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DEPARTMENT OF
CLINICAL RESEARCH

Week of Clinical Research

Access the programme here:



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Open Research Data

In Clinical Studies

Dr. habil. Olga Churakova

DCR Day of Clinical Research



Image: © UB UniBE

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Research Data Management Data Stewards



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and Social Sciences
[Jennifer Morger](#)



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Theology
Digital Humanities
[Ursula Loosli](#)



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Vetsuisse
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Data Science IT
[Dr.-Ing. Federico Grasso Toro](#)



Human Sciences
[Dr. Christine Krebs](#)

u^b Open Research Data

- Open Research Data Strategy
- Go FAIR and CARE
- Research Data Management Lifecycle
- Support

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Open Research Data Strategy

Swiss National Science Foundation

"Research data should be freely accessible to everyone –
for scientists as well as for the general public".

SNSF

If there are no legal, contractual or ethical restrictions
«**Open as possible, protect as necessary**»

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Open Research Data Strategy

Swissuniversities

"Open Research Data (ORD) has to do with facilitating access to and reuse of research data."

"ORD practices support transparent, reproducible research findings."

swissuniversities

<https://www.swissuniversities.ch/en/topics/digitalisation/open-research-data>

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FAIR Principles

Go FAIR

scientific **data**

[Explore content](#) ▾ [About the journal](#) ▾ [Publish with us](#) ▾

[nature](#) > [scientific data](#) > [comment](#) > article

Comment | [Open access](#) | [Published: 15 March 2016](#)

The FAIR Guiding Principles for scientific data management and stewardship

[Mark D. Wilkinson](#), [Michel Dumontier](#), [IJsbrand Jan Aalbersberg](#), [Gabrielle Appleton](#), [Myles Axton](#), [Arie Baak](#), [Niklas Blomberg](#), [Jan-Willem Boiten](#), [Luiz Bonino da Silva Santos](#), [Philip E. Bourne](#), [Jildau Bouwman](#), [Anthony J. Brookes](#), [Tim Clark](#), [Mercè Crosas](#), [Ingrid Dillo](#), [Olivier Dumon](#), [Scott Edmunds](#), [Chris T. Evelo](#), [Richard Finkers](#), [Alejandra Gonzalez-Beltran](#), [Alasdair J.G. Gray](#), [Paul Groth](#), [Carole Goble](#), [Jeffrey S. Grethe](#), ... [Barend Mons](#)  [+ Show authors](#)

[Scientific Data](#) **3**, Article number: 160018 (2016) | [Cite this article](#)

658k Accesses | **6405** Citations | **2137** Altmetric | [Metrics](#)

<https://doi.org/10.1038/sdata.2016.18>



<https://www.go-fair.org/fair-principles/>

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FAIR Principles Go FAIR



Physica Medica
Volume 82, February 2021, Pages 158-162



Invited commentary

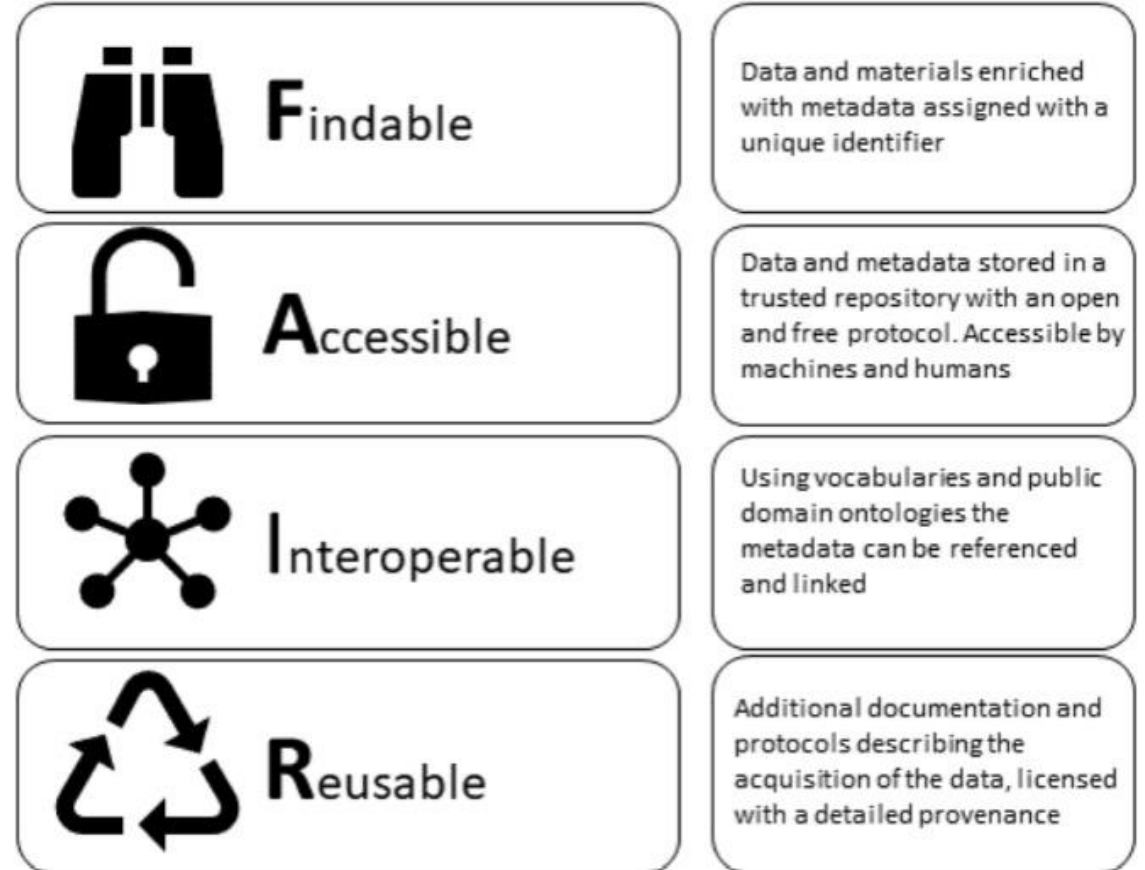
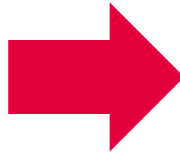
Making radiotherapy more efficient with FAIR data

