claudia Becherer^{cd}, Christine Currat^b, Francisca Joerger^{ce}, Thomas R. Geiger^g, Elke Hiendlmeyer^{cf}, Julia Maurer^h, Timo Staubⁱ, Effy Vayena^a

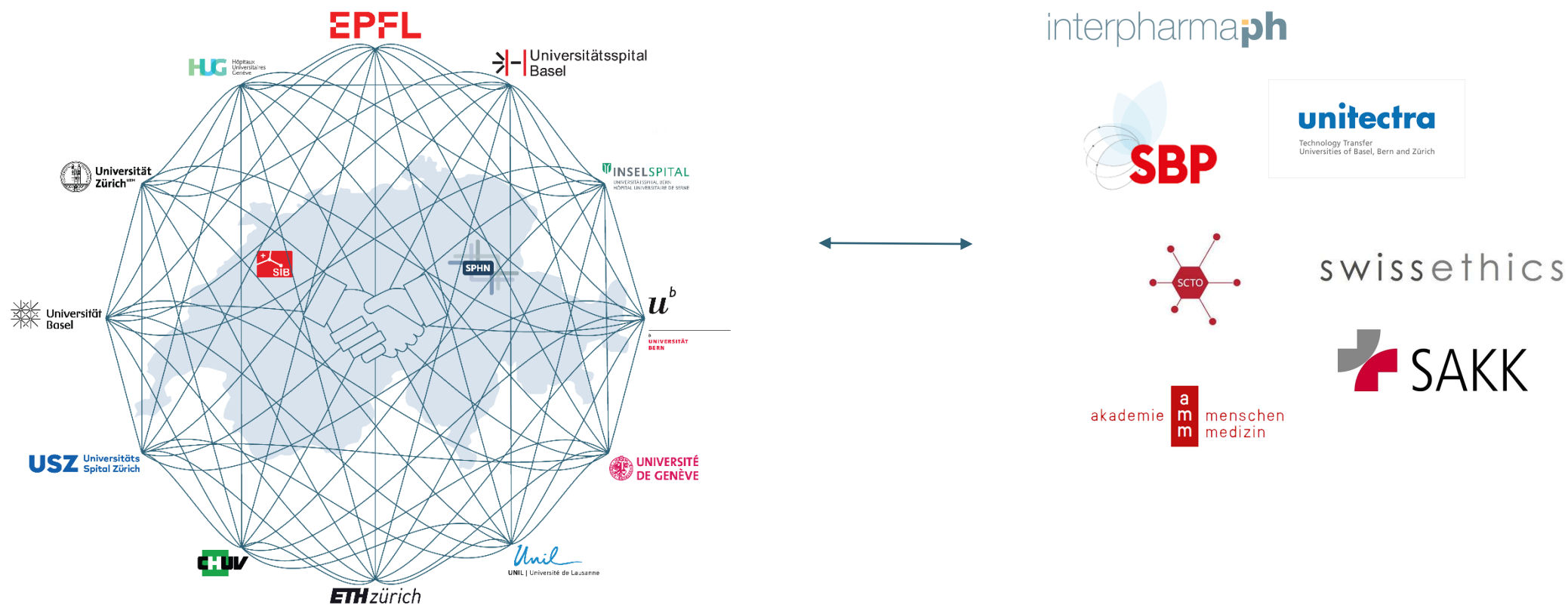
Potential areas for action

Given our study results, how can Switzerland continue to improve its national data sharing and access capabilities? First, given the many areas with questions and uncertainties, a common understanding of the requirements and close coordination and harmonisation of processes, practices, and interpretation of the law is needed at the national level. While streamlined significantly in recent

