DATA PROTECTION ASPECTS OF CLINICAL TRIALS

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LEGAL FRAMEWORK

- Article 8(1) of the Charter of Fundamental Rights of the EU
- GDPR (recitals 156 and 161)
- Clinical Trials Regulation (Article 93)

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PERSONAL DATA

Any information relating to an identified or identifiable natural person

Identifiable person = can be identified, **directly or indirectly**, by one or more factors specific to their identity

name, an identification number, location data, factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity

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PERSONAL DATA

Pseudonymised data: personal data that can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately

Anonymous data: information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable

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PROCESSING

any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction

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LEGAL BASIS
GDPR Article 6(1)

- the data subject has given **consent** to the processing of his or her personal data for one or more specific purposes;

- processing is necessary for the **performance of a contract** to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract;

- processing is necessary for compliance with a **legal obligation** to which the controller is subject;

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LEGAL BASIS

- processing is necessary in order to protect the **vital interests** of the data subject or of another natural person;

- processing is necessary for the performance of a task carried out in the **public interest** or in the exercise of **official authority** vested in the controller;

- processing is necessary for the purposes of the **legitimate interests** pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.

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SPECIAL CATEGORIES OF PERSONAL DATA GDPR Article 9(1)

Processing of personal data revealing:

- racial or ethnic origin
- political opinions
- religious or philosophical beliefs
- trade union membership
- genetic data
- biometric data for the purpose of uniquely identifying a natural person
- **health**
- sex life or sexual orientation

is **FORBIDDEN!**

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SPECIAL CATEGORIES OF PERSONAL DATA DEROGATIONS - GDPR Article 9(2)

- **consent**
- carrying out rights and obligations under employment and social security and social protection law;
- **vital interests of the data subject**
- personal data of members
- data manifestly made public by the data subject
- establishment, exercise or defence of legal claims
- necessary for reasons of substantial public interest
- necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services

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SPECIAL CATEGORIES OF PERSONAL DATA DEROGATIONS - GDPR Article 9(2)

- necessary for reasons of public interest in the **area of public health**, such as protecting against serious cross-border threats to health or ensuring high standards of **quality and safety of health care and of medicinal products or medical devices**

- necessary for archiving purposes in the **public interest, scientific** or historical **research** purposes or statistical purposes

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LEGAL BASIS IN CLINICAL TRIALS

PRIMARY USE – RELIABILITY AND SAFETY RELATED PURPOSES

- the purposes: protection of health, while setting standards of quality and safety for medicinal products
- all processing operations related to a specific clinical trial protocol during its whole lifecycle
- LEGAL OBLIGATION – GDPR Article 6(1)(c)
- REASONS OF PUBLIC INTEREST IN THE AREA OF PUBLIC HEALTH – GDPR Article 9(2)(i)

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LEGAL BASIS IN CLINICAL TRIALS

PRIMARY USE – RESEARCH

- processing purely related to research purposes
- CONSENT– GDPR Article 6(1)(a)
- CONSENT GDPR Article 9(2)(a)

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LEGAL BASIS IN CLINICAL TRIALS

PRIMARY USE – RESEARCH

- ❑ TASK CARRIED OUT IN THE PUBLIC INTEREST - GDPR Article 6(1)(e)

- ❑ LEGITIMATE INTERESTS OF THE CONTROLLER - GDPR Article 6(1)(f)

combined with

- ❑ REASONS OF PUBLIC INTEREST IN THE AREA OF PUBLIC HEALTH – GDPR Article 9(2)(i)

- ❑ SCIENTIFIC RESEARCH – GDPR Article 9(2)(j)

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CONSENT

- ❑ different from CTR consent
- ❑ freely given, specific, informed, unambiguous
- ❑ explicit consent for special categories of data
- ❑ controller shall be able to demonstrate that the data subject has consented to processing
- ❑ request for consent shall be presented in a manner which is clearly distinguishable from the other matters, in an intelligible and easily accessible form, using clear and plain language

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CONSENT

- right to **withdraw** the consent at any time
- all data processing operations that were based on consent remain lawful
- controller shall stop the processing actions concerned
- the data should be deleted (unless there is other lawful basis)