Petros Kalendralis  , Matthijs Sloep, Johan van Soest, Andre Dekker, Rianne Fijten¹

Department of Radiation Oncology (Maastr), GROW School for Oncology, Maastricht University Medical Centre+, 6229 ET Maastricht, The Netherlands

<https://doi.org/10.1016/j.ejmp.2021.01.083>

FAIR ≠ OPEN → Metadata



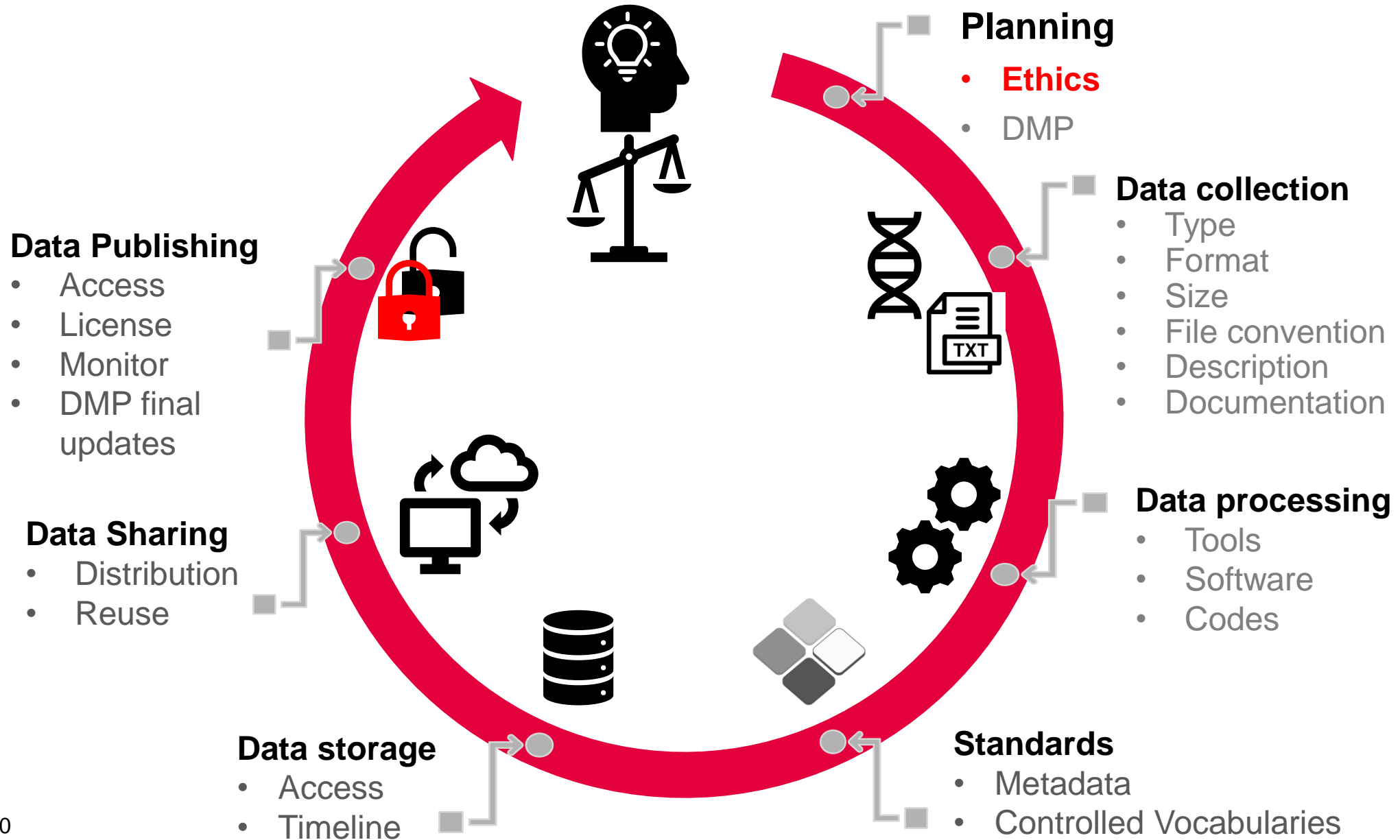
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FAIR and CARE Principles



Carroll SR, et al. Front Genet. 2022. doi: 10.3389/fgene.2022.1052620.

