MUNI ICS

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MAKING NEW TREAT MENTS POSSIBLE

SHARING OF RESEARCH DATA IN ACADEMIC ENVIRONMENTS – TRANSNATIONAL EXPERIENCE FROM BBMRI-ERIC

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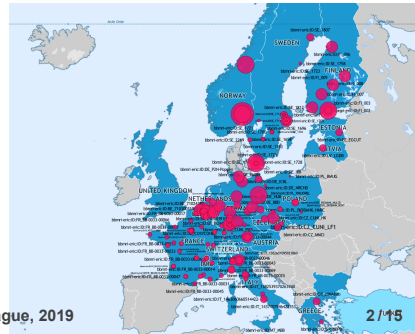
WHAT IS BBMRI-ERIC?

- **One of largest European RIs for medical research**
  - spans **20 member states** + IARC
  - **federated** biobanks and other resources across members states
  - makes **biological samples & medical/health data more FAIR** (findable, accessible, interoperable, reusable) while also compliant to **privacy protection** regulations
  - facilitates adoption of **quality procedures** to **improve reproducibility** of medical research



SPECIFICS OF PERSONAL RESEARCH DATA

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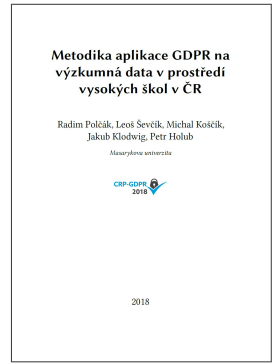
- What it is: **personal data used for research purposes**
  - health, genetic, geo-location (for exposure), …
- What makes **research data specific?**
  - many things are completely different compared to personal data processing for other purposes
  - research is typically **multi-center/international**
  - research needs to be **verifiable** and **reproducible**
  - pressure on publishing research data as FAIR or open
  - need to store data in research infrastructures: **quality-assured data** made available for reuse
  - even industrial research now considers data sharing/pooling: dealing with **mounting costs of collecting high-quality data**

RESEARCH DATA IN CZ UNDER GDPR

- All the public **Czech universities teamed up to develop joint recommendations** how to deal with research data under GDPR
  - https://doi.org/10.5281/zenodo.2532860
  - goal was to utilize flexibility given by the GDPR for research purposes (e.g., where informed consent is not needed) – i.e., **GDPR perceived beneficial**
  - procedural recommendations (e.g., event handling)
  - being updated now after adoption of national GDPR implementation – minor updates only



SHARING DATA FROM CLINICAL TRIALS

- Ohmann, Christian, et al. **”Sharing and reuse of individual participant data from clinical trials: principles and recommendations.”**
  - https://bmjopen.bmj.com/content/7/12/e018647.abstract
  - outcome of CORBEL project
  - 10 principles and 50 recommendations
  - consent management
  - protection of trial participants
  - data standards, rights, types and management of access
  - data management and repositories, discoverability, and metadata


Research methods
Research

Sharing and reuse of individual participant data from clinical trials: principles and recommendations

Abstract

USING PERSONAL OR ANONYMIZED DATA?

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- **Pseudonymized data is personal data**
  - identifier(s) of a pseudonym is replaced by a pseudonym
- **Anonymized data is non-personal data**
  - anonymization is not a perfect process (nothing like perfectly anonymized while still userful exists)
  - anonymization is about finding balance between damage of the data and privacy protection
  - best known anonymization technique – differential privacy – was questioned by WP29 (→ EDPB)

USING PERSONAL OR ANONYMIZED DATA?

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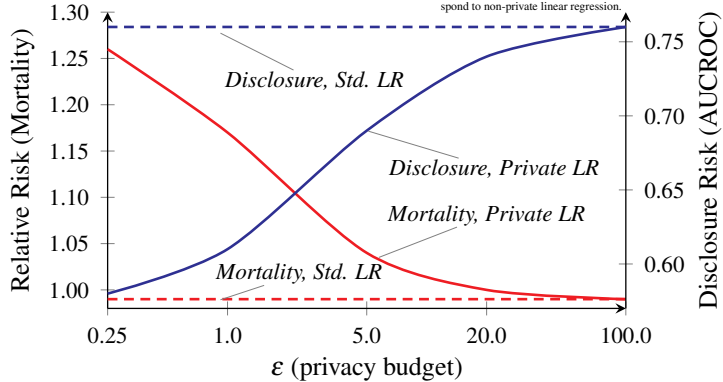
- **For medical research it is almost always better to work with pseudonymized data**
  - one typically has or can obtain a legal basis – justified interest or informed consent
  - possible effect caused by data damage are highly undesirable and helps with reproducibility
  - pseudonymized data allows dealing with incidental findings

USING PERSONAL OR ANONYMIZED DATA?

