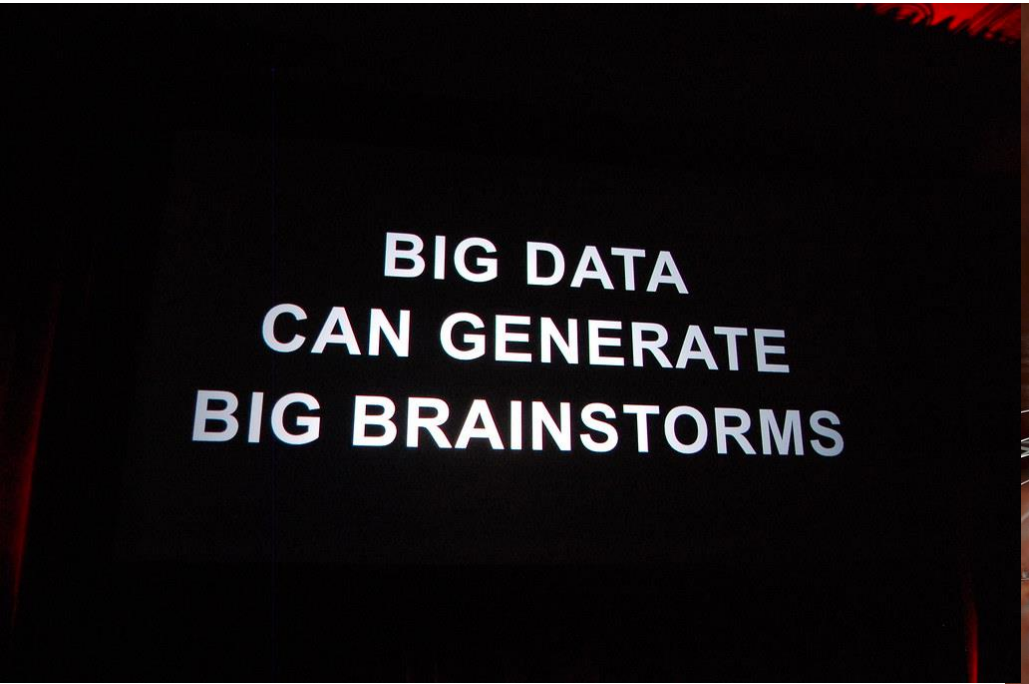
Data management in health technologies

Keynote

Sven Trelle, CTU Bern

02.03.2021



Menu

Topics to be covered

- Regulatory framework
- Other requirements and standards
- Some aspects of good science in the 21st century …

Disclaimer

- All content based on **CTU-interpretation** of the Human Research Act, its ordinances, and related documents (e.g. Botschaft, Erläuterungen etc.)
- Interpretation of the act and its ordinances not 100% harmonized across different authorities
- Although all content was checked carefully: Errors and Omissions Excepted (E&OE)

Human Research Act (HRA)

Scope

Art. 2 Scope

[1] This Act applies to research concerning human diseases and concerning the structure and function of the human body, which involves:

a. persons;
b. deceased persons;
c. embryos and foetuses;
d. biological material;
e. health-related personal data.

[2] It does not apply to research which involves:

a. IVF embryos in accordance with the Stem Cell Research Act of 19 December 2003[1];
b. anonymised biological material;
c. anonymously collected or anonymised health-related data.

