# Facts and pitfalls of observational studies

# Instructions

Go to

**www.menti.com**

Enter the code

**7856 5796**

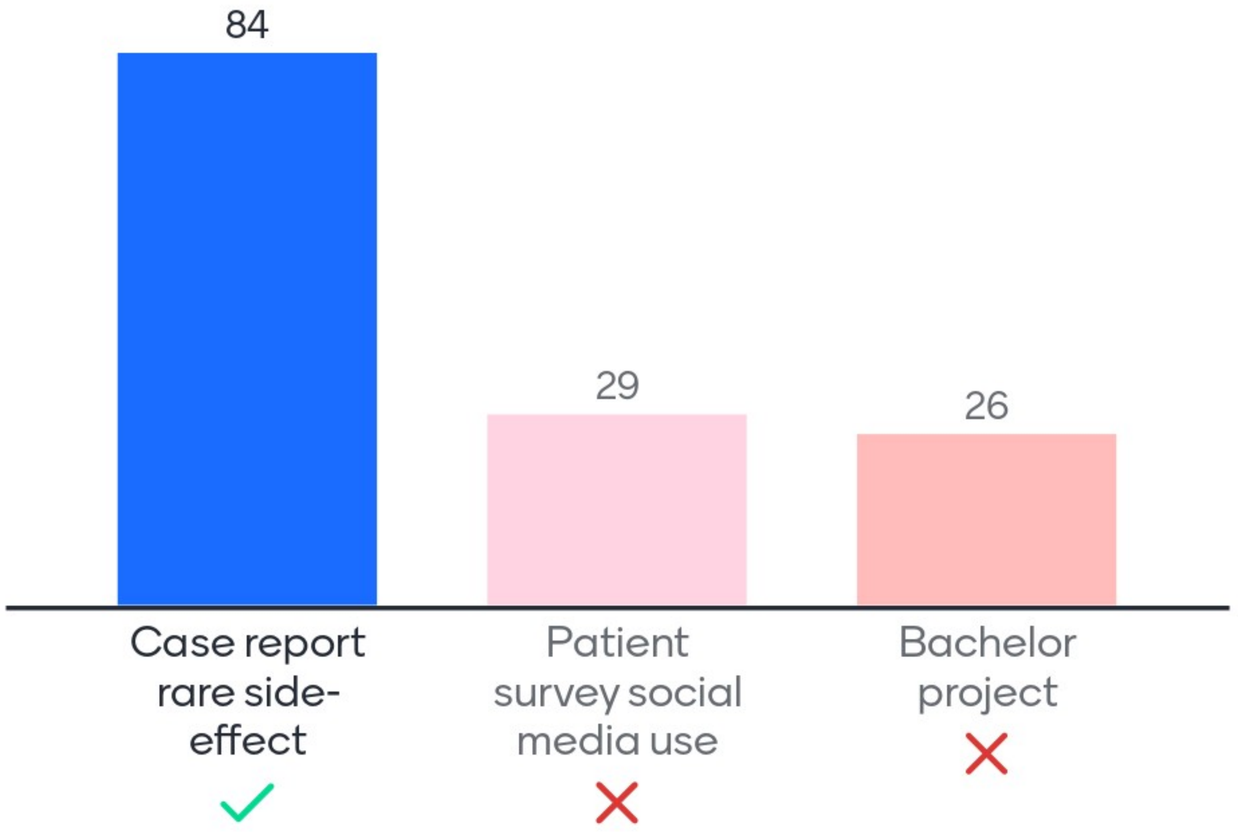
Or use QR code

# First step: HRA yes or no?