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LEGAL BASIS IN CLINICAL TRIALS

SECONDARY USE – RESEARCH

- OUTSIDE DE SCOPE OF THE PROTOCOL
- OTHER LEGAL BASIS
- COMPATIBLE PURPOSE

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CONTROLLER

- the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the **purposes** and **means** of the processing of personal data

- where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law

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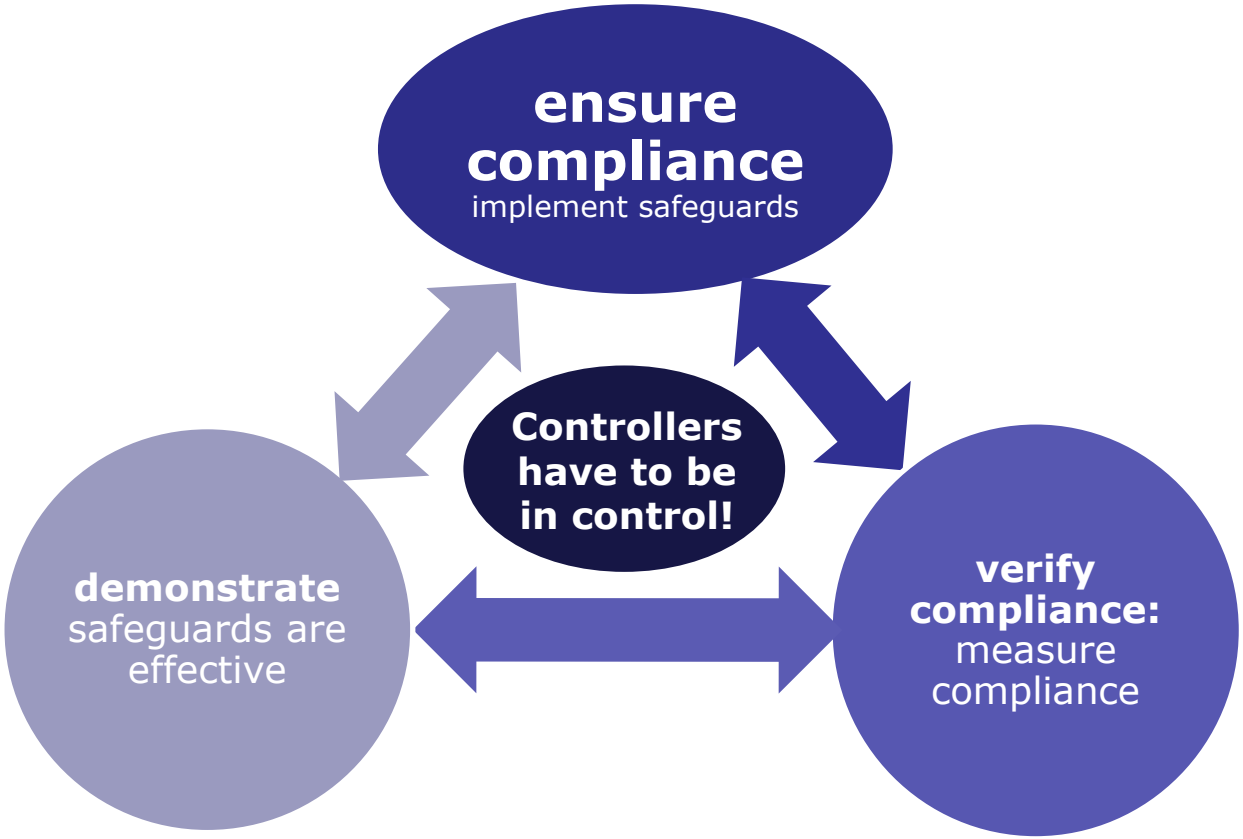
Accountability and Compliance



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JOINT CONTROLLERS

- two or more controllers jointly determine the purposes and means of processing
- must determine their respective responsibilities
- arrangement between them
- essence of the arrangement shall be made available to the data subject
- the data subject may exercise his or her rights under GDPR in respect of and against each of the controllers

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PROCESSOR

- carries out processing on behalf of the controller
- only processors providing sufficient guarantees to implement appropriate technical and organizational measures to meet GDPR requirements
- written contract with the controller

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DATA PROTECTION BY DESIGN AND BY DEFAULT

Data Protection by Design

- Implement data protection principles
- both at the time of the determination of the means for processing and at the time of the processing itself

Data Protection by Default

- = strictest privacy settings automatically apply

➔Common sense + think privacy!