Human Research Act

Development over time

UNIVERSITÄT BERN

2010

- Constitution

2011

- Human Research Act (HRA)
  Explanation in *«Botschaft»*

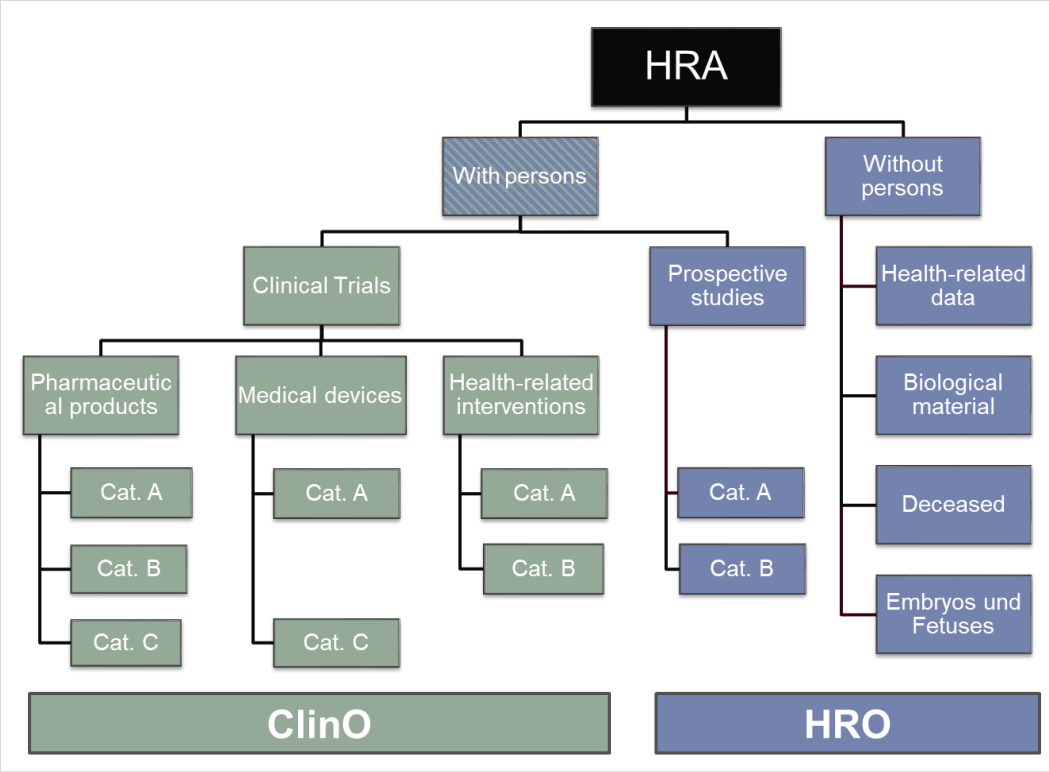
2014

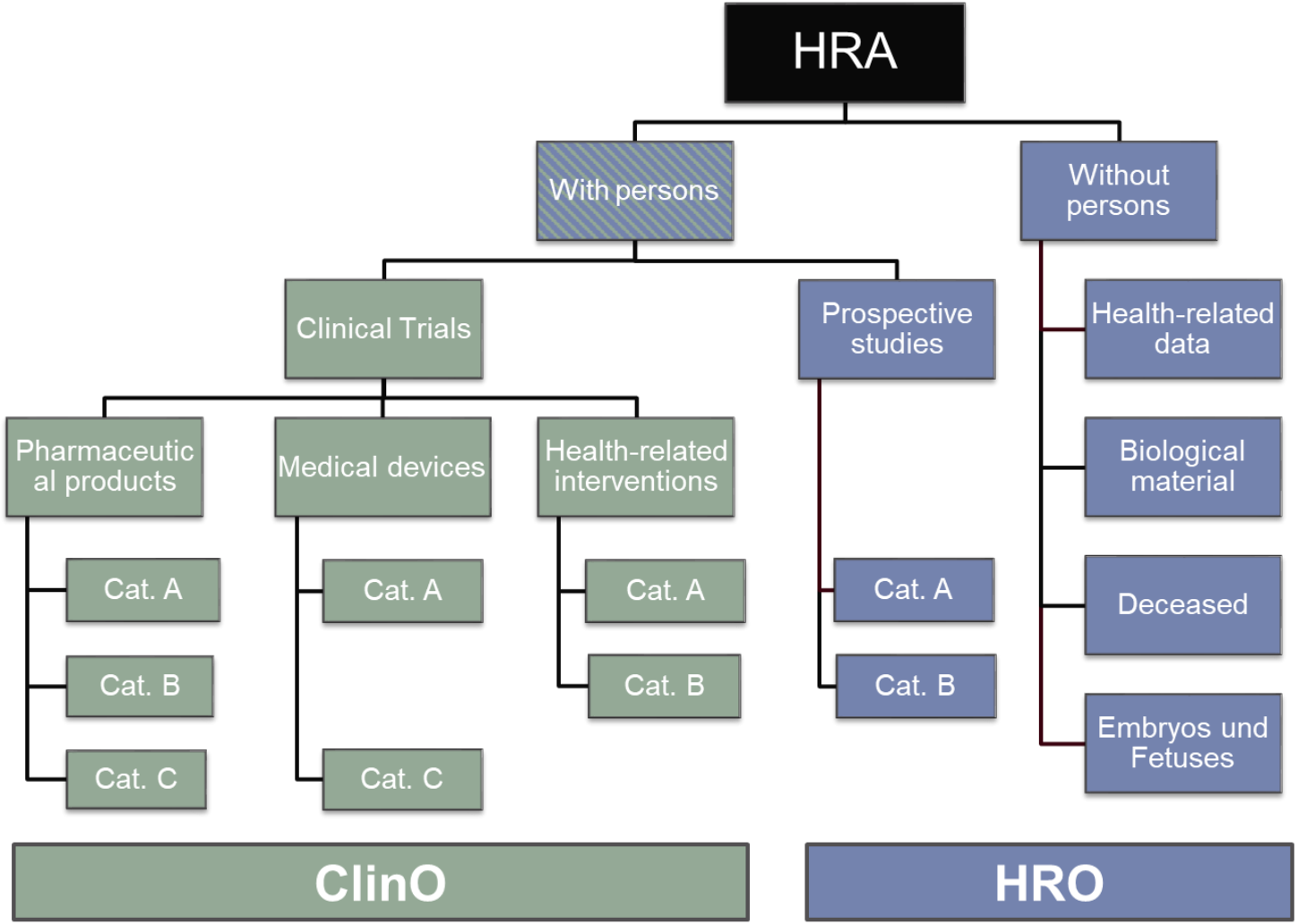
- ClinO
- HRO
- OV-HFG

- Explanation in *«Erläuterungen»*
- *Rütsche B (Hrsg). Humanforschungs-gesetz (HFG). Bern: Stämpfli. 2015.*

Human Research Act

Overview




HRA
With persons
Without persons
Clinical Trials
Prospective studies
Health-related data
Biological material
Deceased
Embryos und Fetuses
Pharmaceutical products
Medical devices
Health-related interventions
Cat. A
Cat. B
Cat. C
Cat. A
Cat. C
Cat. A
Cat. B
Cat. A
Cat. B
ClinO
HRO

Federal Act on Data Protection (FADP)

Sensitive personal data

Art. 3 Definitions
The following definitions apply:

…

c. *sensitive personal data*: data on:

1. …
2. health, the intimate sphere or the racial origin,
3. social security measures,
4. …

…

Human Research Ordinance (HRO)

Data storage

Art. 5 Storage of health-related personal data and biological material

[1] Any person who stores health-related personal data for research must take appropriate operational and organisational measures to protect it, and in particular:

a. restrict the handling of the health-related personal data to those persons who require this data to fulfil their duties;
