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

Owe Langfeldt
Directorate-General Justice and Consumers – Data Protection
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)
GDPR and clinical research

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
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