eHealth week

Organised by:

In collaboration with:

Collecting and Handling Health Data in a GDPR World

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@DIGITALEUROPE

WHO IS DIGITALEUROPE

- Represents the digital technology sector in Europe
- A wide range of Multinational Companies (60) and National Trade Associations (37)
- Represents more than 27,000 businesses and 2 million employees

WHERE ARE WE TODAY?

- Directive 95/46/EC
  - Sensitive personal data – includes data concerning health
  - Afforded ‘higher standard’ of protection
  - General prohibition of processing without explicit consent
  - Some level of fragmentation across EU with sub-categories

WHERE WILL WE BE IN MAY 2018?

- General Data Protection Regulation (“GDPR”)
  - Regulation vs. Directive
  - More organisations caught by scope
  - New safeguards requirement
  - Increased transparency
  - Higher fines

TRANSPARENCY AS A CORE FOCUS

- Certain information needed to explain use of personal data
- GDPR requires more info:
  - Will data be transferred?
  - How long will it be kept?
  - Is profiling being used?

EXPANSION OF ‘SENSITIVE PERSONAL DATA’

- GDPR continues to include ‘health data’
- GDPR includes ‘genetic’ and ‘biometric data’
- GDPR permits Member States to introduce further conditions

MORE ORGANISATIONS CAUGHT

- Processors are subject to direct legal obligations
- Organisations not established in the EU require compliance

PROCESSING ‘HEALTH DATA’

- Lawful processing reflects Directive
- Explicit consent is not the only option
- Lawful processing also for public interest, preventative or occupational medicine, medical diagnosis, provision of health or social care or treatment, etc.
- Questions remain on ‘scientific research’

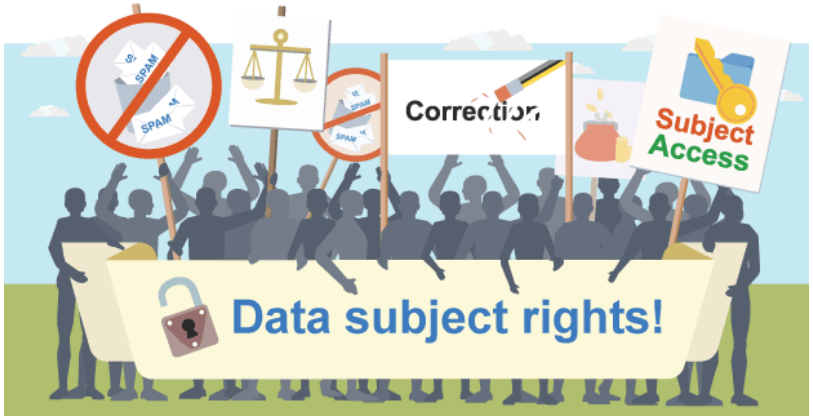
HOW TO OBTAIN CONSENT?

- Freely given, specific, informed and unambiguous indication of individual's wishes
- GDPR places burden on controller to demonstrate consent
- Must be obtained in a manner distinguishable from other matters, in an easily accessible form and using clear and plain language

IMPORTANCE OF SCIENTIFIC RESEARCH

- Qualified compliance framework if safeguards in place
- No clear definition on ‘scientific research’
- What about health research, driven primarily for ‘commercial gain’?

SCIENTIFIC RESEARCH VS. RIGHTS OF INDIVIDUALS



- GDPR strengthens individuals rights
- Introduction of new rights like ‘data portability’
- Scientific research tempers effects of some rights (e.g. right to erasure & right to object)
- Member State derogations exist

DATA BREACH NOTIFICATION

- Not industry specific
- Triggered if breach 'likely to result in high risk to individuals'
- Nature of 'health data' likely to result in 'high risk' to individuals if breached
- Conditions on breach

DOCUMENTATION & MORE DOCUMENTATION

- Controllers & processors now have documentation obligations
- Record of processing activities must be kept
- Nature of ‘health data’ likely to result in ‘high risk’ to individuals if breached
- Conditions on breach

APPOINTING DATA PROTECTION OFFICER

- Obligation to appoint DPO when ‘core activities consist of the processing of sensitive data on a large scale’

- This will catch large amount of:
  - Healthcare providers;
  - Insurance
  - Pharma
  - Biotech
  - Digital tech

WHAT'S LEFT TO BE DONE?

ARTICLE 29
Data Protection Working Party

- Article 29 Working Party 'guidance documents'
- Aim is to give clarity to controllers and processors
- Published in draft form for stakeholder input
- 'Data Protection Impact Assessments' next

ANYTHING ELSE?

- Codes of conduct & certification
- Adherence to either to be used as sign of compliance
- Health industry can explore developing a code tailored for their specific requirements
- ‘Certified’ controllers or processors also option

IS THAT REALLY ALL?

- Ensure harmonised implementation across Member States
- Minimise (or maximise) Member State opening clauses
- Ensure clarity in ‘unclear areas’

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Thank you!

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