
Collection and use of RWD in the view of data protection concerns

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Introduction

- ▶ Technological advances are increasingly making it easier to collect and analyse Real World Data (RWD)
- ▶ RWD gathered in large observational studies is attempting to close the gap between experimental, artificial study settings and clinical realities.
- ▶ Real-world data can complement evidence from controlled trials and address questions that trials can't address – particularly the performance of a medicine when used in clinical practice



Sources of RWD

▶ RWD can be collected from various sources such as:

- Patient registries
- Electronic health records
- Insurance databases
- Social media and patient research networks
- ...



Questions regarding use of RWD and Data protection issues

- ▶ Are RWD used for research purposes, for reliability and safety issues of the products, or is part of a routine patient care?
- ▶ Which regulations are applicable when processing RWD data?
- ▶ What is the lawful basis for processing RWD in the framework of relevant data protection regulations?



Status of RWD under the EU General Data Protection Regulation (GDPR)

- ▶ Only personal data falls under the scope of the GDPR

- ▶ Definition of Personal data:

*‘any information relating to an **identified or identifiable natural person** (“data subject”); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to his physical, physiological, genetic, mental, economic, cultural or social identity of that natural person’ (Article 4 (1), GDPR)*

- ▶ Anonymous or anonymized data **are not** considered as personal data
- ▶ Pseudonymized or key-coded data **are** considered as personal data



Patients data and re-identifiability

- **Individual-level vs. Institution-wide health administrative data**
- **Sharing minimum amount of information or aggregate data is not identifying**
- **Re-identifiability of genomic data due to linking with other databases, etc..**



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Re-identifiability of genomic data and the GDPR

Assessing the re-identifiability of genomic data in light of the EU General Data Protection Regulation

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Special Categories of Data (Article 9, GDPR)

- ▶ Processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, **data concerning health** or data concerning a natural person's sex life or sexual orientation shall be prohibited.
- ▶ Processing of special categories requires meeting stricter requirements. (e.g. Data Protection Impact Assessment)



Legal basis for collection and use of RWD

I. Processing related to reliability and safety issues

II. Research activity



Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art. 70.1.b))


Adopted on 23 January 2019



I. Processing related to reliability and safety issues (Clinical Trials Regulation)

- ▶ The processing operations expressly provided by the Clinical Trials Regulation (CTR) and by relevant national provisions, and which are related to reliability and safety purposes, can be considered as falling within “legal obligation(s) to which the controller is subject” under Article 6(1)(c) of the GDPR.



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- ▶ The processing of personal data in the context of safety reporting or in the context of **an inspection by national competent authority, or the retention of clinical trial data in accordance with archiving obligations set up by the CTR or, as may be the case, relevant national laws**, have to be considered as necessary to comply with legal obligations to which the sponsor and/or the investigator are subject to.
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II. Lawful grounds for sharing personal data for research purposes (GDPR)

- Research related activities may either fall under:
 - The data subject's **explicit consent** (Article 6(1)(a) in conjunction with Article 9(2)(a)),

(Note: the informed consent foreseen under the Clinical Trials Regulation must not be confused with the notion of consent as a legal ground for the processing of personal data under the GDPR.)

- or a task carried out in the **public interest** (Article 6(1)(e)),
 - or the **legitimate interests of the controller** (Article 6(1)(f)) in conjunction with Article 9(2)(i) or (j) of the GDPR.
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Sharing data under research exemption rules

- Processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law...(Art. 9(2)(j) in conjunction with Art 89 (1))
- A broad definition of scientific research (Recital 159)
- Subject to t

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REVIEW ARTICLE



Rules for processing genetic data for research purposes in view of the new EU General Data Protection Regulation

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Safeguards for processing data under research exemption

- Technical measures such as pseudonymisation of data to mitigate the risks of re-identification
- Models of data sharing and controlled data access: Open access vs. controlled access
- To increase accountability of the data controllers and data users in access to data



Data Protection Impact Assessment (Article 35, GDPR)

The assessment shall contain at least:


- ▶ a systematic description of the envisaged processing operations and the purposes of the processing, including, where applicable, the legitimate interest pursued by the controller;
- ▶ an assessment of the necessity and proportionality of the processing
- ▶ an assessment of the risks to the rights and freedoms of data subjects
- ▶ the measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of personal data and to demonstrate compliance with this Regulation



Discussion and concluding remarks

- ▶ Difficult to clearly separate research from clinical practice in the context of RWD. For example, advocates of **learning health systems** have challenged the research-practice distinction, but unclear if a new system will be preferable and how it satisfies current research regulations
- ▶ Use of RWD data in clinical trials: The distinction between primary use vs. secondary use is important.



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- ▶ Data protection issues are not only addressed by Data Protection Officers (DPOs), but ethics committees and other oversight bodies also play a role.
 - ▶ Despite the enactment/and implementation of EU level clinical trials and data protection regulations, still many aspects of the data processing is regulated by the relevant national laws.
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Thanks for your attention!