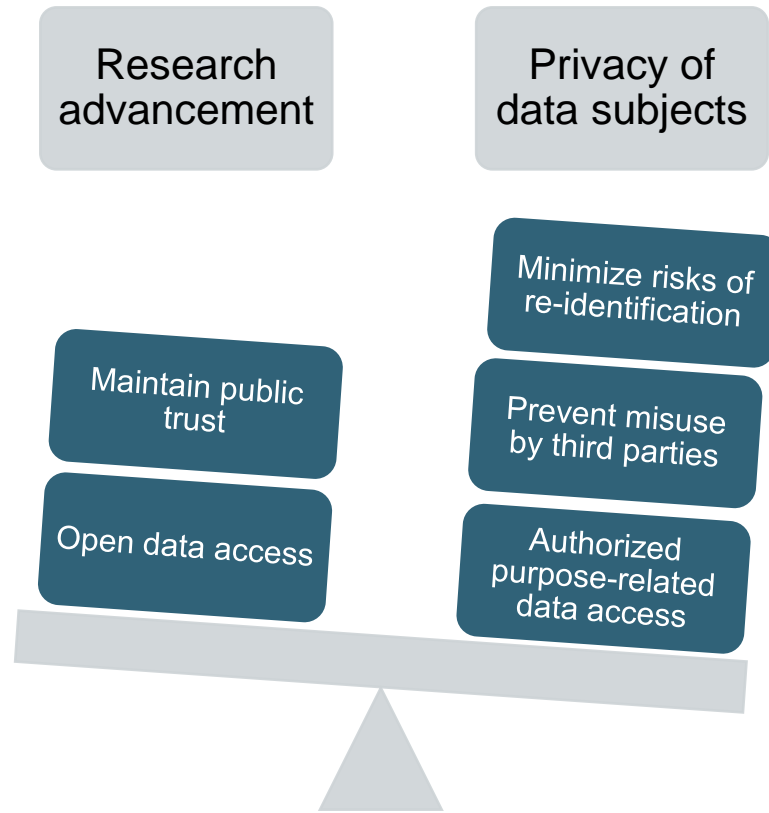
years, logistics could still benefit from additional standardisation and transparent communication, including the potential consideration of a single contact approach at each institution, templates recognised across Switzerland's healthcare institutions and regulatory bodies, and a nationally harmonised general consent process. The guidance

streamlining them. Additionally, organisations could create FAQ documents about how various international privacy and data-sharing laws compare to Swiss laws or clarify some of the questions around the general consent process.

Data Governance Working Group to align on a consolidated data sharing strategy



Balancing competing interests



Data alone is not enough

- For a functioning data ecosystem and broad use of health data in research and innovation, there is a need for:
 - Biomedical expert knowledge
 - Scalable and sustainable core infrastructures
 - A smart governance framework
 - Public acceptability
 - Close coordination at national and international level
 - A change in research culture, to foster collaboration, transparency, and to ensure responsible data practices



Acknowledgements

The SPHN Implementation Teams (MO and DCC):

Thomas Geiger, Christine Remund, Deepak Unni, Harald Witte, Jan Armida, Judit Kiss Blind, Julia Maurer, Manuela Paganini, Michaela Egli, Michael Müller-Breckenridge, Owen Appleton, Patricia Fernandez Pinilla, Petar Horki, Regan Geissmann, Sabine Österle, Sarah Vermij, Shubham Kapoor, Sergio Guarino, Simone Guzzi, Vasundra Touré

The **SPHN NSB** and **NAB**, **Task Forces & WGs**

The **BioMedIT Board** and **workforces** @ ETHZ, Unibas, Unil/SIB

The **Hospital workforces** @ USZ, USB, CHUV, Insel, HUG



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www.BioMedIT.ch
www.sib.swiss/phi