b. prevent unauthorised or accidental disclosure, alteration, deletion and copying of the health-related personal data;
c. document all processing operations which are essential to ensure traceability.

[2] …

Proportionality principle

HRO Art. 5, Para. 2, Let. a

– HRO in-line with data protection regulations e.g. Datenschutzgesetz Bern (KDSG) Art. 5

> [3] Die Personendaten und die Art des Bearbeitens müssen für die Aufgabenerfüllung geeignet und notwendig sein.

– Concerns mainly access to identifying information (names, contact details, AHV No. etc.)

– But applies also to the data as such

Laissez-faire?

Practice

Die Bundesversammlung — Das Schweizer Parlament

LEICHTE SPRACHE PARLNET KONTAKT DE FR IT RM EN

ORGANE RATSBETRIEB ÜBER DAS PARLAMENT SERVICES INTERNATIONALES

... > SERVICES > NEWS > DATENSCHUTZGESETZ: KEIN KOMPROM...

Freitag, 03. Juli 2020 11h00

MEDIENMITTEILUNG

DATENSCHUTZGESETZ: KEIN KOMPROMISS BEIM PROFILING

Eine der noch nicht beseitigten Differenzen zwischen Nationalrat und Ständerat bei der Revision des Datenschutzgesetzes betrifft das Profiling. Die Staatspolitische Kommission des Nationalrates lehnt die vom Ständerat verabschiedete Kompromisslösung ab und beantragt ih-

AUTOR

SPK-N
Sekretariat der Staatspolitischen Kommissionen

Views on data protection/privacy

Personal experience only!

