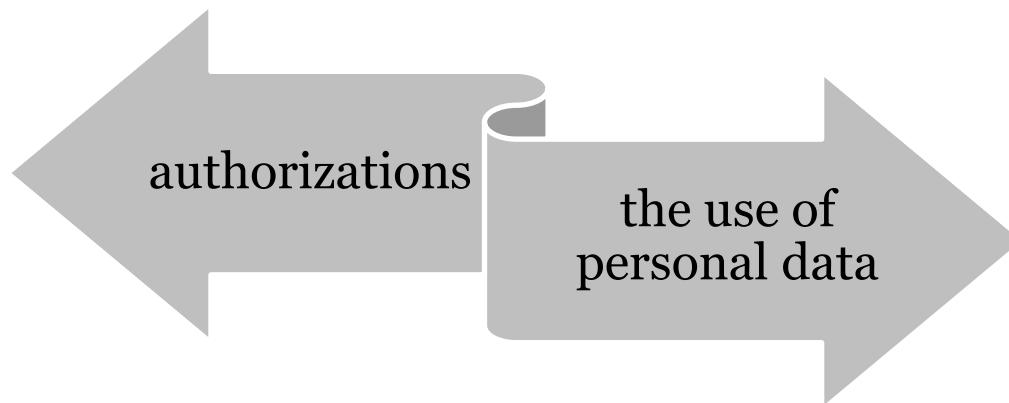


**How is the New Privacy
Regulation in the EU
Impacting on Efficient
Conduct of Clinical Trials**

Introduction to regulatory challenges in clinical trials:

Practical legal aspects to consider when initiating and conducting a clinical trial in Romania:



❖ Authorizations for establishing medical units where to conduct the trials

- not as well known as the authorization procedure of the clinical trial itself
- the medical unit requires **prior authorization procedure** with the National Agency for Medicines and Medical Devices of Romania (ANMDM)
- more stringent national law allowed under the Clinical Trials Directive

This prior authorization to be included in the dossier for authorizing the clinical trial by the sponsor.

Problematic:



- no deadline for issuance
- unclear requirements
- renewal of authorization

Solution:

- communication and confirmations from ANMDM and other authorities involved
- simplification of the procedures

❖ Privacy and personal data



European Commission – Q&A on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR)



European Data Protection Board – Opinion on the interplay between the CTR and the GDPR

The CTR does not derogate from the GDPR. GDPR and CTR are applied simultaneously. However, GDPR rules applicable to clinical trials also under the current regulatory regime.

Principle of lawfulness under the GDPR – what does it mean?

Each personal data controller should establish a legal basis for processing personal data. Justified, transparent and documented (consent forms, balancing test for legitimate interest etc.)

Non-compliance:

Fines up to 20,000,000 EUR or up to 4% of the total worldwide annual turnover of the previous year

Fine in Greece – wrong legal ground for processing employees' data – 150,000 EUR

Legal basis for processing personal data in the context of clinical trials



Who is responsible: the data controller. *i.e. the sponsor, the clinic-institution of the investigator, could be the CRO, debatable whether the central laboratory.*

For special categories of personal data (health data): both a legal basis (art 6 GDPR) and a special condition (art. 9 GDPR)



*Consent does not cover
all personal data
processing operations in
a clinical trials*

Primary use of the personal data – data related to the clinical trial protocol

Processing related to reliability and safety purposes



Legal basis: **compliance with a legal obligation**

e.g. safety reporting, archiving of the clinical trial master file and of the medical files of subjects in the clinical trial, disclosure of data to authorities during inspections

Special condition: processing necessary for reasons of public interest in the area of public health, such as [...] ensuring high standards of quality and safety of health care and of medicinal products or medical devices

Processing related to research activities



Legal basis: **legitimate interest of the data controller**

Special condition: processing is necessary [...] for scientific research purposes [...] based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject



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Processing related to research activities



Legal basis and special condition: **consent of the subjects** (different from consent to participate in the trial)

*Should be explicit, **freely given**, specific, informed, unambiguous*

Problematic in clinical trials: situations of imbalance of power between the sponsor/investigator and the participants, right to withdraw consent for the processing (obligation to stop the processing operations – deletion of data, unless another lawful basis), transfer to entities outside of EU should only as a last resort be based on consent – other safeguards

EDPB recommendation: other ground besides consent more appropriate

Legal basis: processing necessary for the **performance of a task in the public interest**

Limited applicability: when the clinical trial falls within the mandate/ mission vested in a private body by EU or national law, e.g. emergency clinical trials



*Special condition: **processing is necessary [...]** for scientific research purposes [...] or processing necessary for reasons of public interest in the area of public health, such as [...] ensuring high standards of quality and safety of health care and of medicinal products or medical devices*

Secondary use of the personal data – use of the data outside of the clinical trial protocol for scientific purposes



e.g. medical data collected to conduct a clinical trial on breast cancer used to run a study aiming to identify new biomarkers (which was not in the protocol)

Obligation to establish a legal basis for such personal data processing – different or not from the legal basis for primary use



Not applicable if personal data is **anonymized** – applicable if personal data is **pseudonymized**

Could be consent – consent for secondary use to be asked separately (separate consent sheets), should be specific

GDPR: when not possible to **fully identify the purpose of personal data processing** for scientific research purposes at the time of data collection, the subjects should be allowed to give their consent to **certain areas of scientific research** or **parts of research projects**.

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Thank you!

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