University of Basel

Department of Clinical Research

University Hospital Basel

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

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MF-DAC Explained, Version 2023-11-15

What is the purpose of a Data Access Committee?

Why does the Medical Faculty need a Data Access Committee?

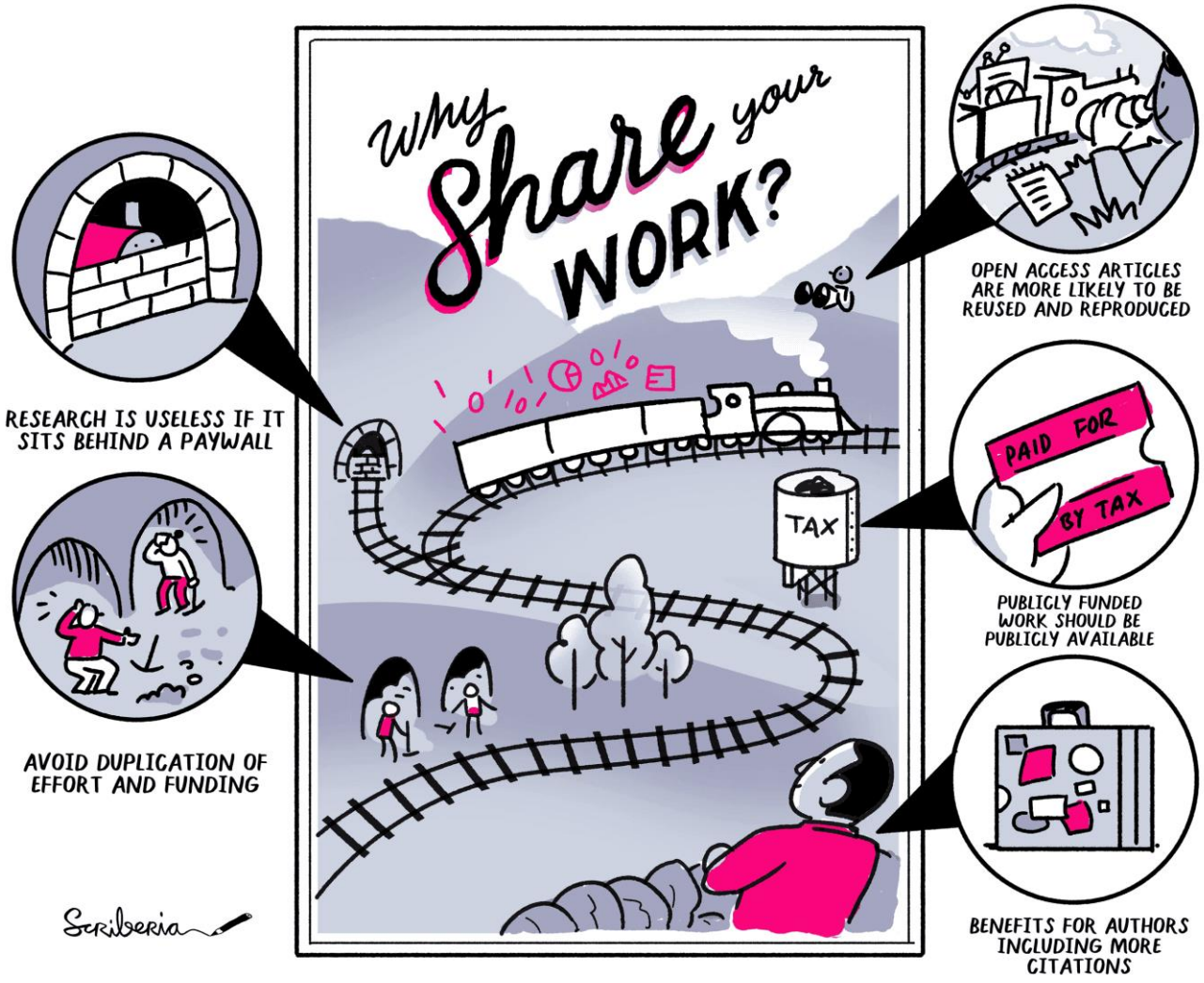
Data Access.