UNIVERSITÄT BERN

- Clinician-researchers are relatively liberal (naïve) when it comes to data protection and clinical research
- Informal proof: CTU Bern regularly receives datasets with directly identifying information e.g. names, date of birth (at least monthly) and there is lack of understanding on the other side if we reject these datasets and ask them to de-identify

Storage

HRO Art. 5, Para. 2, Let. b

b. prevent unauthorised or accidental disclosure, alteration, deletion and copying of the health-related personal data

- Location of storage: central storage/server
- Access: user management
- Internal standards and defined processes: quality management and standard operation procedures
- Prospective studies (data entry): dedicated study management system with a data model
  - Frontend i.e. electronic case report forms
  - Backend i.e. relational database

Storage

HRO Art. 5, Para. 2, Let. c

c. document all processing operations which are essential to ensure traceability.

- Internal standards and defined processes: quality management and standard operation procedures
- Audit trail or version control: who, when, what

Simply administrative burden?

Complaints everywhere

FMH Aktuell 4

Repräsentative Befragung der Ärzteschaft im Auftrag der FMH

Der administrative Aufwand der Ärzteschaft nimmt weiter zu

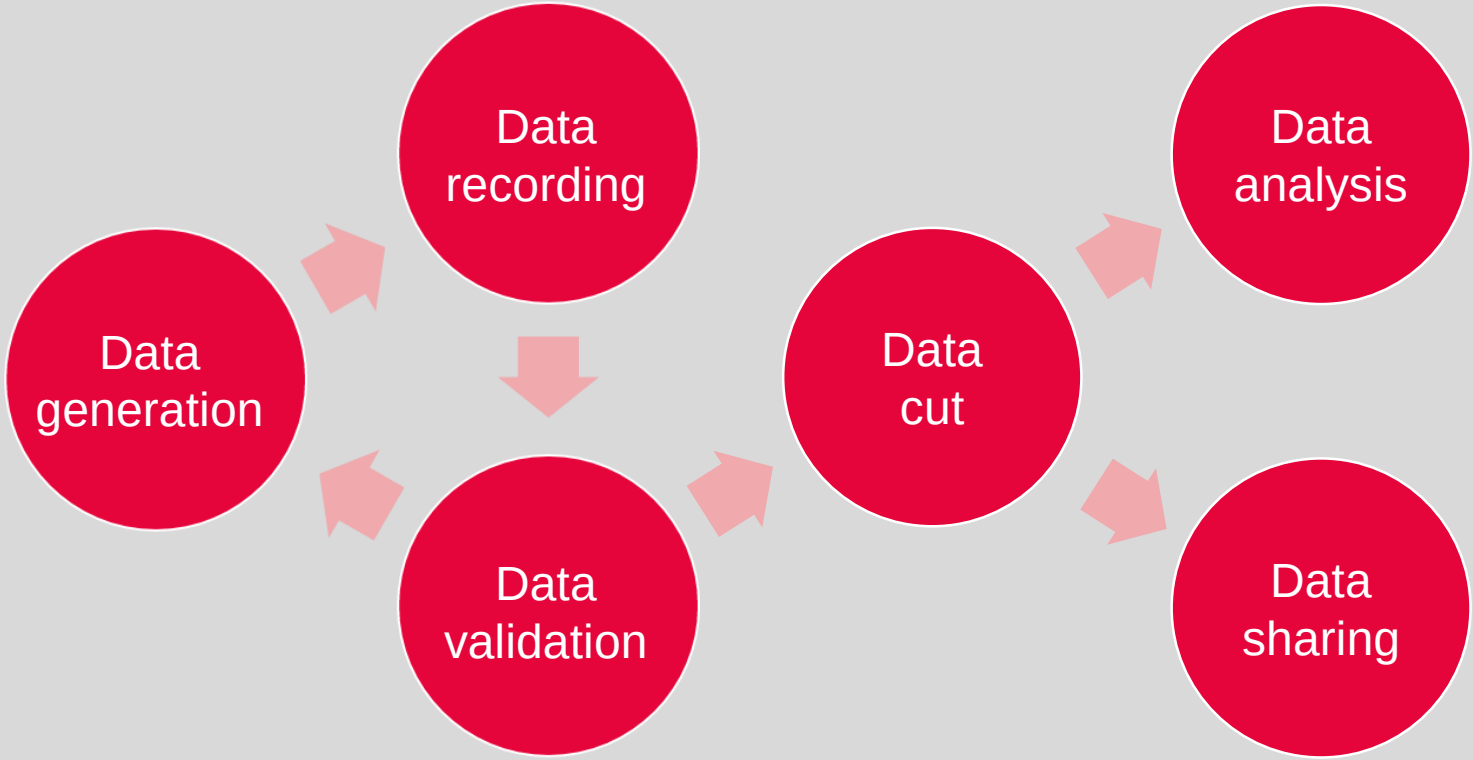
Bruno Trezzini[a], Beatrix Meyer[b], Melanie Ivankovic[c], Cloé Jans[d], Lukas Golder[e]