Research Data Management Life Cycle



Manage Research Data Ethically

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Kanton Bern
Canton de Berne

Ethics commissions
authorisation required



Faculty ethics committees
National research councils

Cantonal Ethics Commission **KEK**
[Swissethics](#), [Swissmedic](#)

Non-sensitive

Sensitive

Highly sensitive

- [Code of conduct for scientific integrity](#)
- [University of Bern Act \(01.01.2023\)](#)
- [Animal Welfare Act](#)

- [Cantonal law](#)
- [nFADP](#)
- [IT Security Officer CISO](#)
- [Data Protection Officer UniBE](#)
- [Data Governance \(Insel\)](#)
- [Online –Tool Vademecum](#) Insel

- [Human Research Act HRA](#)
- [Ordinance on Clinical Trials with Medical Devices](#)
- [Clinical Trials Ordinance](#)
- [Human Research with exception of clinical trials Ordinance](#)
- [Therapeutic Products Act](#)



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Data Collection

Sensitive Personal Data



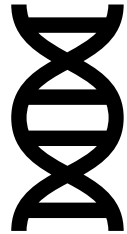
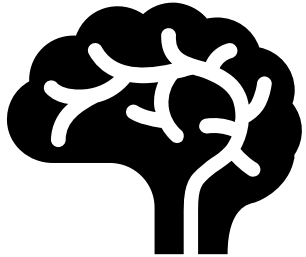
- Data relating to religious, philosophical, political or trade union-related views or activities
- **Data relating to health, the private sphere or affiliation to a race or ethnicity**
- **Genetic data**
- **Biometric data that uniquely identifies a natural person**
- Data relating to administrative and criminal proceedings or sanctions
- Data relating to social assistance measures

Data Protection Act, [FADP](#)