- Open Access & FAIR Data Sharing
- Controlling Access to Sensitive Research Data: MF-DAC & USB DGB
- MF-DAC (Data Access Committee of the Medical Faculty of the University of Basel)
  - Purpose
  - Response
  - Composition
  - Processes
  - Contact & Review Board
  - Data Repositories

Data Access.

> Data access entails …

- Distributing data
- Sharing data
- Publishing data
- Linking data to outputs
- Controlling access
- Establishing copyright
- Disseminating data to wider audiences



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.5706310

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.

OPEN ACCESS

Public funders of research projects (e.g. SNSF) and peer-reviewed medical journals request **sharing of the underlying data** of publications

Open Access > Research Data.

The Swiss National Science Foundation (SNSF) requires that at least the data underlying a publication be submitted to appropriate public data repositories, as do many publishers and other research funding agencies.

Schweizerischer Nationalfonds

OPEN ACCESS

https://www.snf.ch/en/dah3uC2QX95tfPNd/topic/open-science

General implementation regulations for the Funding Regulations

2.13 Material costs: **Costs for granting access to research data (Open Research Data)**
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 recognised 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**.

Open Access > Research Data.

Data sharing

All submitted research Articles must contain a data sharing statement, which 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 to others ("undecided" is not an acceptable answer); 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 (eg, study protocol, statistical analysis plan, informed consent form); when these data will be available (beginning and end date, or "with publication", as applicable); 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—eg, with or without investigator support, after approval of a proposal, with a signed data access agreement, or any additional restrictions).

THE LANCET

Open access

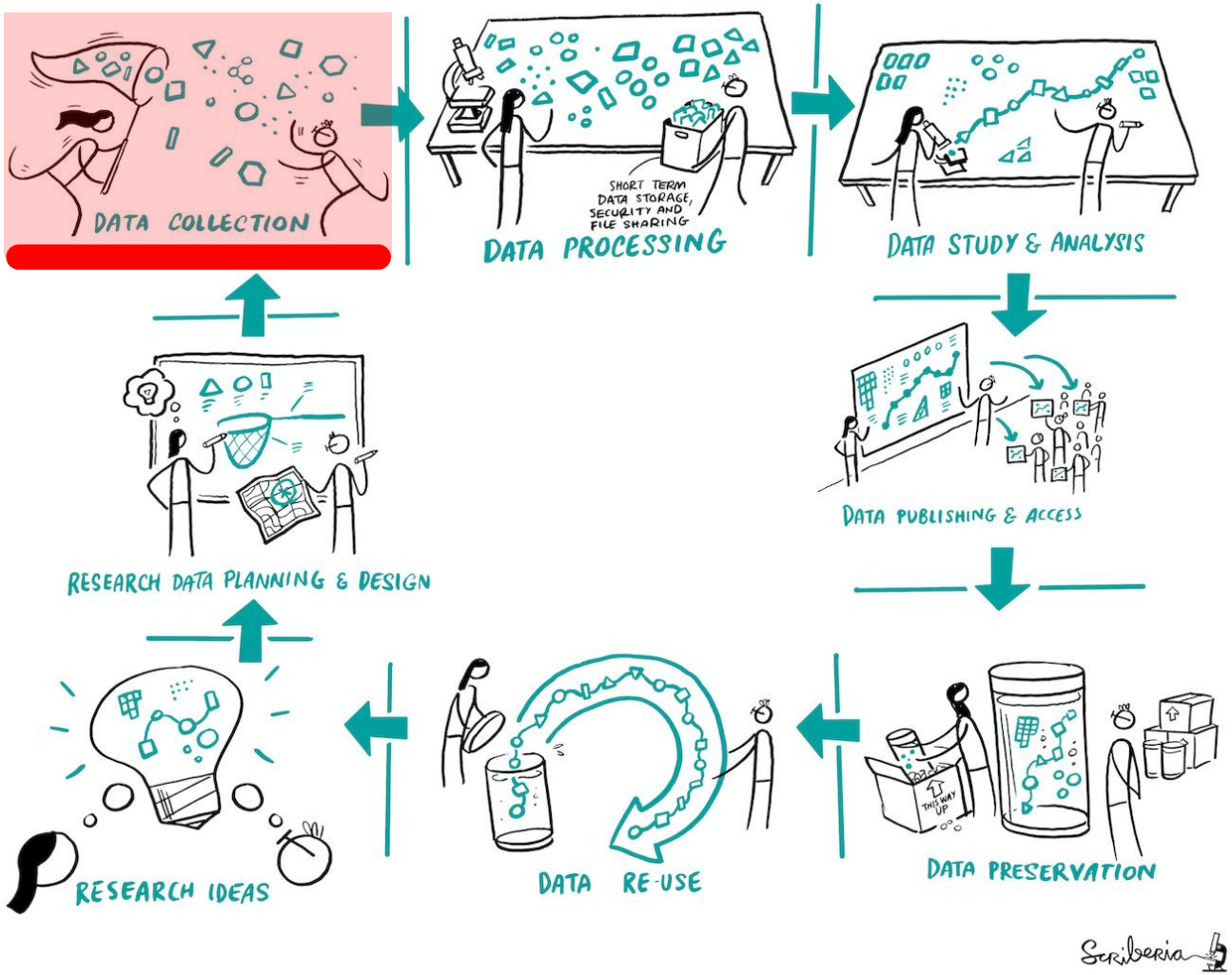
Open Access > Sensitive Research Data.