HRO Lunch Session - Part II

Data sharing and open research data – details for HRO projects

Claudia Saupper, Clinical Data Center, DKF Operations, University Hospital Basel

– **Open Access**



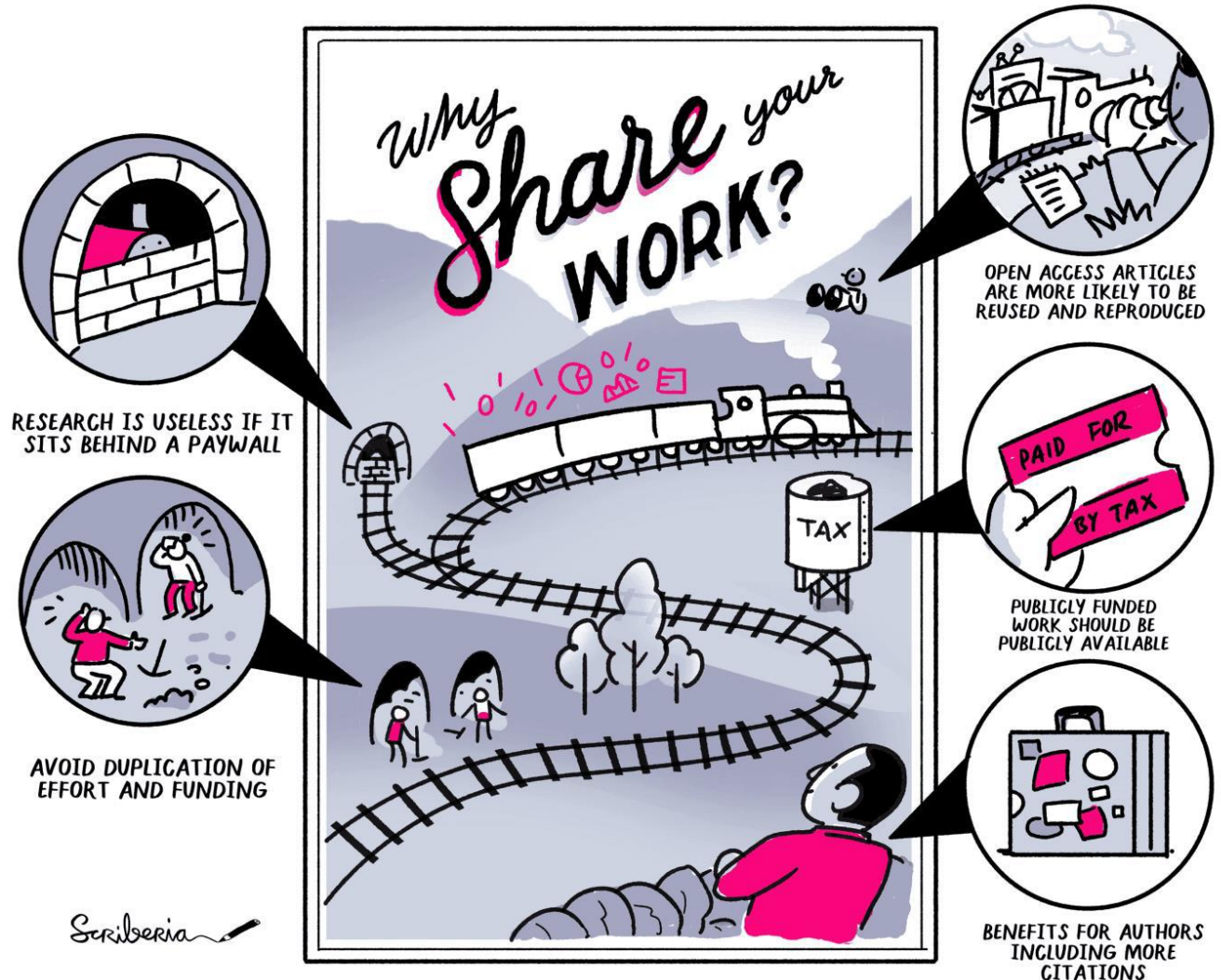
– **FAIR Principles**



– **MF-DAC**

– Data Access Committee of the Medical Faculty of the University of Basel

- **Data access entails ...**
 - Distributing data
 - Sharing data
 - Publishing data
 - Linking data to outputs
 - Controlling access
 - Establishing copyright
 - Disseminating data to wider audiences



- Public funders of research projects (e.g. SNSF) request **open access publication of the results** of funded research projects
- No problem so far
 - There are many **open access journals** where **research results** can be published

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80 LANGUAGES	136 COUNTRIES REPRESENTED	13,783 JOURNALS WITHOUT APCS	20,996 JOURNALS	10,559,174 ARTICLE RECORDS
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- Public funders of research projects (e.g. SNSF) and peer-reviewed medical journals request **sharing of the underlying data** of publications



© Adobe Stock | Maksim Kabakou

The SNSF requires grantees to make the results of SNSF-funded projects available in an open access (OA) publication or database. Researchers can apply for grants to cover OA publishing costs.



General implementation regulations for the Funding Regulations

2.13 Material costs: **costs for granting access to research data (Open Research Data)** - *shortened version*

The costs of enabling access to research data that was collected, observed or generated under an SNSF grant are eligible if the following requirements are met:

- The research data is deposited in recognized scientific, digital data archives (data repositories) that meet the FAIR principles and do not serve any commercial purpose.
- The costs are specifically related to the preparation of research data in view of its archiving, and to the archiving itself in data repositories
- The maximum charge per grant is generally **CHF 10,000**.

THE LANCET

Data sharing - shortened version

All submitted research Articles must contain a **data sharing statement**, to be included at the end of the manuscript. Data sharing statements must include:

- **Whether data collected for the study**, including individual participant data and a data dictionary defining each field in the set, **will be made available**;
- **What** data will be made available (deidentified participant data, participant data with identifiers, data dictionary, or other specified data set);
- **Whether additional, related documents will be available** (e.g. study protocol, informed consent form);
- **When** these data will be available;
- **Where** the data will be made available (including complete URLs or **email addresses** if relevant);
- **By what access criteria** data will be shared (including with whom, for what types of analyses, by what mechanism – e.g., with or without investigator support, with a **signed data access agreement** - or any additional restrictions).