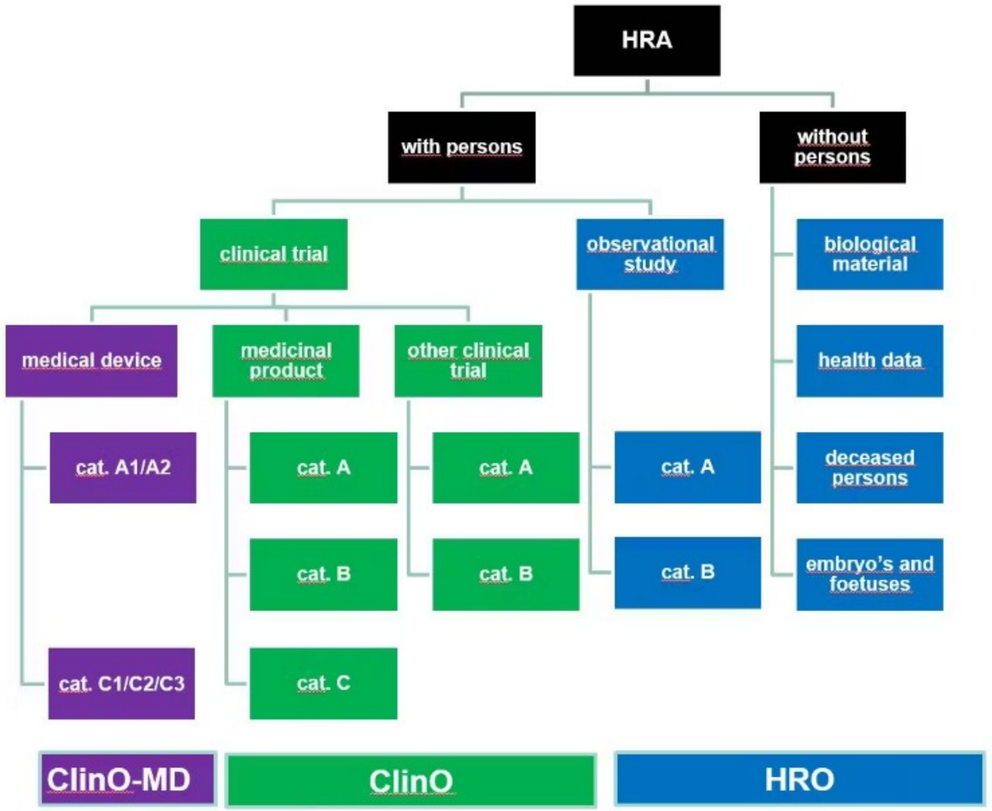
- Inclusion criteria:
  - method-driven search
  - diseases/functioning of the body
  - generalisable knowledge
- Exclusion criteria:
  - anonymous data/samples

HRA YES/NO?