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.



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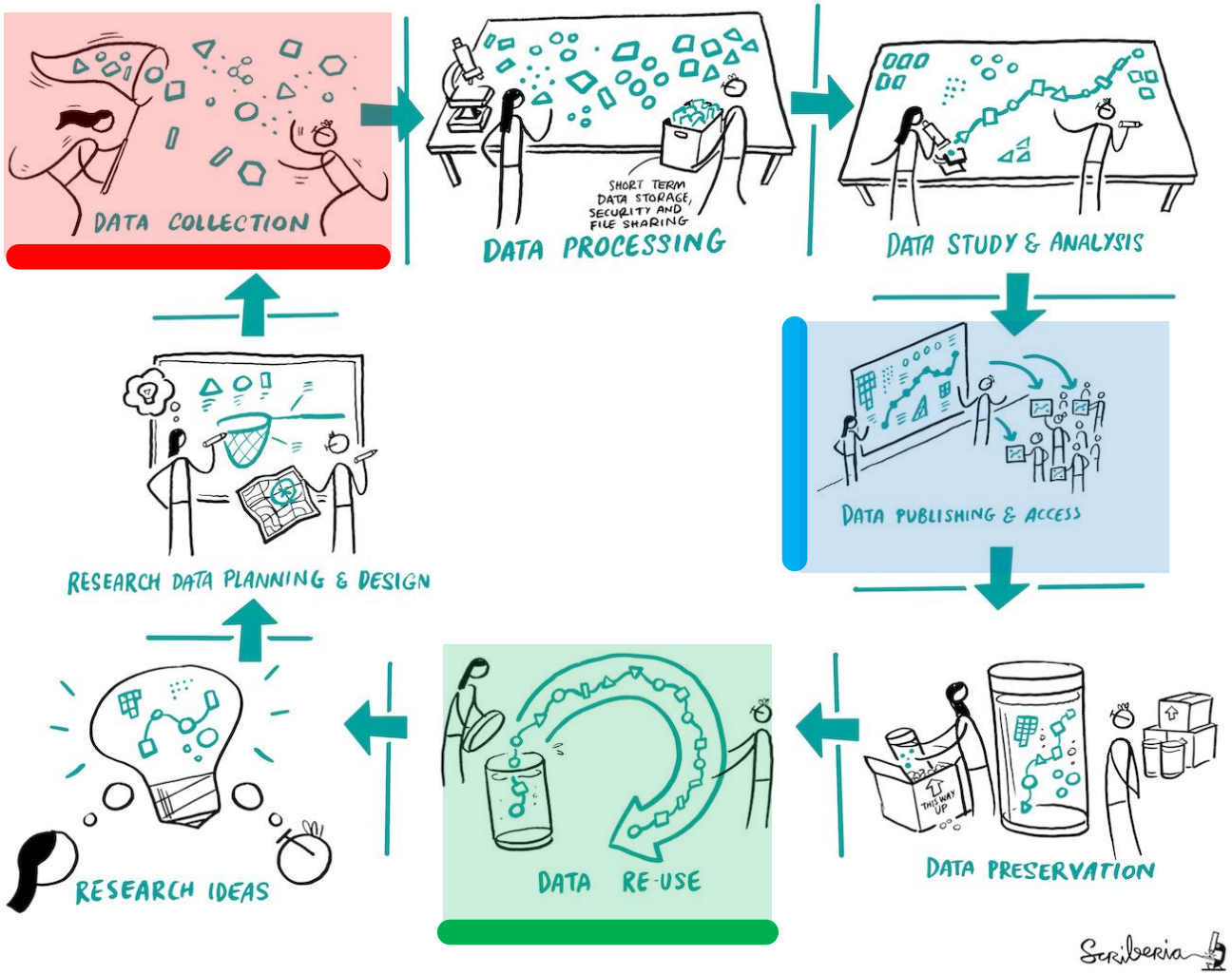
How can sensitive research data from projects be made accessible while preserving the legal and ethical rights of the data donors?

