Existing regulatory framework

- GDPR
  - Facilitates movement of data and promotes individual rights and freedoms
  - Data concerning Health
  - Article 9 exemptions tied to EU/MS laws:
    - Public interest for quality/safety
    - Necessary for scientific research

- MDR
  - Replaces the regulatory framework under the Medical Device Directive No 993/42/EEC ("MDD").
  - Covers software in addition to traditional medical devices
  - Mandatory compliance for medical device companies

Existing regulatory framework

EDPS Preliminary Opinion January 2020

- Issues identified
- Definition of "scientific research"
- Boundary between private sector and traditional academic research

- Recommendations
- Intensifying dialogues
- EU Codes of Conduct for scientific research

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EU Initiatives: Digital Health

European Health Data Space:

- System for data exchange and access
- Objectives:
  - strengthen the use of health data for research and innovation purposes
  - help healthcare authorities in decision-making
  - effectiveness and sustainability of healthcare systems
  - support the work of regulators in assessing medical products to demonstrate safety, efficacy and quality
  - interoperability

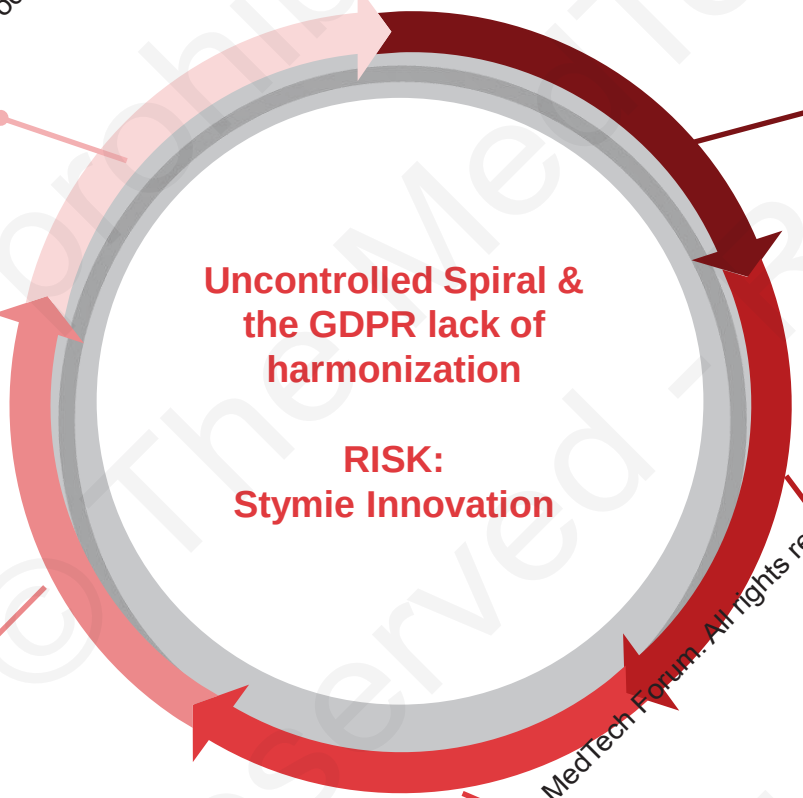
European Health Data Strategy

Uses of health data:

- Primary uses
- Secondary uses

European Health Data Strategy names 3 broad functions which can be distinguished involving processing of health data

GDPR Challenges to Using Health Data



All data uses tarred with the same brush

- Lack of Sector knowledge: Big Tech and Life Sciences treated the same
- Consent = False Positive
- Increasing need for / reliance on Real World Data

Laws and Standards

- Patchwork of laws / regulations / standards
- Inconsistent interpretations / enforcement
- Conflict of law issues

Rapid, Evolving Technology / Data Access

- Lack of parity between laws / regulations / standards and new data uses/technologies
- Challenging healthcare research
- "Traditional" processing models are focus of most supervisory authorities
- Lack of understanding among clinic DPOs

Consent = False Positive

- Different requirements between ICFs and consent for GDPR
- Compatible use or Issue of further / secondary use
- Challenges to facilitating withdrawal if data pseudonymised

De-indentification / Pseudonymisation / Anonymization

- Each term has different meaning
- No pre-defined checklist
- Different approaches required

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Opportunities

- Harmonisation – Stakeholder education / EDPB guidance?
- European Health Data Strategy
- Adoption of Standards: ENISA pseudonymisation and other EC or EU level support
- GDPR Code of conduct

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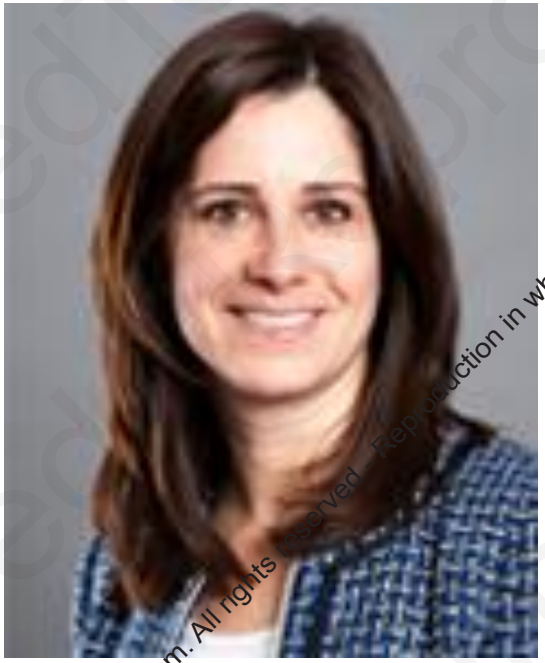
Cynthia O'Donoghue

Partner

Reed Smith



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