# Which project is NOT method driven?



# Human Research Ordinance



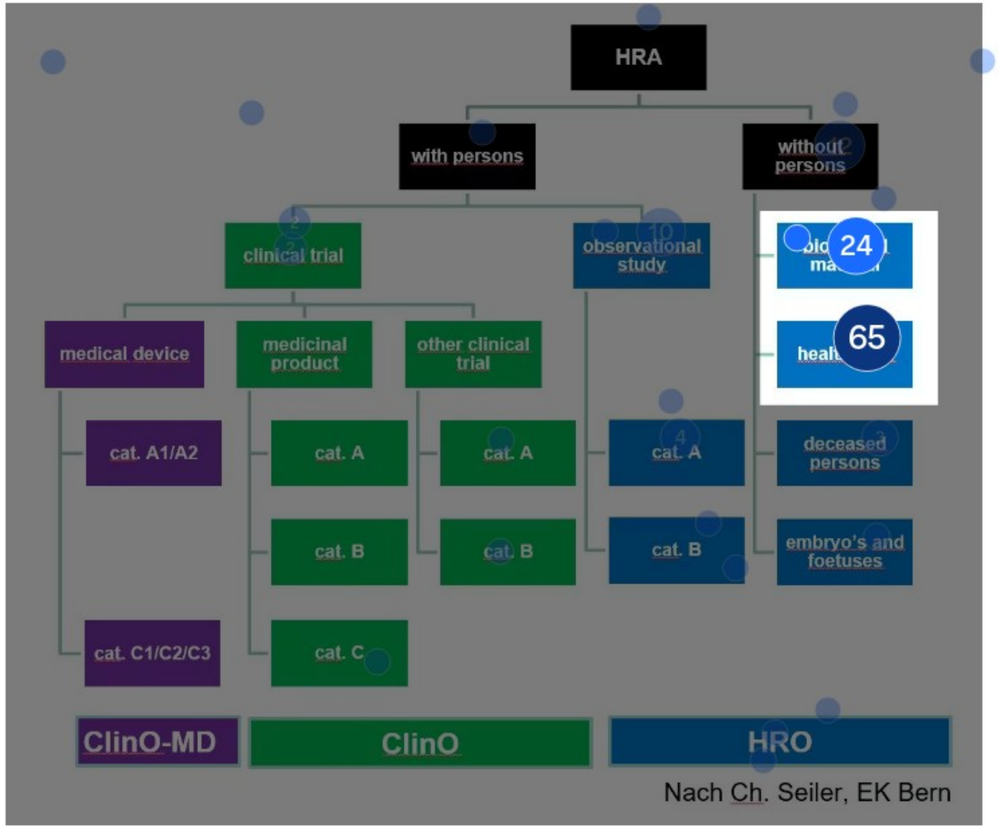

Nach Ch. Seiler, EK Bern

# ClinO(-MD) versus HRO

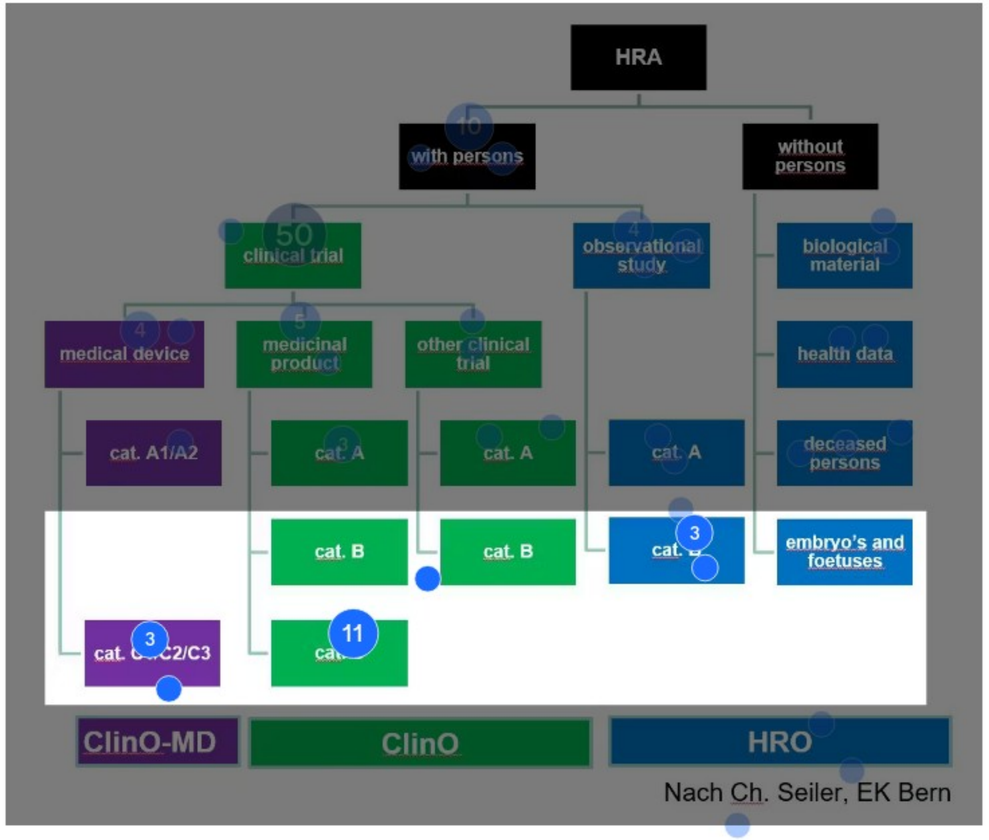
# Categorization

- clinical trial
- observational study
- further use of data/samples

# Study-specific ICF or General Consent



# EC meeting: ordinary or simplified



# points raised by ECs

POINTS RAISED BY THE ETHICS COMMITTEES