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



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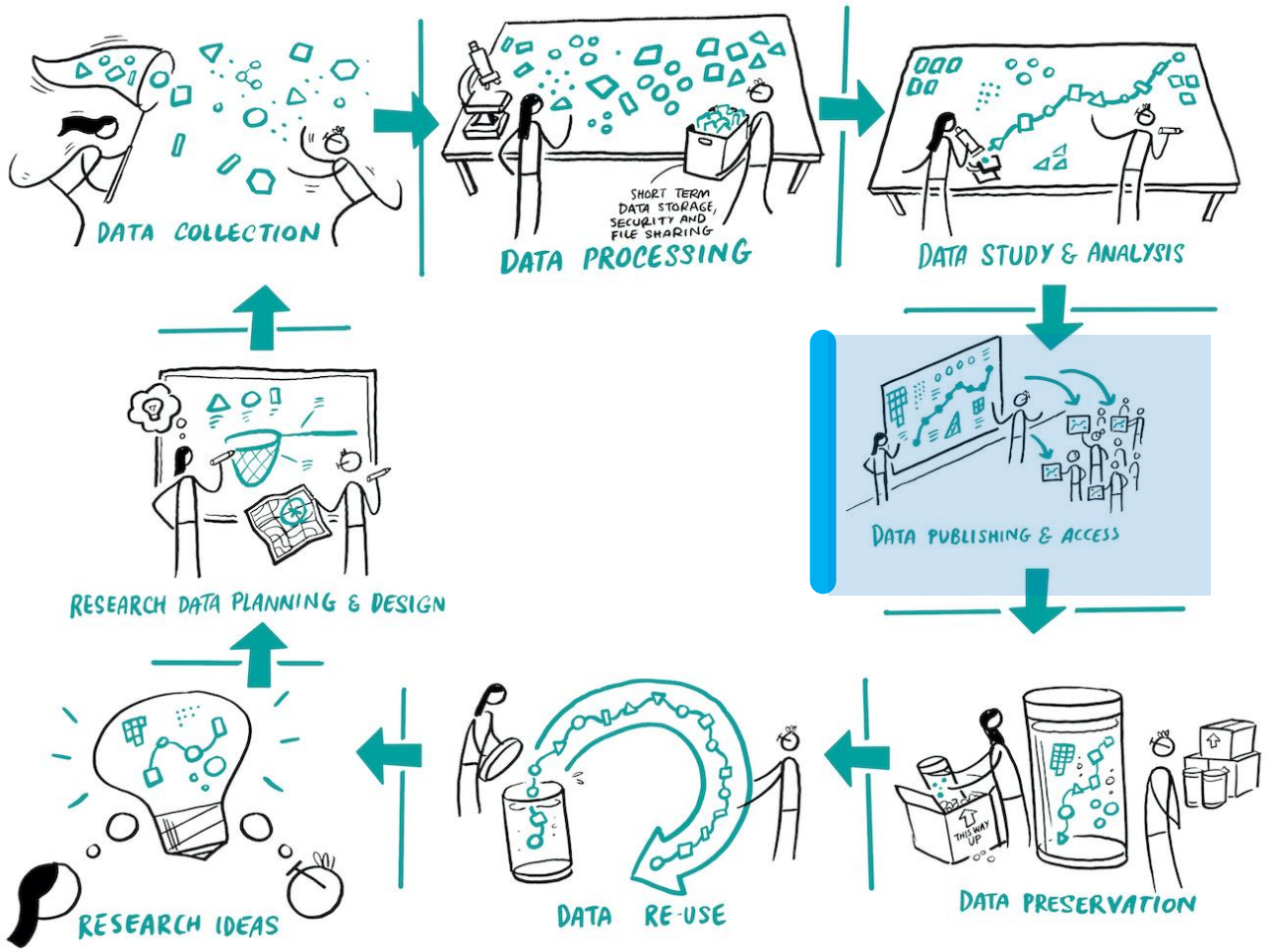
Open Access > FAIR Principles.