- Is it necessary to process personal data at all?

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DATA PROTECTION PRINCIPLES

- lawfulness, fairness and transparency
- purpose limitation
- data minimisation
- accuracy
- storage limitation
- integrity and confidentiality
- accountability

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DATA SUBJECTS RIGHTS

- right to be informed
- right of access
- right to rectification
- right to restriction of processing
- right to erasure
- right to data portability
- right to object
- not to be subject to automated individual decision making

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PRIVACY STATEMENT

WHO-WHAT-WHY-HOW

concise, transparent, intelligible and easily accessible form, using clear and plain language

Articles 13 and 14 of GDPR

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PERSONAL DATA BREACH

- breach of security leading to the accidental or unlawful **destruction**, **loss**, **alteration**, **unauthorized disclosure** of, or **access** to, personal data
- not the same as serious breach according the Article 52 of CTR
- notify to **Data Protection Authority** without undue delay, not later than within 72 hours unless unlikely to result in a risk to the rights and freedoms of natural persons (GDPR Article 33)
- communicate to the data **subject** without undue delay, if likely to result in a high risk to the rights and freedoms of the natural person (GDPR Article 34)
- document all facts and actions

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DATA PROTECTION IMPACT ASSESSMENT

- where a type of processing in particular using new technologies, and taking into account the nature, scope, context and purposes of the processing, is likely to result in a high risk to the rights and freedoms of natural persons

- single assessment may address a set of similar processing operations that present similar high risks.

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DATA PROTECTION IMPACT ASSESSMENT

- systematic and extensive evaluation of personal aspects relating to natural persons which is based on automated processing
- processing **on a large scale of special categories** of data
- systematic monitoring of a publicly accessible area on a large scale.

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DATA PROTECTION IMPACT ASSESSMENT

- 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 operations in relation to the purposes;
- an assessment of the **risks** to the rights and freedoms of data subjects
- the **measures** envisaged to address the risks,

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INTERNATIONAL TRANSFERS

- GDPR Chapter V (Articles 44 – 50)

- EDPB Recommendations 01/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data

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INTERNATIONAL TRANSFERS
EDPB recommended steps

- ❑ know your transfers
- ❑ verify the transfer tool your transfer relies on
- ❑ assess the law or practice of the third country
- ❑ identify and adopt supplementary measures
- ❑ take any formal procedural steps
- ❑ re-evaluate at appropriate intervals

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INTERNATIONAL TRANSFERS
Transfer tools

- Adequacy decision
- Appropriate safeguards
- Derogations for specific situations

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INTERNATIONAL TRANSFERS
Adequacy decision

- a third country, a territory or one or more specified sectors within that third country, or the international organisation in question ensures an adequate level of protection

Andorra, Argentina, Canada (commercial organisations), Faroe Islands, Guernsey, Israel, Isle of Man, Japan, Jersey, New Zealand, Switzerland and Uruguay

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INTERNATIONAL TRANSFERS
Appropriate safeguards

- Legally binding and enforceable instrument between public authorities or bodies
- Binding corporate rules
- Standard data protection clauses
- Code of conduct
- Certification mechanism
- Contractual clauses
- Provisions to be inserted into administrative arrangements between public authorities or bodies

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INTERNATIONAL TRANSFERS
Derogations for specific situations

- Consent
- Performance of a contract
- Important reasons of public interest
- Establishment, exercise or defence of legal claims
- Protect the vital interests of the data subject or of other persons
- The transfer is made from a register which according to Union or Member State law is intended to provide information to the public

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THANK YOU FOR YOUR ATTENTION

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