

Interaction btw. the GDPR and Clinical Trials Regulation

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Clinical Trials Regulation (CTR)

- approved in 2014 and will most likely come into effect as of Oct. 2018
- all information btw. the parties circulated through EU portal and database
- strict transparency requirements; with the exception of
 - personal data
 - commercial confidential information unless overriding public interest
 - confidential communication btw. Member States in the preparation of the assessment
 - supervision of the clinical trial

Processing of personal data under CTR

- GDPR is applicable to all processing of personal data in clinical trials by the Member States (CTR Art. 93);
- for processing of personal data within EMA, incl. in the EU portal and database the Regulation 45/2001 on the protection of individuals with regard to the processing of personal data by the Union institutions and other bodies applies;
- a proposal for a new regulation was given on 10.1.2017 (COM(2017) 8 final)

EMA anonymisation guidelines

- External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use, 16.3.2016, EMA/90915/2016
- recommends anonymisation by randomisation or generalisation; masking destroys the usability of data
- supporting documentation to EMA 0070 Publication policy
 1. Phase one: publication of clinical reports (1 Jan. 2015)
 2. Phase two: publishing of individual patient data (later)

CTR provisions on consent

- Informed consent for processing personal health data for clinical trials according to CTR (Arts 28 & 29)
- Qualified informational requirements when subjects belong to vulnerable groups
- Consent may be withdrawn at any time
- relates to consenting in participating in the clinical trial as required by the Charter of Fundamental Rights; any intervention in the field of biology and medicine cannot be performed without the free and informed consent of person concerned. (Recital 27)

CTR consent cont.

- consent under CTR does **not relate to processing of personal data** according to EDPS
- also according to GDPR “for the purpose of consenting to the **participation** in scientific research activities in clinical trials the CTR should apply (Rec. 161)

Consenting for further research uses under CTR

- At the time of giving informed consent the data subject may consent to the use of her personal data outside the protocol of the clinical trial **exclusively for scientific purposes** (Art. 28.2)
- universities and other research institutions should be able to collect data as appropriate under applicable data protection law to be used for future scientific research
- for this processing GDPR applies
- research projects based on secondary use of clinical trials data subject to reviews that are **appropriate for research on human data, e.g. on ethical aspects**, before being conducted. (Recital 29 CTR)

Defining scientific research uses

- CTR: further scientific research tied to universities and research institutions (Rec. 29)
- GDPR: scientific research purposes should be interpreted in a broad manner incl., e.g., technological development and demonstration, fundamental research, applied research and privately funded research
- and studies conducted in the public interest in the area of public health (Rec. 159)
- processing of **health data** in the public interest for research purposes must be based on Union or Member State law which has to meet an objective public interest (Rec. 53)

General Data Protection Regulation (GDPR)

- in force and will be applied as of 25 May 2018 in all EEA States.
- applies to all data processing conducted in connection with clinical trials in the Member States; complemented by local law
- general principles, i.a.:
 - determination of the data controller and possible data processor
 - data protection by default and by design
 - secure data protection environment
 - data breach notification procedures

GDPR general provisions cont.

- data protection officer
- possible data protection impact assessment
- rules relating to transfer of data to third countries;
- note! applies also to data processing in cloud outside of EU when the the data processed is from EU
- administrative fines

GDPR and consent

- Consent must be given for **one or more specific purposes;**
- **for sensitive data, such as health related data,
explicit consent for one or more specified purposes**
- consent can be granted for certain areas of scientific research **when in keeping with recognised ethical standards for scientific research => common Nordic approach?**

Consent cont.

- All consents must include an opportunity for data subject to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose. (Recital 33)
- consent is presumed not to be freely given if it does not allow separate consent to be given to different data processing operations despite it is appropriate in the individual case (Recital 43)
- consent shouldn't provide a valid legal ground in a specific case where there is a clear imbalance btw. the data subject and the controller, in particular where the controller is a public authority (Rec.43)

Consent cont.

- Transitory provisions of the GDPR:
- all consents must be in line with the Regulation if processing still continues after the Regulation is being applied (25 May 2018)
- WP29 will issue guidelines on consent in 2017

Consent for secondary use of CT data

- Consent for secondary use of clinical trial data should be separate from the consent for CT, but may be given in connection with the original consent
- WP 29: 'future research' too wide as a purpose for consent
- Recommendable: draft the consent according to GDPR
- Nordic approach?

Legitimate basis for processing health data for scientific research under GDPR

- Consent
- Legal basis: processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89 (1)
- if the processing involves sensitive personal data, legal basis under art. 89.1 requires that the basis is statutory

Processing of health data for scientific research

- based on Union or Member State **law** which shall be
 - 1) proportionate to the aim pursued,
 - 2) respect the essence of the right to data protection, and
 - 3) provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject

Further safeguards according to Art. 89

- Organisational and technological safeguards for the rights and freedoms of the data subject to ensure, i.a. that no more data is collected than strictly necessary
- If possible, data should be processed in anonymised form
- If this is not feasible for the research in question, pseudonymisation of data may be considered as one of the safeguards

Possibilities for Nordic cooperation

- Technological safeguards for cross-border research use of sensitive data are already being tried out in the Tryggve -pilot project (part of Nordforsk funded Nordic E-Infrastructure Collaboration)
- Common legal provisions with regard to national implementation of the safeguards applicable to processing personal data for scientific research could lay part of the legal foundations for the Nordic research area
- e.g. with regard to ethical review and interoperable technological solutions

- QUESTIONS AND COMMENTS WELCOME!
- THANK YOU!
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