



The implications of the Data Protection Regulation for Life Sciences Research

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EU Draft General Data Protection Regulation (GDPR)

- Still a draft, not voted yet
- Regulation (≠ directive !)
- Extendable to non EU companies
- Volume of text has tripled
- Fines up to 100.000 EUR or 5% of annual worldwide turnover
- Entry into force: 2016-2017?
- Contagious effect



New relevant concepts

- New definition
 - genetic data
 - biometric data
- Amended definitions
 - personal data
 - data concerning health



Data concerning health

- health status
- registration for the provision of health services
- payments or eligibility for healthcare
- number, symbol or particular assigned to **uniquely identify** for health purposes
- any information collected in the course of the provision of health services
- information derived from the **testing or examination of a body part or bodily substance, including biological samples**
- identification of a person as provider of healthcare to the individual
- any information on e.g. a disease, disability, disease risk, medical history, clinical treatment, or the actual physiological or biomedical state
- **independent of its source**, such as e.g. from a physician or other health professional, a hospital, a medical device, or an in vitro diagnostic test.



New obligations

- Consent
- Profiling
- Privacy by design
- Privacy by default
- Data protection impact assessment
- Data protection officer
- Data breach notification
- Rights of data subjects



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