Some research will **use and produce sensitive data** that cannot be shared unconstrained

Personal Data

All information relating to an identified or identifiable person, including health-related personal data.

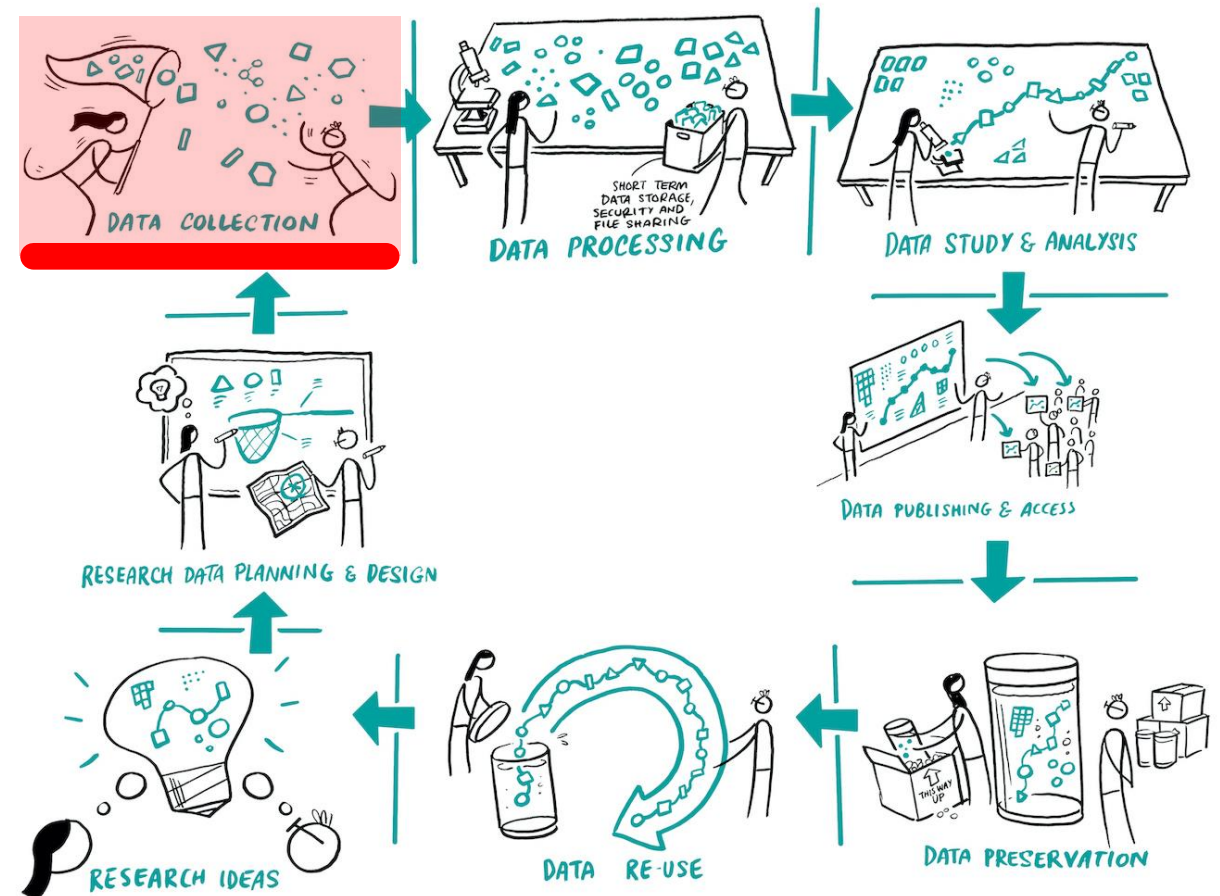
Sensitive Personal Data

Data on:

1. religious, ideological, political or trade union-related views or activities,
2. health, the intimate sphere or the racial origin,
3. social security measures,
4. administrative or criminal proceedings and sanctions.

Health-Related Personal Data

Information concerning the health or disease of a specific or identifiable person, including genetic data.