Compromise of utility vs. privacy[1]

Figure 1: Mortality risk (relative to current clinical practice) for, and VKORC1 genotype disclosure risk of, ε-differentially private linear regression (LR) used for warfarin dosing (over five values of ε, curves are interpolated). Dashed lines correspond to non-private linear regression.



[1] Fredrikson, M., Lantz, E., Jha, S., Lin, S., Page, D., & Ristenpart, T. (2014). Privacy in Pharmacogenetics: An End-to-End Case Study of Personalized Warfarin Dosing. Proceedings of the ... USENIX Security Symposium. UNIX Security Symposium, 2014, 17–32. Retrieved from http://www.biostat.wisc.edu/ page/WarfarinUsenix2014.pdf

ERSONAL OR ANONYMIZED DATA?

GOOD PRIVACY PROTECTION, BUT TENDS TO KILL PATIENTS.

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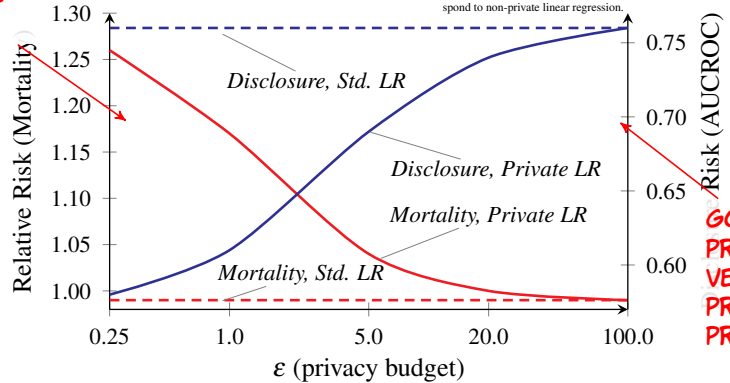

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GOOD TREATMENT PREDICTION, BUT VERY POOR PRIVACY PROTECTION.

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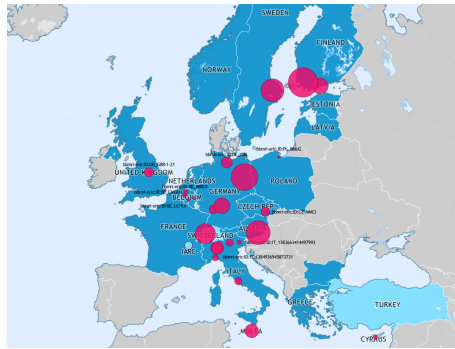
CHALLENGES OF (INTERNATIONAL) SHARING

- **Problem of national GDPR derogations and additional national regulations**
- **Difficult to get Codes of Conduct under Art. 40 ready and approved**
  - e.g., 3 codes in preparation for cloud computing
  - e.g., 2 codes for medical data sharing (one organized by BBMRI-ERIC)
  - process takes years, unclear process in the beginning
  - EDPB slow to start
- Problem with **status of full international organizations** (e.g., EBI/EMBL which is global resource of bioinformatics DBs)
  - ERICs are much easier – defined jurisdiction of EU and hosting country.

CRC-COHORT – EXAMPLE OF THE PROCESS

- **10,000 colorectal cancer cases spread over the Europe**
  - BBMRI-ERIC is coordinator, host, and custodian



CRC-COHORT – EXAMPLE OF THE PROCESS

- **10,000 colorectal cancer cases spread over the Europe**
  - examples of delicate complexities
    - Finnish national derogations and additional regulations prevent data to leave Finland permanently (also influences dbSNP, EGA, and other major European/global databases)
    - Austrian implementation of derogations for research make data handling very delicate – all accesses must be logged
    - lack of cloud computing Code complicates storage and processing – currently only national compliance (BBMRI-ERIC in AT, but storage in IT)
  - Czech implementation of GDPR is one of the least problematic

IMI CONCEPTION – COLLECTING PHARMACOKINETIC DATA FOR BREAST FEEDING

- Lead by Novartis and UMCU
- Building a quality-assured biobank of breast milk sample from the whole Europe under BBMRI-ERIC auspice
- Interconnecting data resources form the whole Europe
  - EUROmediCAT, EUROmediSAFE, existing distributed pharmacokinetic databases by pharma companies, …

CONCLUSIONS

- **Research data is a specific topic** because of global nature of science
- **GDPR is actually positive step forward** for research data sharing – clarifies and harmonizes many things
  - performative nature of GDPR allows for good flexibility
  - gives good flexibility for research purposes, unless hampered by national derogations and/or additional regulations
- Adoption and further development of **common guidelines** needed
  - approval of Art. 40 Codes needs to accelerate
- **ERICs are a good framework for** facilitating **research data** sharing in Europe as demonstrated by CRC-Cohort developed by BBMRI-ERIC

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THANK YOU!

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