[a] Dr. phil., wissenschaftlicher Mitarbeiter, Abteilung Stationäre Versorgung und Tarife, FMH; [b] Leiterin Abteilung Stationäre Versorgung und Tarife, FMH; [c] Junior Projektleiterin gfs.bern; [d] Leiterin operatives Geschäft gfs.bern; [e] Co-Leiter gfs.bern

Der administrative Dokumentationsaufwand hat sich für die Spitalärzteschaft

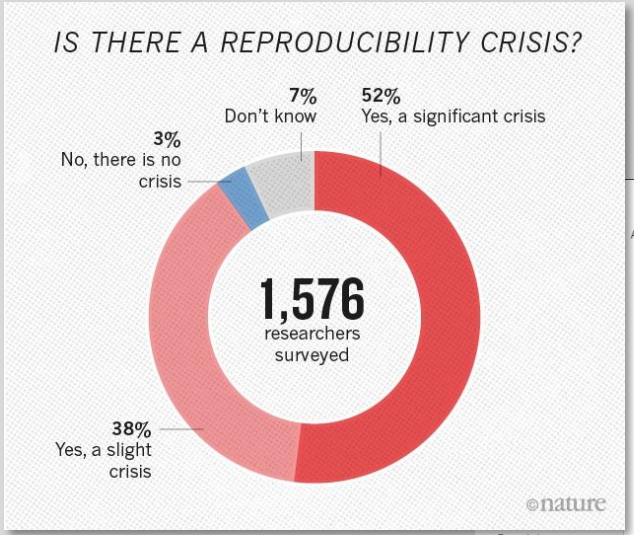
Traceability

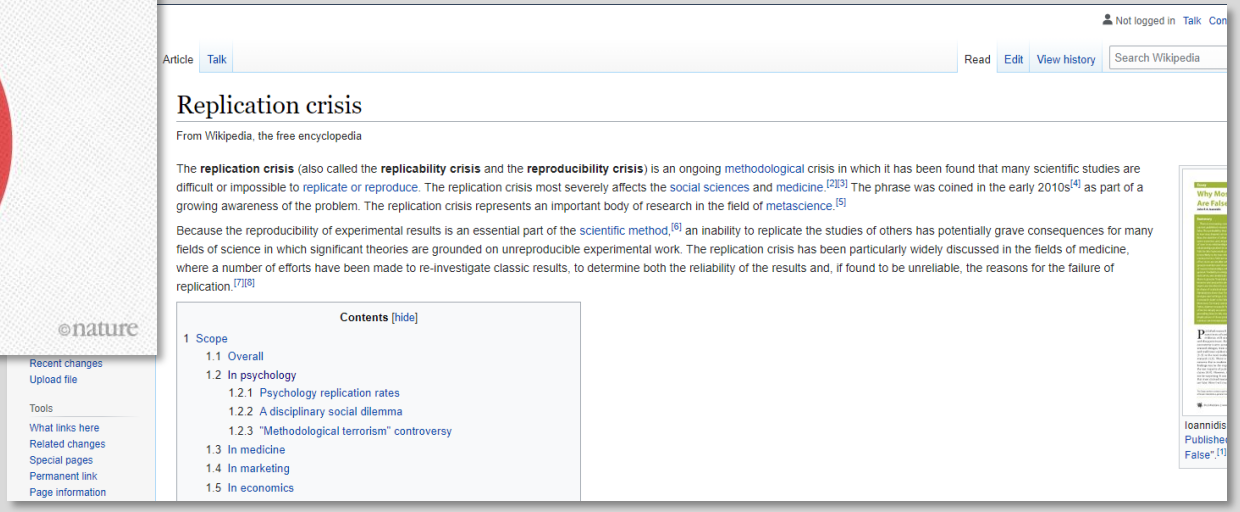
In practice



Reproducibility etc.