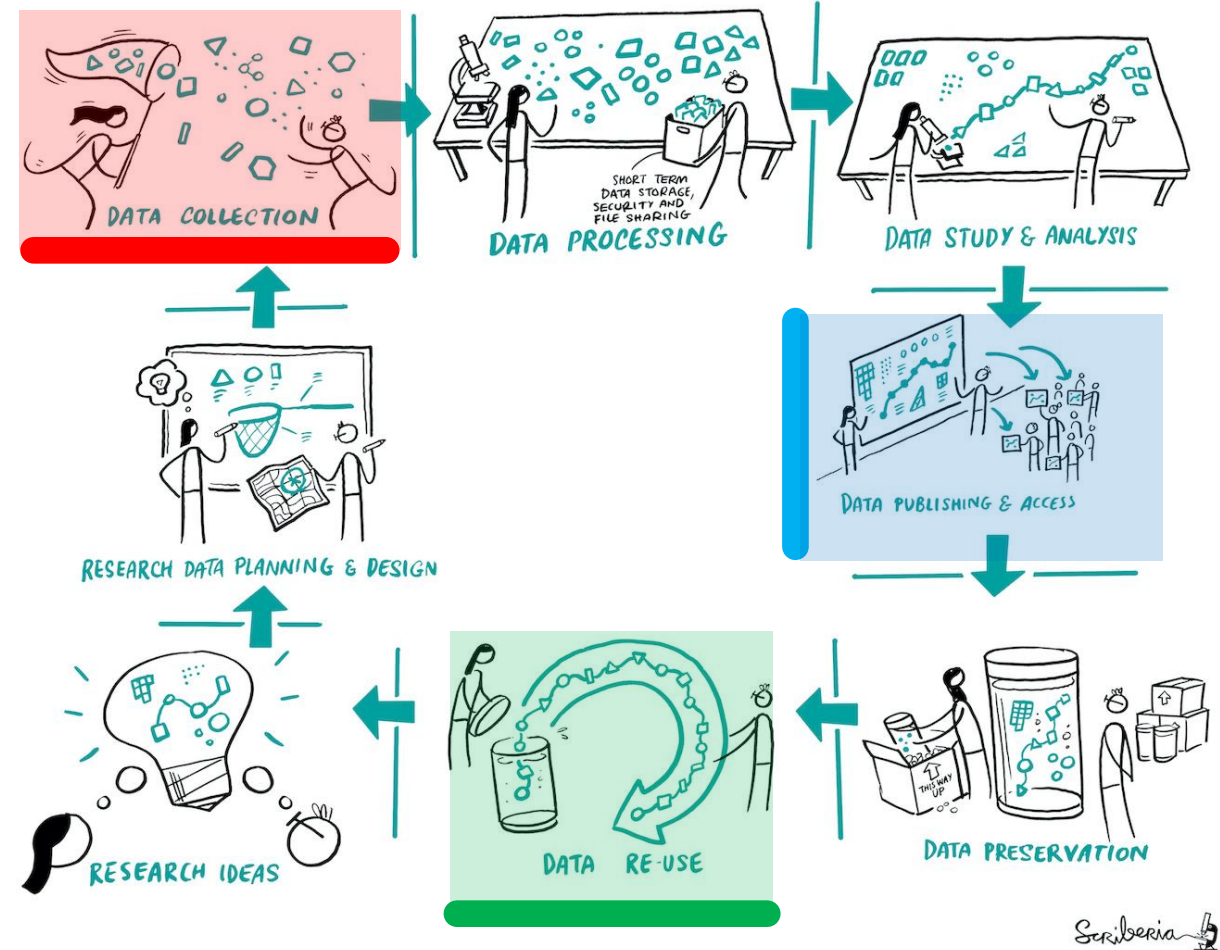


Scriberia

The Turing Way Community. This illustration is created by Scriberia with The Turing Way community. Used under a CC-BY 4.0 licence. DOI: 10.5281/zenodo.3332807