# observational studies I

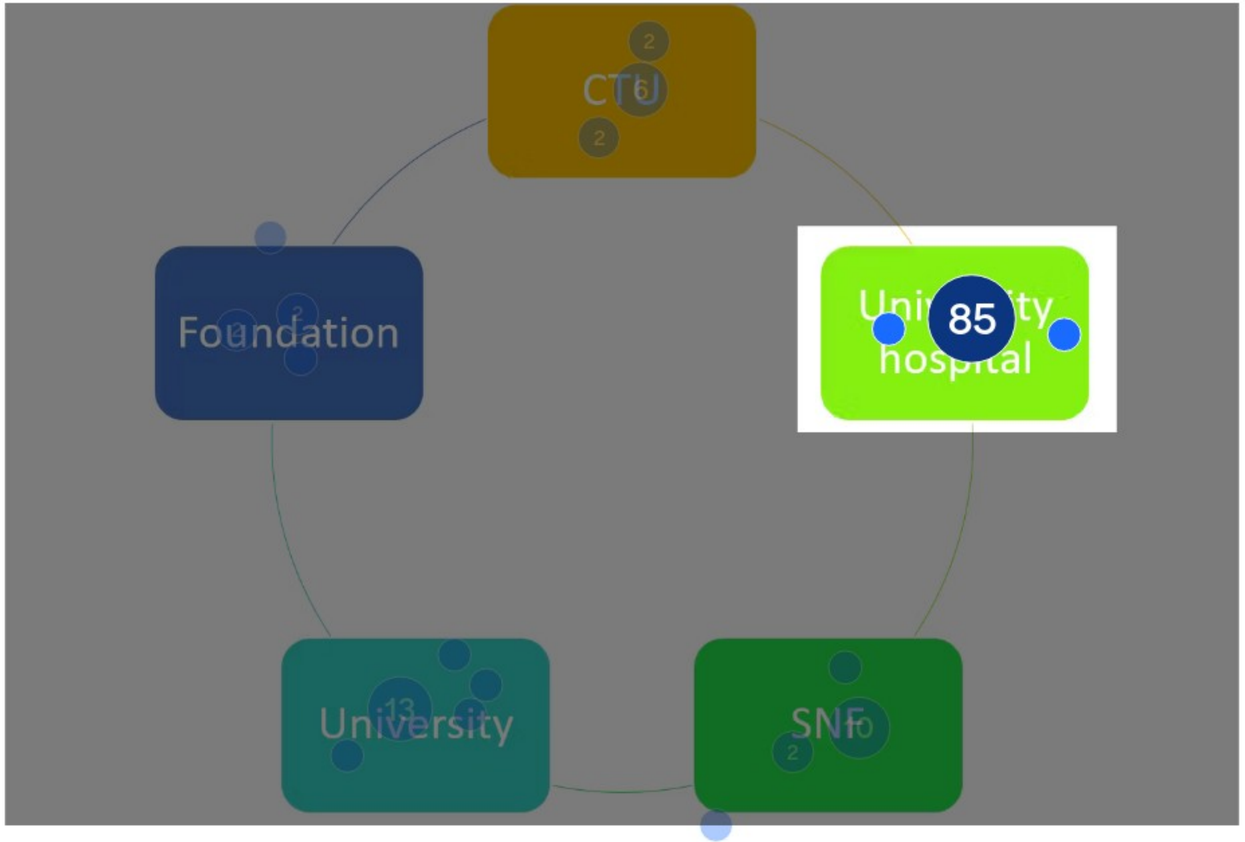
- → wrong study category
- → "anonymized" > "coded"
- → version nr and date in BASEC versus docs
- → add ICF page for further use

POINTS RAISED BY THE ETHICS COMMITTEES

# observational studies II

- protocol and ICF inconsistent
- Excel > REDCap
- submit biobank regulation
- questionnaire: no names
- cv: dated, not older than 2 years