Scientific research





Baker M 2006 and https://en.wikipedia.org/wiki/Replication_crisis

Terminology

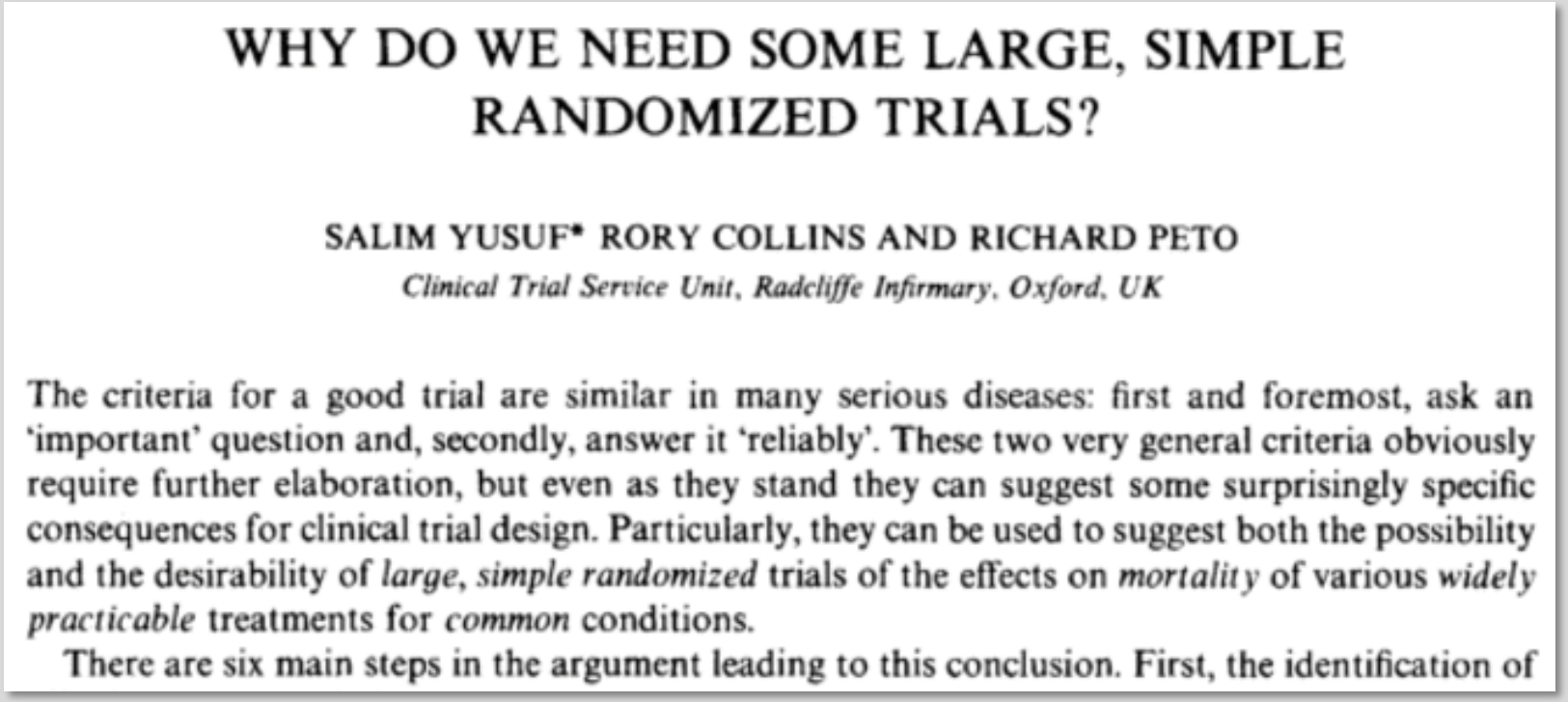
- Reproducibility
- Replicability
- Robustness (sensitivity)
- Generalizability

		Data	
		Same	Different
Analysis (code)	Same	Reproducible	Replicable
	Different	Robust	Generalisable

Kirstie Whitaker (https://youtu.be/NDNYPDm1-2c)

Simple trials?

