



Data Protection and Life Sciences – implications of the GDPR

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Some key terms

- Personal data – data which relates to a living individual who can be identified from that data or from that data when combined with other data
- Sensitive / special personal data – specific categories of data that have to be treated differently
- Data subject – someone about whom the data controller processes data
- Data controller – entity which makes the decision about how data should be processed
- Data processor – process the data on behalf of a data controller
- Processing – anything you do with data

What's not new?

- Compliance with the data protection principles
- Having to have a basis for processing
- Privacy notices
- Not having more data than you need
- Only keeping your data for as long as you are actually required to have it
- Data subjects having rights like subject access requests
- Appropriate data security
- Adequate safeguards for data transfers

DPA vs GDPR – the principles

GDPR

- Lawfulness, fairness and transparency
- Purpose limitation
- Data minimisation
- Accuracy
- Storage limitation
- Integrity and confidentiality

DPA

- Used fairly and lawfully
- Obtained only for one or more specified and lawful purposes
- Adequate, relevant and not excessive
- Accurate and up to date
- Not retained for longer than necessary
- Processed in accordance with rights
- Measures to prevent unlawful use, loss or damage
- Data transfer requirements

What is health data?

“personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status” (Article 4(15))

- Biometric and genetic data
- All data pertaining to past current and future physical or mental health information
- Information collected in provision of healthcare services
- A number, symbol or other particular assigned to an individual for health purposes which uniquely id's that individual
- Information derived from testing or examining a body part or substance
- Patient information received from a doctor or from a medial device

Specific 'life science' sector considerations (1)

- New responsibility for data processors
- Key coded (pseudonymised) data – is it now personal data?
- Pharmacovigilance – new legal grounds for processing data
- International data transfers

Specific 'life science' sector considerations (2)

- Medical research:
 - Clarify current ambiguity
 - Permissive processing of scientific data for research purposes
 - Processing can extend past that which is compatible with initial purpose
 - Data subjects rights to be forgotten?



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