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 [1,2]



(1) Wilkinson et al. (2016), The FAIR Guiding Principles for scientific data management and stewardship, Scientific Data 3, doi:10.1038/sdata.2016.18
(2) https://www.go-fair.org/fair-principles/

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Findable | Accessible | Interoperable | Re-usable

Open Access data and FAIR data are not the same

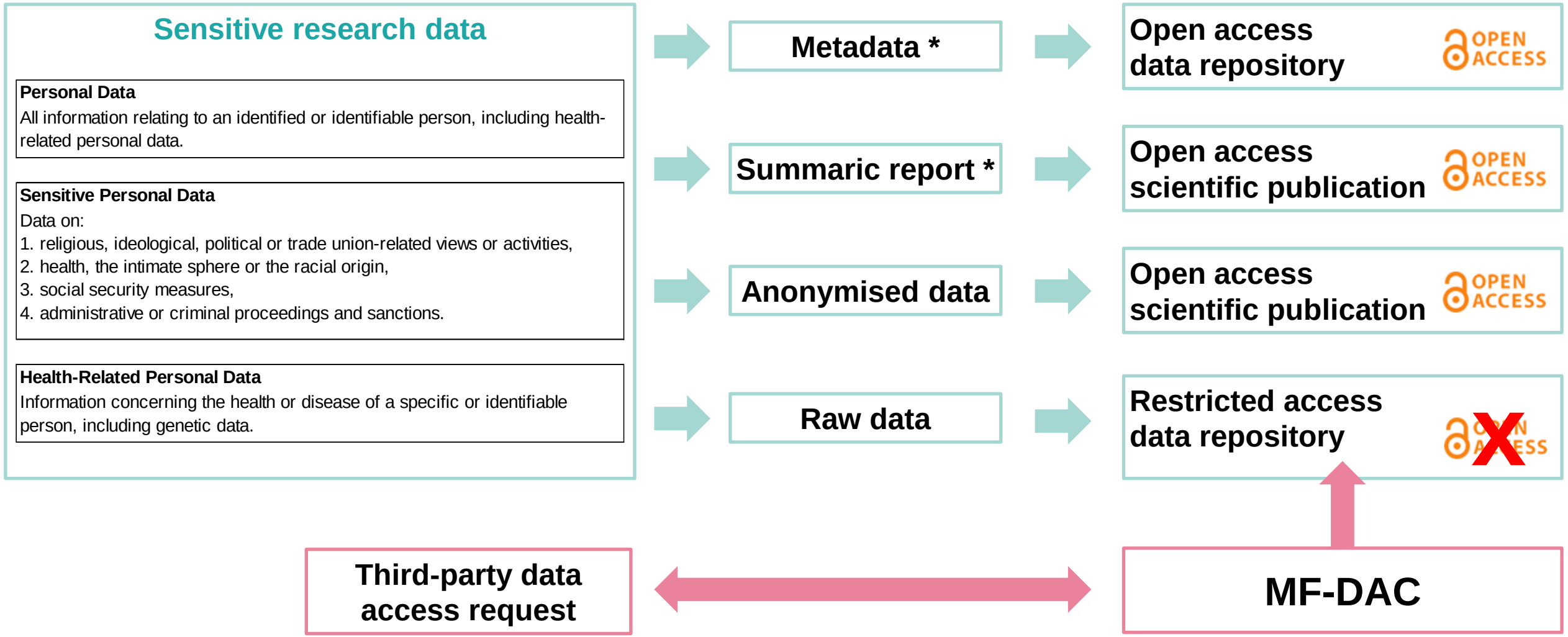
FAIR data are

- **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 Research Data.



* without sensitive information

Open Access > Controlling Access to Sensitive Research Data.