What do we mean by simple, though?



WHY DO WE NEED SOME LARGE, SIMPLE RANDOMIZED TRIALS?

SALIM YUSUF* RORY COLLINS AND RICHARD PETO

Clinical Trial Service Unit, Radcliffe Infirmary, Oxford, UK

The criteria for a good trial are similar in many serious diseases: first and foremost, ask an 'important' question and, secondly, answer it 'reliably'. These two very general criteria obviously require further elaboration, but even as they stand they can suggest some surprisingly specific consequences for clinical trial design. Particularly, they can be used to suggest both the possibility and the desirability of *large, simple randomized* trials of the effects on *mortality* of various *widely practicable* treatments for *common* conditions.

There are six main steps in the argument leading to this conclusion. First, the identification of

Yusuf S et al. 1996: Stat Med 3; 409-22-

How clinical research is organized

The problem with trust and good intentions

UNIVERSITÄT BERN

Quality control and assurance

Trials versus (?) observational

- Dedicated personnel at sites
- Embedded in routine practice
- Regular monitoring of the data
- Feedback and contact with sites
- Reporting

GARFIELD-AF register

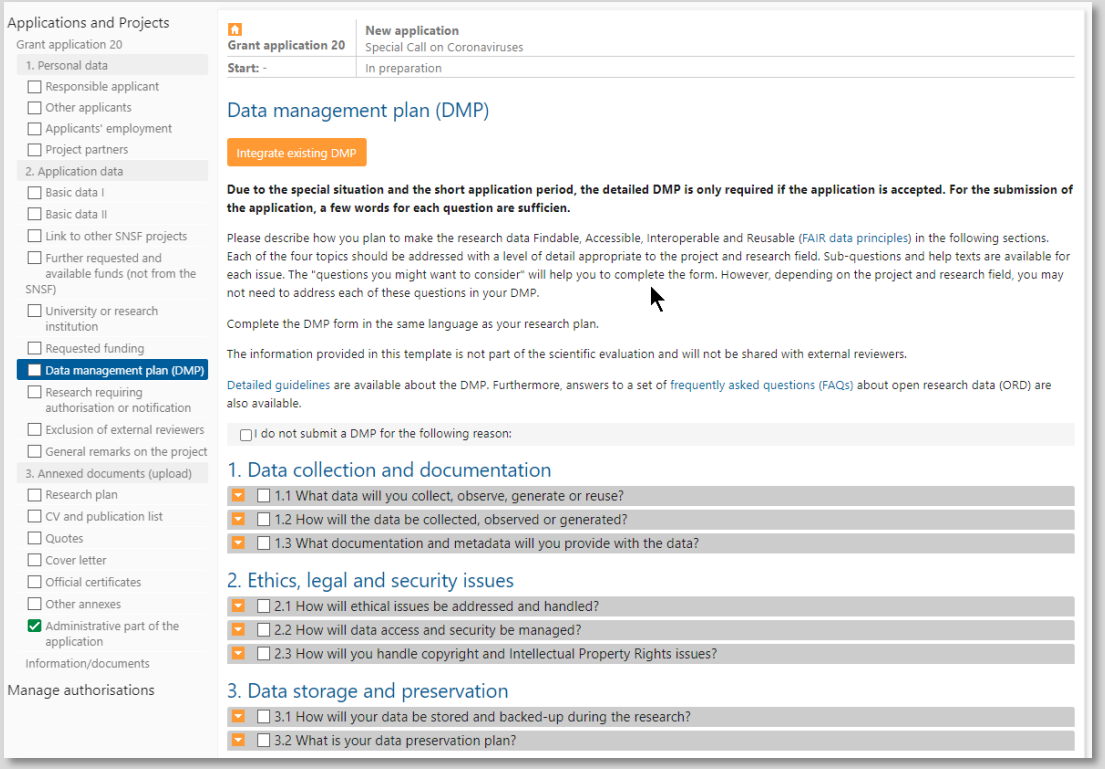
Aims: *The value of data obtained depend critically upon robust quality standards (including source data verification [SDV] and training); features that are commonly absent from registries.*

Conclusion: *The quality standards in GARFIELD-AF have the potential to inform a future 'reference' for registries.*