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Data Collection

Data Type and File Format



Define data type

- Survey
- fMRI image
- Genomic data
- Video
- Voice recording



Voice Memos (4+)
Apple
★★★★★ 4.7 • 20.2K Ratings
Free



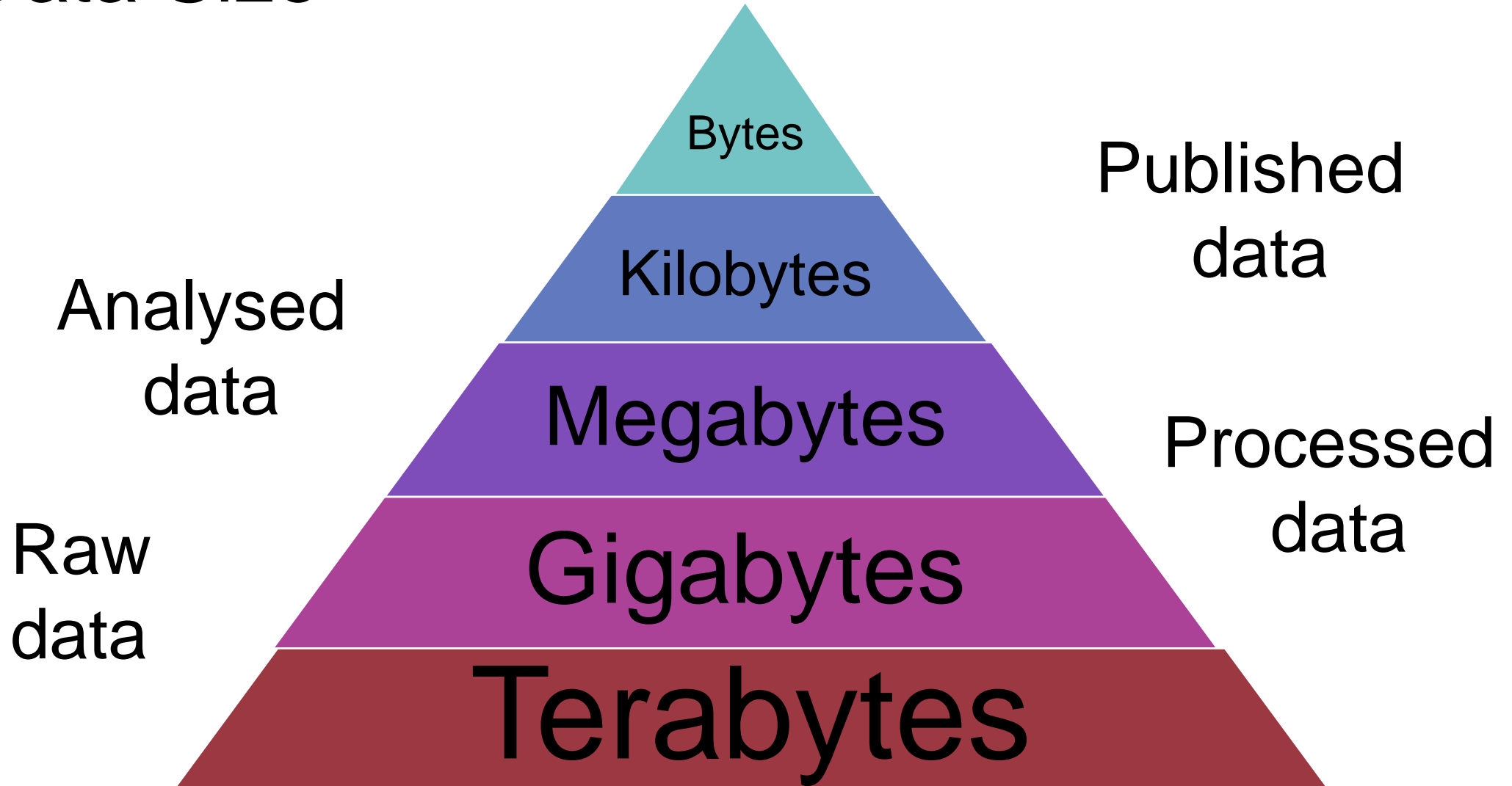
File format

- .csv
- .nifti
- .PDF/A
- .txt
- .wav

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Data Collection

Data Size



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Data Collection

Informed Consent (IC)



A written, signed and dated form includes everything you plan to do with data:

- Purpose, nature and extent of data processing
- Duration of data storage (e.g., 10-years [SNSF guidelines FAQ o](#), Art. 5.1; 15-years for clinical studies, [swissethics](#)) and deletion (if applicable)
- Measures to protect data (anonymization, access control, etc.)
- Disclosure of data to third parties / data publication and sharing

*“Informed Consent (IC) is a process by which a subject **voluntarily** confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate.”*

International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use [ICH-GCP E6\(R2\)](#), 2016 Sec 1.28

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Data Collection

Electronic Informed Consent (eIC)



The **eIC** can make use of electronic media

- Video / Audio interviews
- Podcasts
- Interactive Websites
- Applications for tablets and smart phones, etc.
- To convey the information, while the subject's consent must still be documented on paper with a **hand-written signature** of the **participant (>14y)/legal representatives** and the **investigator**.

[Swissethics](#)

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Data Documentation

File-level: ReadMe, Codebook



- **Who** created the data?
- **What** is the content of the data?
- **Why** were the data developed?
- **Where** is it geographically located?
- **When** were the data created?
- **How** were the data developed?

- **Codebook - Information on variables:** labels, codes, classifications, units, reference to question numbers missing values, aggregations

WFHN RedCap Codebook

Variable / Field Name	Field Type	Field Label	Choices, Calculations, OR Slider Labels	Field Note	Required Field?
rti_id_number	text	RTI ID Number		Participant ID	
rti_watch_order	dropdown	RTI Watch Order	1, 1 2, 2 3, 3 4, 4 5, 5	Order of a given watch for the RTI participant	
rti_industry	text	RTI Industry			
rti_site	text	RTI Site			
rti_wave	text	RTI Wave			
rti_assign_date	text	RTI Assign Date			
rti_return_date	text	RTI Return Date			

[Readme_Template_EN.txt \(3KB\)](#)

Documentation Tools



Searchable
Protocol, sample,
data set

Automated
Report generation,
manuscript writing,
or inventory
tracking



Consistent
Results are accurate
and reproducible

Collaborative
Knowledge exchange
among researchers and
stakeholders, regulatory
bodies, and funders



Traceable
Track experiments,
samples, protocols,
and results

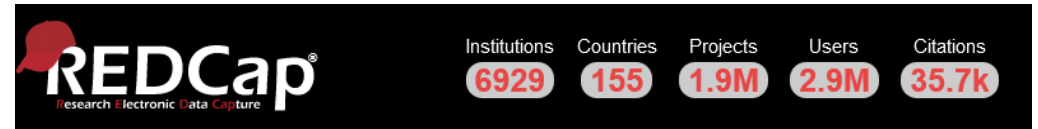
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Data Documentation

Tools



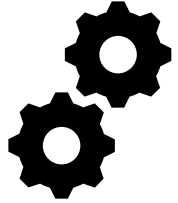
- Study protocols, documents exchange
- Research Electronic Data Capture [REDCap](#)
- For clinical studies GCP-compliant [secuTrial](#)
- LIMS [openBIS documentation](#)
- [Jupyter notebooks](#)
- [git](#)



