GDPR and research – where to go from here?

ESMO Public Policy Webinar "General Data Protection Regulation and its impact on clinical research" 21/05/2021

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GDPR and clinical research

Data protection rules as ‘code of the road’

- Ensuring protection of people against overreach by organisations;
- Enabling them to make their own choices;
- What for? To protect dignity and autonomy of individuals, while also ensuring that fair and lawful processing can take place;
- GDPR is evolution, not revolution - most principles date back to the former data protection directive 95/46/EC, if not all the way to Council of Europe Convention 108 (1981).

GDPR and clinical research

Quick recap of (some) main rules

- Lawful bases (Articles 6 and 9)
  - Role of different lawful bases for processing – not only consent!
  - Recital 33 on “broad” consent – interaction with information obligations;
  - See also 9(2)(i) & (j)): processing for “reasons of public interest in the area of public health” or which is “necessary for […] scientific or historical research purposes or statistical purposes”, based on laws which “provide for suitable and specific measures to safeguard the fundamental rights” of the data subject.
- Possibility for additional MS rules in the health field (9(4)) (study for EC on implementation)

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Quick recap

- Transparency and data subject rights (12-22, recitals 33, 57)
  - People have a right to know, to have incorrect data rectified etc.
- Presumption of compatibility and safeguards (5, 89)
  - certain privileging of research over other secondary uses, but safeguards required, e.g. reference to pseudonymisation in Article 89.
  - MS law may lay down derogations from data subject rights (e.g. access) under certain circumstances

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What's next?

EDPB Guidelines on scientific research

- EC invited EDPB to provide guidance in 2020 GDPR evaluation;
- EDPB provided first indications in reply to EC questions;
- EDPB is working on Guidelines, likely to cover e.g. "broad" consent, secondary use, indirect collection, Article 89 GDPR safeguards;
- Stakeholder event took place on 30/04/21 to collect feedback;
- Timing: to be adopted this year / standard procedure: version for public comments to be published.

What’s next?

European Health Data Space legislative proposal

- Sharing, access and control of patients over their health data for healthcare;
- Access to and re-use of health data for research, policy making and regulatory decision-making;
- Fostering a single market for digital health services and products, incl. AI;
- Public consultation open until 26/07; publication of legislative proposal scheduled **Q4/21**.

Thank you

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