Fox KAA et al. 2017

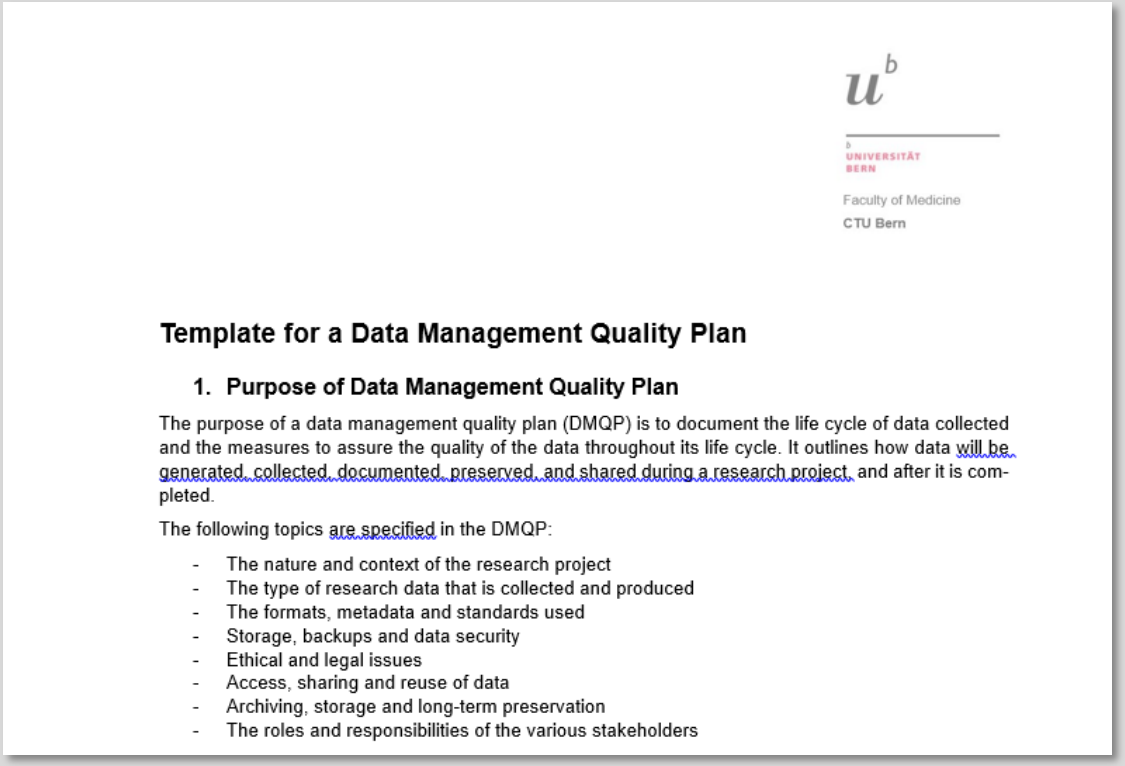
Documentation and planning

Plans, plans, plans …



(Internal) Data Management (Quality) Plan

A (version) controlled document



UNIVERSITÄT BERN

Faculty of Medicine

CTU Bern

Template for a Data Management Quality Plan

1. Purpose of Data Management Quality Plan

The purpose of a data management quality plan (DMQP) is to document the life cycle of data collected and the measures to assure the quality of the data throughout its life cycle. It outlines how data will be generated, collected, documented, preserved, and shared during a research project, and after it is completed.

The following topics are specified in the DMQP:

- The nature and context of the research project
- The type of research data that is collected and produced
- The formats, metadata and standards used
- Storage, backups and data security
- Ethical and legal issues
- Access, sharing and reuse of data
- Archiving, storage and long-term preservation
- The roles and responsibilities of the various stakeholders

Table of content

(Data) Sharing

UNIVERSITÄT BERN

- Trial protocol
- Patient information and consent form
- Data Management Plan
- Statistical Analysis Plan
- Monitoring reports
- Documentation on protocol deviations
- (Narratives?)
- Data dictionary
- Data
- Statistical code
- …

Who controls access to data?

Governance and data ownership

Thank you

for your attention!

Sven Trelle, CTU Bern

UNIVERSITÄT BERN

Workshop: Best Practice with Patient (Person) Data

- What is anonymized data?
- What is coded data?