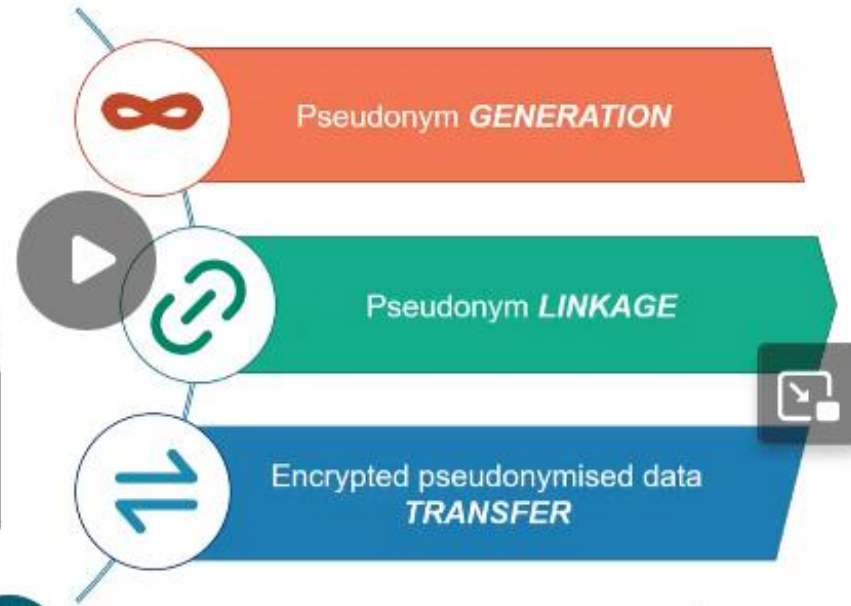
 [Recommendation on research data documentation from the Open Science Team \(PDF, 141KB\)](#)

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Data Processing Pseudonymisation Tool

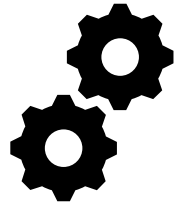


Main Functionalities



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Data Processing Anonymization Tool

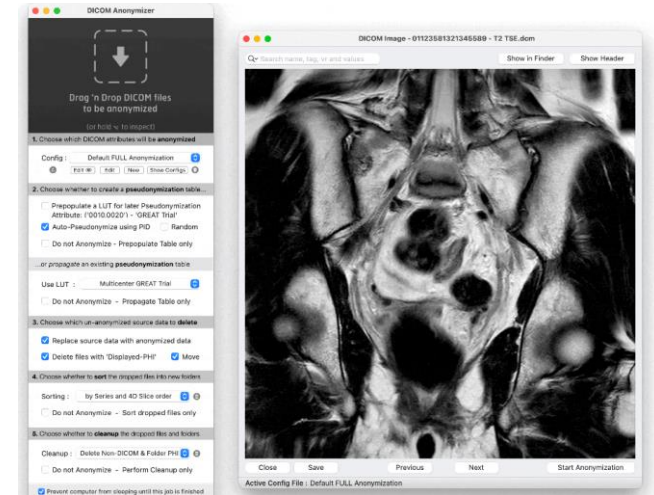


ARX is a comprehensive open-source software for anonymizing sensitive personal data <https://arx.deidentifier.org/>



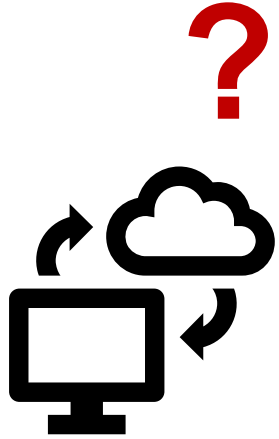
<https://amnesia.openaire.eu/>

DICOM Anonymizer



<https://dicomanonymizer.com>

Data Sharing



VeraCrypt 1.26.7

Idrix

[VeraCrypt](#)

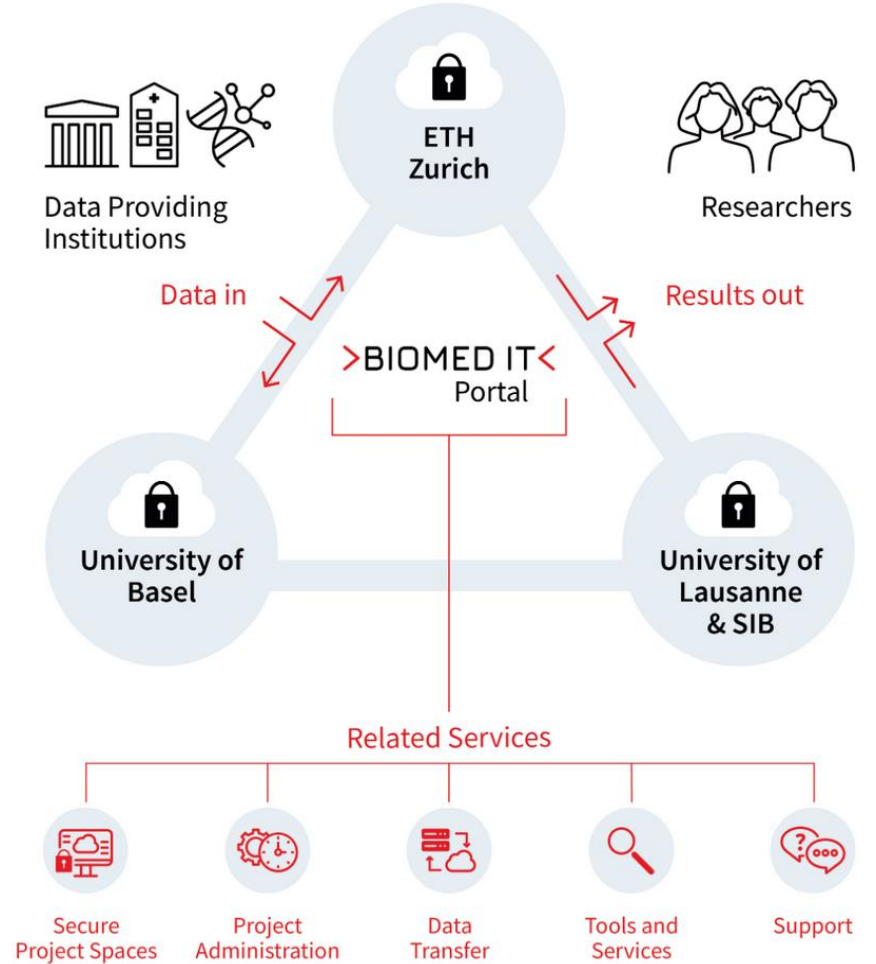
[Cryptomator](#)