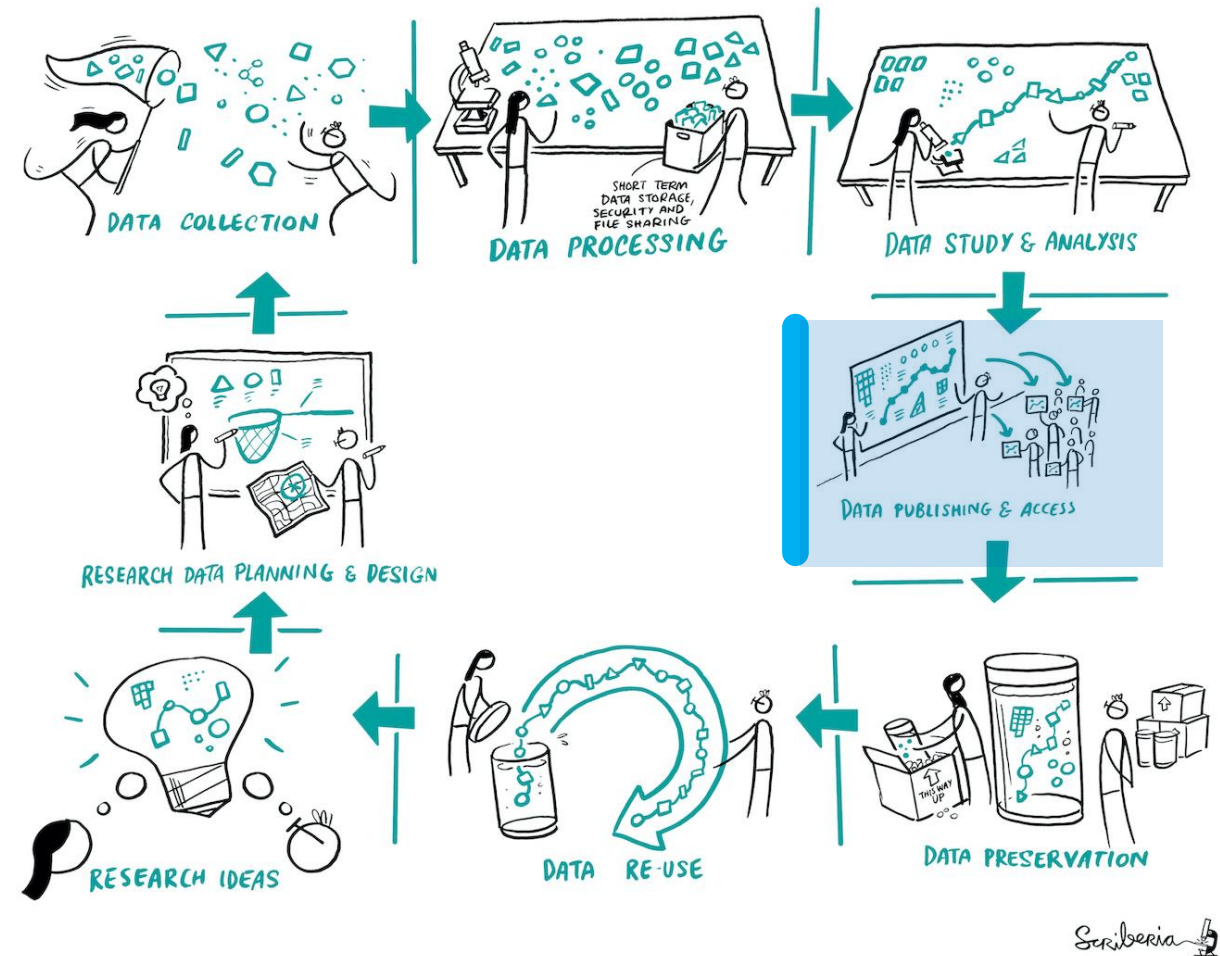
How can **sensitive research data** from projects be made accessible while preserving the legal and ethical rights of the data donors?

- To fulfill requirements of scientific journals when **submitting publication manuscripts**?
- For **re-use by other researchers**?



Install an **independent Data Access Committee (DAC)** that will **manage access requests** for your **sensitive research data**.

- The DAC is ideally referenced in the **Data Management Plan** of your project
- Build on the **FAIR Principles** for scientific data management and stewardship



The Turing Way Community. This illustration is created by Scriberia with The Turing Way community. Used under a CC-BY 4.0 licence. DOI: 10.5281/zenodo.3332807

Findable | **A**ccessible | **I**nteroperable | **R**e-usable

Open Access data and FAIR data are not the same

FAIR data are

- Easier to find and understand
- Accessible under well defined conditions (e.g. through a DAC with clear access rules)

Principles when publishing and sharing your sensitive research data

- Share sensitive data as openly as possible, but as closed as necessary
- Ensure legal and regulatory compliance when making sensitive research data available to the public
- Make at least the metadata tagged with unique identifiers available in an openly accessible non-commercial repository
- Ensure third party data access requests to sensitive research data are handled by an **independent Data Access Committee**

Open Access > Controlling Access to Sensitive Data

Sensitive research data

Personal Data

All information relating to an identified or identifiable person, including health-related personal data.

Sensitive Personal Data

Data on:

1. religious, ideological, political or trade union-related views or activities,
2. health, the intimate sphere or the racial origin,
3. social security measures,
4. administrative or criminal proceedings and sanctions.

Health-Related Personal Data

Information concerning the health or disease of a specific or identifiable person, including genetic data.

