Anforderungen an RWD-Studien aus Sicht der Ethikkommission

Josef Haas
Institut für Medizinische Informatik, Statistik und Dokumentation
und
Ethikkommission der Medizinischen Universität Graz
Forum Österreichischer Ethikkommissionen

RWD???

- FDA: **Real-world data** are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. Examples of RWD include data derived from electronic health records, medical claims data, data from product or disease registries, and data gathered from other sources (such as digital health technologies) that can inform on health status.
- **Real-world evidence** is the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD.

RWD – type of data

IQVIA – RWD in the drug life cycle – data sources:

- EMR - Electronic Medical Records
- LRx - Longitudinal Prescription
- Claims Data
- Hospital Data
- Genomic Data
- Oncology Data
- Biomedical Global Data
- (??? Future Data derived from tissue)

Data Sources

- Patient registries
- Healthcare Databases – Electronic Health Records
- Pharmacy Databases
- Health Insurance Databases
- Social Media
- Patient Networks
- Dazu Initiativen wie MyData
- Consumer credit-card spending, geospatial data, behavioral data (diet lifestyle)

SHARE DATA or PROTECT DATA

Ist das ein (echter) Widerspruch??

Post-Market Surveillance

- MDR, IVD-R: „all activities carried out by the manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from their devices placed on the market, made available or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions" → Tätigkeiten & Ziele
- FDA 21 CFR part 822: „The active, systematic, scientifically valid collection, analysis, and interpretation of data or other information about a marketed device." → Tätigkeiten

Post Market Surveillance (PMS)

- Update Clinical Evaluation →Hersteller
- Vigilanzsystem → Hersteller und Regulators
- Marktüberwachung→ Regulators
- CAPA Corrective Action and Preventive Action → QM

RWD - regulators

Regulators
- NIS
- PASS – Post Authorization Safety Study (PRAC)
- PAES – Post Authorization Efficacy Study (PRAC)
- PMCF – Post Marketing Clinical Follow-Up (MDR)
- PMPF – Post Marketing Performance Follow-Up (IVDR)

Commercial
- Drug Life Cycle
- Market Analytics

Researcher
- Secondary use (???)
- Best Practice
- Efficiency & Effectiveness (in contrast to Efficacy)

PRAC - Pharmacovigilance Risk Assessment Committee

Ideal World vs. Real World

Ideal World

- Informed Consent
- Valid data
- Transparency
- No misuse
- Fair Share
- Risk Aversion Principle
- Non-identifiable Data

Real World

- Consent ?
- ?
- How?
- Hopefully no misuse
- Who cares?
- Utilitarian Principle
- ?

Declaration of Taipei

Ethical Considerations regarding Health Databases and Biobanks - Ethical Principles & Governance

11. The collection, storage and use of data and biological material from individuals capable of giving consent must be voluntary. If the data and biological material are collected for a given research project, the specific, free and informed consent of the participants must be obtained in accordance with the Declaration of Helsinki.

Declaration of Taipei

12. If the data or biological material are collected and stored in a Health Database or a Biobank for multiple and indefinite uses, consent is only valid if the concerned individuals have been adequately informed about:
    - The purpose of the Health Database or Biobank;
    - The risks and burdens associated with collection, storage and use of data and material;
    - The nature of the data or material to be collected;
    - The procedures for return of results including incidental findings;
    - The rules of access to the Health Database or Biobank;
    - How privacy is protected;
    - The governance arrangements as stipulated in paragraph 21;
    - That in case the data and material are made non-identifiable the individual may not be able to know what is done with their data/material and that they will not have the option of withdrawing their consent;
    - Their fundamental rights and safeguards established in this Declaration; and
    - When applicable, commercial use and benefit sharing, intellectual property issues and the transfer of data or material to other institutions or third countries.

RWD - Allgemein

- Informed Consent – ist einzuholen wenn möglich und zumutbar; wie wird der Informed Consent eingehol? (specific consent vs. broad consent vs. ~~open consent~~ vs ~~no consent~~)
- Identifiable data: Personenbezogen – pseudonym – anonym (zusätzlich anonym vs. anonymisiert) →Wie wird anonymisiert? HIPAA, k-Anonymität, L-Diversität
- Verwendungszweck – in der Folge Data Transfer and Usage → DSGVO
- Prospektiv oder retrospektiv
- Transparenz (damit verbunden Widerspruch,…) DSGVO

RWD - Ethik

- Prinzip der (nationalen) Leit-Ethikkommission gibt es (derzeit) nur bei AMG und MPG-Studien
- Antrag bei (fast) jeder Ethikkommission
- Datenquelle; Informed Consent, (Non-)Identifiable data, Datentransfer (vor allem in Drittländer), Zweck,

Aus der täglichen Praxis

- Protokolle sind verbesserungswürdig
- Eigenartige Definitionen von „retrospektiv“ und „anonym“
- Unkenntnis der DSGVO
- Registerstudie vs. Registerverwertungsstudie
- Kombination von Register + Biobanking + Patientenkontakt

Offene Fragen

- NORA – Nonobvious relationship Awareness
- „Vigilanz“ der Daten um Missbrauch zu verhindern oder einzuschränken
- Wie erzeugt man Transparenz für die Betroffenen, für die Öffentlichkeit?
- Eigentumsrechte
- Kombination mit anderen Daten, Proben
- Abgrenzungsfragen z.B. RWD – Bezug zu AMG, MPG, SaMD Software as Medical Device, Künstliche Intelligenz
- EU AI Act (June 14, 2023)

RWD

Scheinbar eine einfache Frage

aber

Datenschutz, Persönlichkeitsrechte, verteilte Verantwortung, unklare Zuständigkeiten, hohes technisches Niveau

erschweren die Darstellung (Studienplan), Beurteilung (Ethikkommission), Umsetzung und Transparenz