Institutions	Countries	Projects	Users	Citations
6929	155	1.9M	2.9M	35.7k

[RedCap](#), GCP compliant



<https://www.secutrial.com/>



[The BioMed IT](#)

Manage Data Access Ethically



Open

Open access to dataset

Embargoed

Enter date after which dataset will be released

Restricted

Upload dataset and grant access on request



Closed

No data upload, but meta-data should be entered to verify existence of dataset

Data Transfer and Use Agreement (DTA)

- recommended for data that cannot be shared openly
- individually define re-use conditions for dataset
- share DTA along with data for others to download and sign



Data Transfer and Use Agreement (DTA)

Colour code:
Grey background = To be completed;
Yellow background = the internal references to the contract (to be updated if necessary) or Optional text.

DATA TRANSFER AND USE AGREEMENT

This agreement (hereinafter referred to as the “Agreement”) is made and entered into by and between:

[name], [(registration number if any)], [address]

(the “PROVIDER”)

and

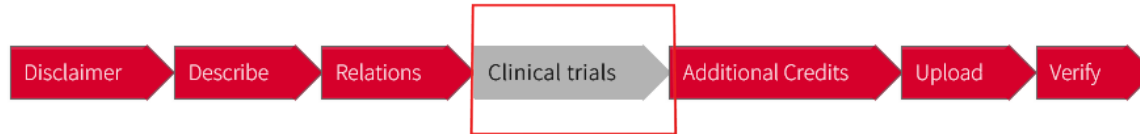
[name], [(registration number if any)], [address]

(the “RECIPIENT”)

- Contract between data provider and data recipient person intending to re-use data
- Regulates the conditions under which data are disclosed to recipient
- Conditions may include guaranteeing appropriate confidentiality, integrity, availability and security of the systems used to process data

Hereinafter jointly referred to as the “PARTIES” and individually as a “PARTY”.

Publish Data Ethically Metadata



* You are submitting in Research Data

⚠ * If you are not able to find your organization or affiliation, please contact us: borisportal@ub.unibe.ch

< Previous Cancel Save **Next >**

If you are affiliated at the University Hospital of Bern (Inselspital) or at the Clinical Trials Unit (CTU), you have to fill out the information below.

The clinicaltrials.gov identifier of the underlying primary data source (study). Format: NCT#####

clinicaltrials.gov
identifier of the
underlying primary
data source (study)

The BASEC identifier of the underlying primary data source (study). Format: ####-#####

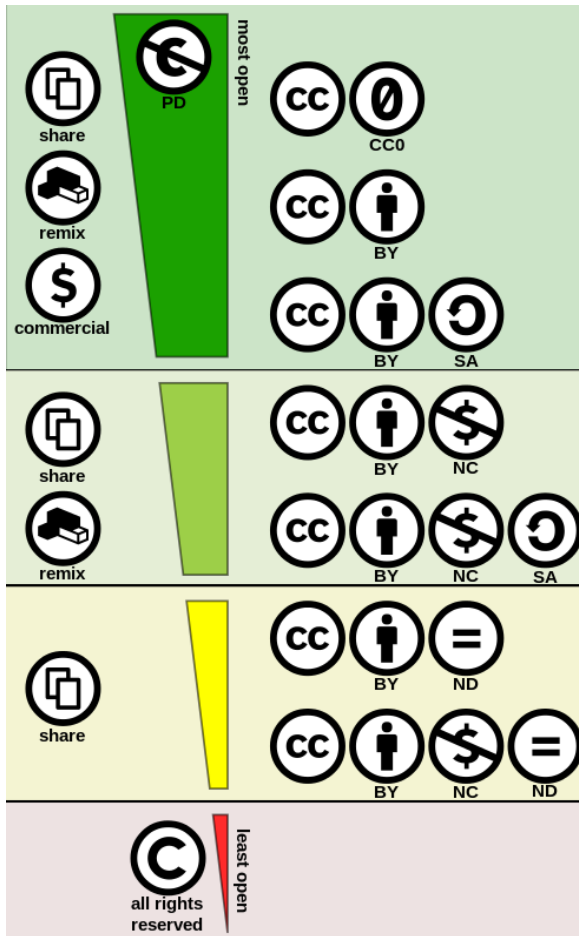
BASEC identifier of
the underlying
primary data source
(study)