Metadata *

Summary report *

Anonymised data

Raw data

Open access
data repository



Open access
scientific publication



Open access
scientific publication



Restricted access
data repository



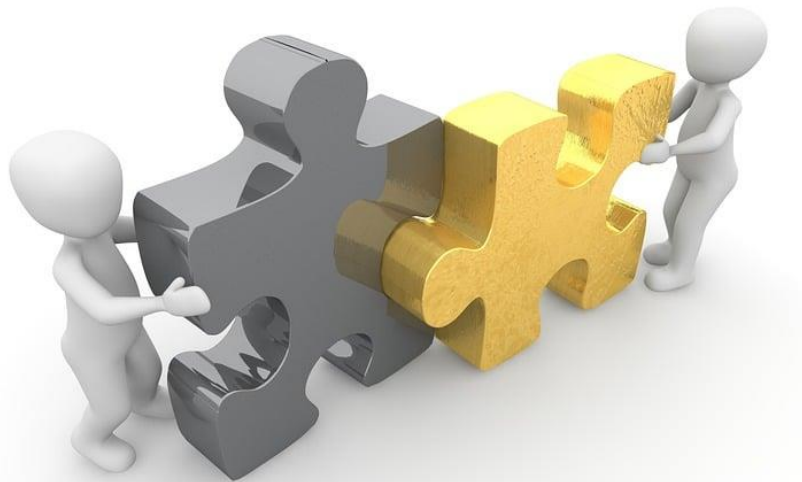
Third-party data
access request

Data Access Committee

* without sensitive information

Open Research Data vs. Sensitive Personal Data

- How did the Medical Faculty of the University of Basel solve this issue?



Open Access > Controlling Access to Sensitive Data

USB Data Governance Board

Reviews and approves sharing of
USB routine data

MF-DAC

Reviews and approves sharing of
sensitive research data

Governance Documents

USB / DKF Guideline “Herausgabe von Patientendaten zu Forschungszwecken”

Guidance “Data Access Committee of the Medical Faculty of the University of Basel”

Data

USB clinical routine patient and laboratory data

Sensitive biomedical research data created by researchers affiliated with the University Hospital Basel and/or the Medical Faculty of Uni Basel

Request types

Request for feasibility query

Data access request by USB / DBM / DBE researcher

Data access request by external researcher

Request for establishment of a DAC (Data Submission Process)

Request from the scientific community to access USB / Medical Faculty biomedical research data

Data Access Committee of the Medical Faculty of the University of Basel (MF-DAC)

Mandate

- Facilitate access and sharing of sensitive research data
- Preserve the legal and ethical rights of the data donors (e.g. patients)
- Provide an independent committee for researchers affiliated with the University Hospital Basel and/or the Medical Faculty of the University of Basel to manage access to sensitive research data
- Represent the University Hospital Basel and the Medical Faculty of the University of Basel as review board to approve requested secondary use of sensitive research data

Data Access Committee of the Medical Faculty of the University of Basel (MF-DAC)

Satisfy the requirements of the most relevant stake holders

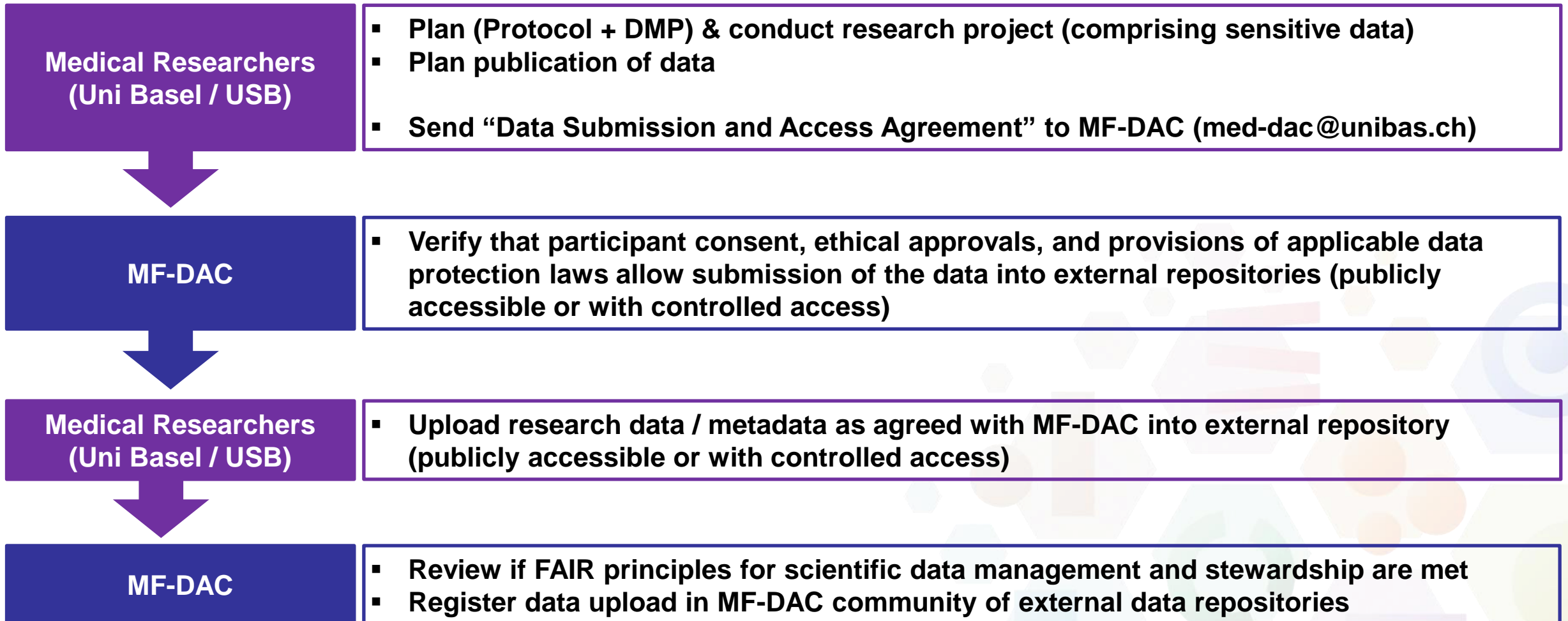
- Peer-reviewed medical journals
- Public funders of research projects (e.g. SNSF)
- Researchers of the scientific community
- Data repositories