	USB Data Governance Board	**MF-DAC**
	Reviews and approves sharing of USB routine data	**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**

MF-DAC > Purpose.

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

MF-DAC > Response.

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

MF-DAC > Composition.

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, representatives of the Legal Department of the University of Basel, representatives of the University Hospital Basel D&ICT Research and Analysis Services, or the Data Protection Officer of the University of Basel.

MF-DAC > Processes > Data Submission.

Medical Researchers (Uni Basel / USB)

- Plan (Protocol + DMP) & conduct research project (comprising sensitive data)
- Plan publication of data
- Send “Data Submission and Access Agreement” to MF-DAC (med-dac@unibas.ch)

MF-DAC

- Verify that participant consent, ethical approvals, and provisions of applicable data protection laws allow submission of the data into external repositories (publicly accessible or with controlled access)

Medical Researchers (Uni Basel / USB)

- Upload research data / metadata as agreed with MF-DAC into external repository (publicly accessible or with controlled access)

MF-DAC

- Review if FAIR principles for scientific data management and stewardship are met
- Register data upload in MF-DAC community of external data repositories

MF-DAC > Processes > Data Submission.

> Documents to be submitted by USB / University of Basel researchers who would like the MF-DAC to act as a trustee for their sensitive research data

- Completed and signed form "Data Submission and Access Agreement“
- Description of the research data and related metadata
- Approved informed-consent form associated with the research data
- Approved study protocol and all approved study protocol amendments related to the research data including respective ethics committee approvals
- Information where the research data are stored, how they can be accessed in case only metadata are uploaded into the repository, how long the research data must be archived, and how the research data must be treated after this period (ideally documented in a Data Management Plan (DMP))
- If applicable, reference to study registration in BASEC and on ClinicalTrials.gov
- Statement of the researchers on their institutional affiliation (work contract with USB or Uni Basel to clarify which institution has the function of Data Controller of the sensitive biomedical research data)

MF-DAC > Processes > Data Access Request.

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**

MF-DAC > Contact & Review Board.

> 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)

MF-DAC > Data Repositories.

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

- **Used for storage of …omics data**
- Admin: Claudia Saupper (DKF Operations) and DBM Bioinformatics CF (Robert Ivanek / Julien Roux)

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

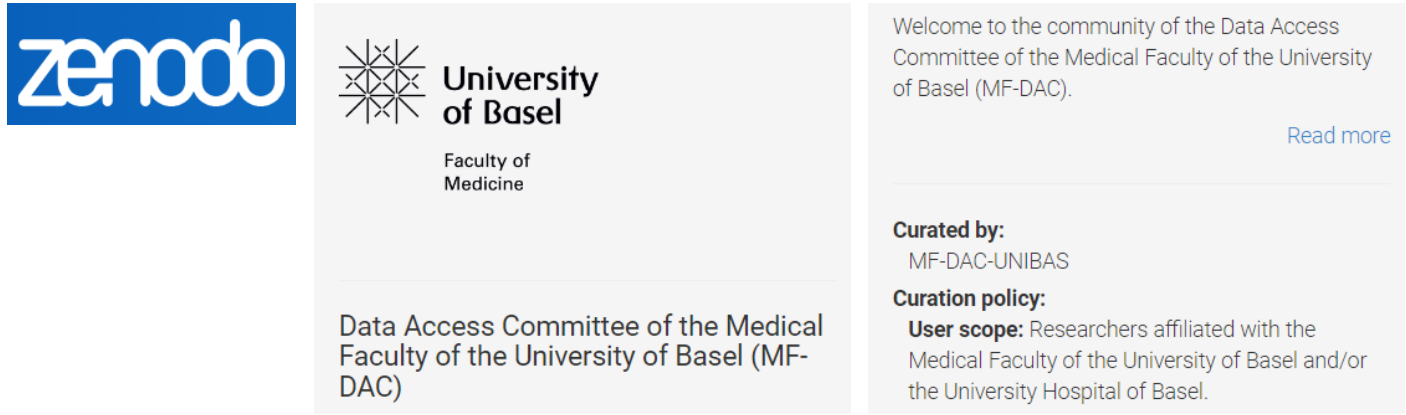
EUROPEAN GENOME-PHENOME ARCHIVE

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

MF-DAC > Data Repositories.

> **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)



Thank you
for your attention.

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