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Licenses

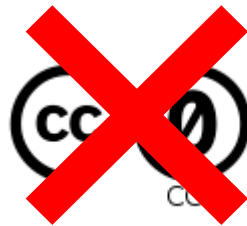
Ownership



- **Data results are owned** by the Institution that generate them
- Licenses
- Ownership (including joint ownership)
- Data transfer and use agreement



- If there are **NO** ethical, legal or contractual issues
- Metadata
- Supplementary material

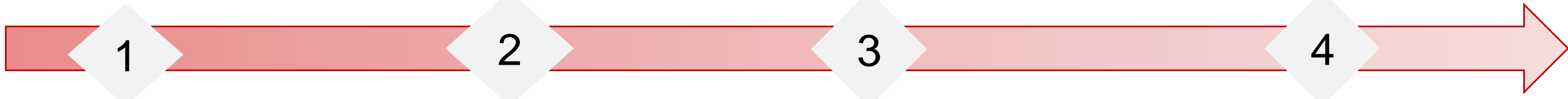
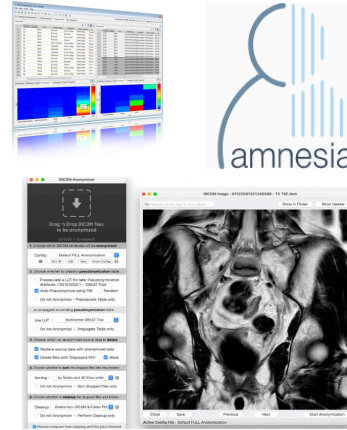
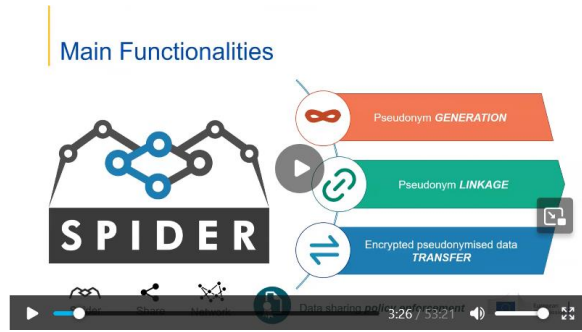
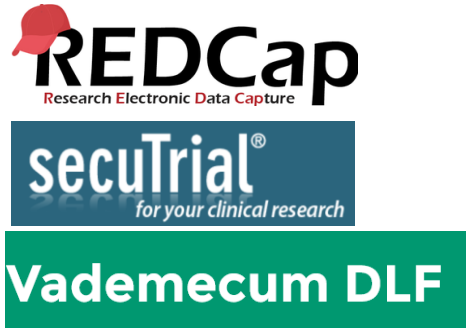


- Some forms of processed data (e.g., elaborate visualisation)
- Data will be commercially exploited (patents)