# Who is the Sponsor?



# Safety in observational studies

serious events

POINTS RAISED BY THE ETHICS COMMITTEES

# Further use studies

- protocol as scan (image)
- start and end date in BASEC wrong
- protocol: table with/without consent
- GC/ICFs are missing

# 24762

BASEC users

## Further use of health-related personal data and/or biological material / Further use part of the project

**Your project involves ***

non-genetic data only

**Please select how your research data will be kept ***

For information about anonymization and coded data, see art. 25-27 HRO.

coded

**Consent for further uses of data/material ***

If you have an informed consent from before the human research act (2014), check whether it is conformable to the law (Articles 28-32 HRO, in DE, FR, IT). If not, the consent is not sufficient. If there is pre-existing consent for some samples/records, but not for others, Art 34 HRA may apply (DE, FR, IT). In this case select "prior consent/general consent exists" and "no consent -art. 34 HRA".

- [x] prior consent/general consent exists
- [ ] consent to be sought
- [x] no consent - Art. 34 HRA

# Art 34 Argumentation

- → impossible or VERY difficult to get consent
- → no documented refusal
- → interest of research > interest of the person

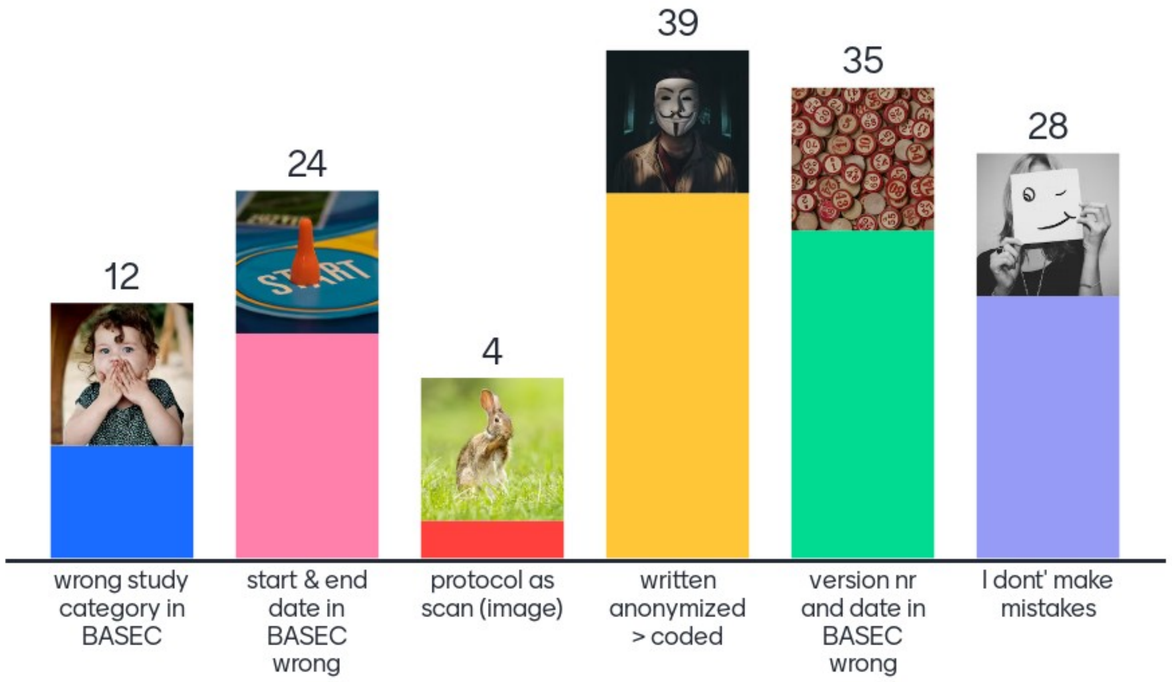
POINTS RAISED BY THE ETHICS COMMITTEES

# Research with deceased persons

- → GC doesn't apply
- → consent body donation/autopsy
- → contract is missing
- → art38 projects; define "small quantity"

POINTS RAISED BY ETHICS COMMITTEES

# Truth or dare: have you ever...




# Questions for discussion