Group Legal

EU Clinical Trial Regulation: A view from Data Privacy

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1. From Directive to Regulation

- Tendency of the EU to regulate certain aspects through Regulation and not Directives

- Homogeneous approach
- Homogeneous implementation
- Reduction of bureaucracy
- Reduction of different interpretations

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2. Regulation on Informed Consent

- EU Regulation on Clinical Trials contains very clear, detailed and specific instructions as to how the ICF must be in order to be valid:
  - It must be in a manner distinguishable from other matters;
  - In an easily accessible form and using clear and plain language; and
  - Individuals must be able to withdraw their consent easily.
- It also contains instructions for determined types of patients: minors, incapacitated, pregnant women

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3. Consent to the use of data outside the protocol of the clinical trial exclusively for scientific purposes

One of the concerns expressed by the medical research community was the potentially stricter rule around further processing of health data.

Both the EU Regulation on CT and GDPR state that further processing of data exclusively for scientific research purposes is permitted, so long as the framework for safeguards around scientific research is complied with.

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4. References to Directive 95/46 EC Regulation (EU) 2016/679 (General Data Protection Regulation)

- The EU Regulation on Clinical Trials refers to the Directive 95/46/EC of the European Parliament and of the Council, of October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, which will be no longer valid when the GDPR enters into force in 2018
- However, all references should be understood as made to the GDPR, since the GDPR does not contradict the provisions on Privacy contained in the EU Regulation on Clinical Trials

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QUESTIONS?

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