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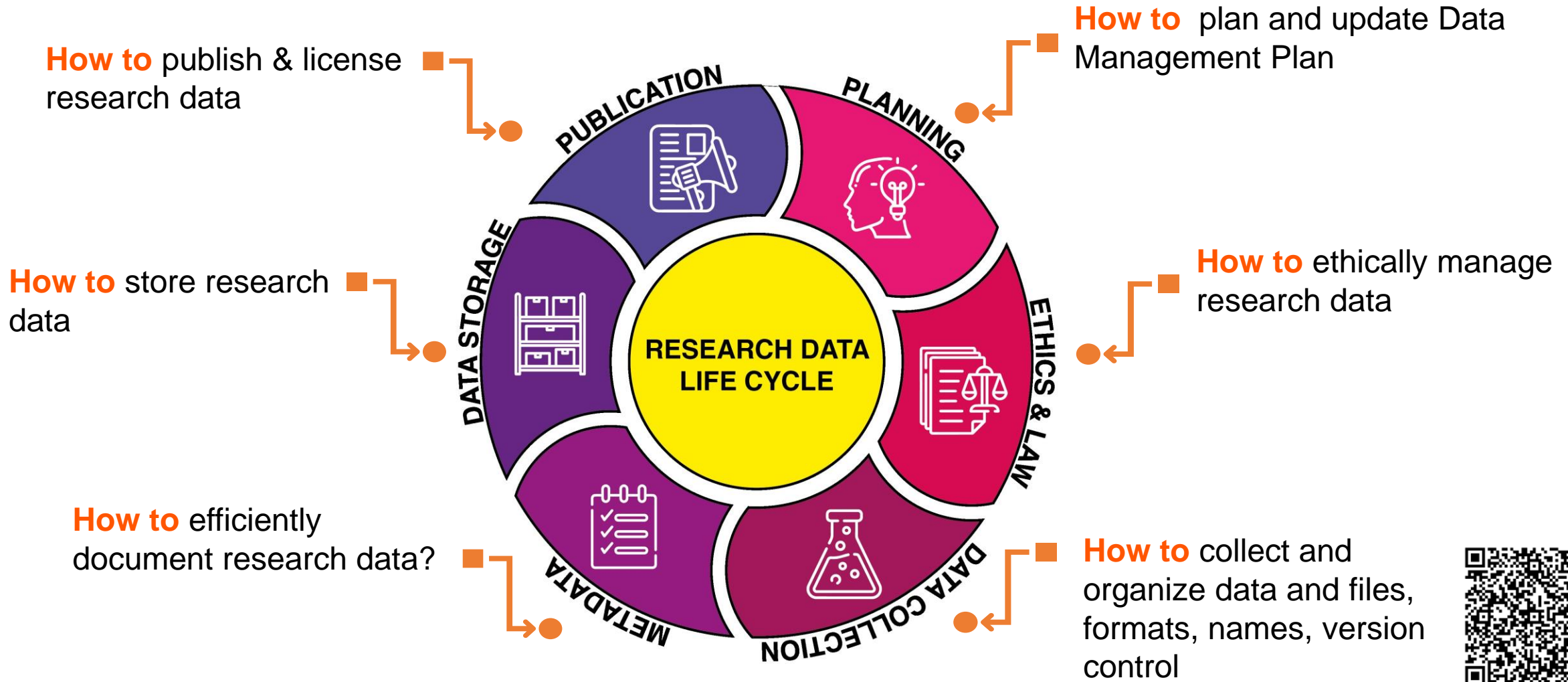
How to Manage Research Data Ethically

Summary



- 1
 - Ethics approvals
 - [ISDS analysis](#)
 - Information security management ([ISO](#))
 - Password-protected access
 - IT-UniBE support helpdesk@id.unibe.ch
 - Insel Group [Support](#)
 - [Online –Tool Vademecum](#) Insel
- 2
 - [SPIDER- pseudonymisation](#)
- 3
 - Anonymisation tools
 - [Arx.deidentifier](#)
 - [Amnesia](#)
 - [Dicom](#)
- 4
 - Closed = No data access → Metadata
 - Embargoed
 - Restricted
 - [Data Transfer Agreement](#)
 - Data documentation

Support in Research Data Management Training



Support in Research Data Management

Data Management Plan Review

University Library of Bern UB

The screenshot shows a web page for 'Data Management Plan Review'. At the top is a red navigation bar with links: UB, Research, Services, Faculty libraries, and About us. Below it is a breadcrumb trail: < Research Data Management. The main heading is 'Data Management Plan Review'. The text explains that users can upload their DMP for review by the RDM team before submission to the research funding agency. It also mentions that for SNSF, users are recommended to watch short introduction videos on YouTube. An alternative option is to send the DMP by email. The form includes fields for Name, First name, Email address, and Funder submission deadline (with a date picker showing TT.MM.JJJJ). There is an 'Upload' section with a file selection button labeled 'Durchsuchen...' and the text 'Keine Datei ausgewählt.'. Below this, a note states 'Ideally, you should upload the document in Word format.'. A 'Comment' text area is provided at the bottom, followed by 'Submit' and 'Restore' buttons.

- Data Management Plan review [online](#)
Feedback within 1-3 working days

- Video modules [YouTube](#)

- DMP examples:
[SNSF](#)
[NIH](#)

 **openscience@unibe.ch**

Support in Research Data Management

CTU Data Management Plan

CTU Bern



- Home
- Training/Courses
- Research/Projects
- Services
- Tool Kit
- About Us
- Intranet

- Consulting Services
- Study Registration
- Data Management**
- REDCap
- secuTrial
- Study Website
- Monitoring
- Statistics and Methodology
- Clinical Study Management
- Quality Management
- Give us Feedback
- Timelines, Costs, T&C, etc.

Data Management


The Data Management (DM) division at CTU Bern is supporting you during the creation of your study database. We are offering different models of service and support, depending on your level of expertise:

- CONTACT
- datamanagement.ctu@unib...
- [CTU Bern Service Timelines](#)
- [Terms and Conditions](#)

@ datamanagement@ctu.ch

- Team members**
- Overview
- Full Service
- REDCap Light
- CDMS
- Support

Team members

	Wegmann Miriam, MSc Head of Data Management miriam.wegmann@unibe.ch	Phone	+41 31 684 56 73
---	---	-------	-------------------------

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Support in Research Data Management Newsletter

- Funder's news
- Training sessions and courses
- Developments in Open Access and Research Data



Image: © UB UniBE

To subscribe:

<https://www.unibe.ch/ub/osnews>



Contact

Dr. habil. Olga Churakova

Data Steward:

Medicine, Vetsuisse, Insel

Research Data Management Support

E-Mail: olga.churakova@unibe.ch



Image: © UB UniBE

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