Data Access Committee of the Medical Faculty of the University of Basel (MF-DAC)

Independent multi-membered cross-domain body

- DKF Operations Data Specialist (MF-DAC Coordinator)
- DKF Operations Regulatory Affairs Manager
- Representative of the University Hospital Basel Legal Department
- Independent Medical Expert of the Medical Faculty's Department concerned
- If needed, the MF-DAC can decide to leverage the opinion of additional experts, e.g. members of ethics committees, additional domain experts



External Researchers

- Third party request (Data Requesters) to access sensitive research data created by researchers affiliated with the USB and/or the Medical Faculty of the University of Basel
- Data Requesters submit “Data Access Request” to MF-DAC (med-dac@unibas.ch)

MF-DAC

- Review and decide on data access request
- Upon approval: Organize DTUA and transfer of the requested research data to Data Requesters

Contact

- med-dac@unibas.ch
- <https://dkf.unibas.ch/de/services/data-science/data-access-committee/>

MF-DAC Review Board

- Claudia Saupper (DKF Operations, IT Operations) (MF-DAC Coordinator)
- Claudia Becherer (DKF Operations, Regulatory Affairs)
- Thomas Gruberski (USB, Legal Department)
- Matthias Briel (DKF, Clinical Epidemiology) / Robert Ivanek (DBM, Bioinformatics Core Facility)

EGA MF-DAC Data Repository (<https://ega-archive.org/dacs/EGAC00001002981>)

- Managed by the DBM Team (Robert Ivanek / Julien Roux)) für -omics data uploads
- Managed by MF-DAC Coordinator for all other data uploads

Data Access Committee of the Medical Faculty of the University of Basel (MF-DAC)



Dac ID	Contact Person	Email	Access Information
EGAC00001002981	MF-DAC Coordinator	med-dac [at] unibas [dot] ch	No additional information is available

MF-DAC - Zenodo (<https://www.zenodo.org/communities/mf-dac-unibas/>)

- Used for storage of metadata of sensitive clinical research data
- Admin: Claudia Saupper (DKF Operations)



**University
of Basel**

Faculty of
Medicine

Data Access Committee of the Medical
Faculty of the University of Basel (MF-
DAC)

Welcome to the community of the Data Access
Committee of the Medical Faculty of the University
of Basel (MF-DAC).

[Read more](#)

Curated by:

MF-DAC-UNIBAS

Curation policy:

User scope: Researchers affiliated with the
Medical Faculty of the University of Basel and/or
the University Hospital of Basel.



Many Thanks for your attention.

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> Document version:

2024-11-13

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Thank you for participating!

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SCTO PLATFORMS

11 September	BASEC – A practical walk-through for HRO projects
2 October	Mastering Consent: Key insights into general and informed consent for HRO projects
13 November	Data sharing and open research data – details for HRO projects
4 December	Sample management and biobanking – essentials for HRO projects

More information and registration:
sctoplatforms.ch/HRO-training-series