FAIR Human Data under GDPR

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ELIXIR All-Hands
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FAIR Human Data
— What to look out? Can it work?

Findable Accessible Interoperable Reusable

Health data + Genomics data
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- Use data catalogs to advertise data collections
  - Use standards such as CDISC, DATS, ISO 11179 standards
    - Clinical Data Interchange Standards Consortium
    - Data Tag Suite model
    - ISO 11179 – Metadata registry standard
  - Example from ELIXIR-LU, using part of CDISC
    https://datacatalog.elixir-luxembourg.org/

- Only aggregated metadata should be used
  - No personal data should ever be shared w/o adequate safeguards
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- Data subject needs to be informed
  - In *advance* of sharing with stakeholders
  - About the respective *purposes* of the use (Art 13)

- Fix rights, obligations and responsibilities *before* giving access (Art. 26, 28)
Any access (not just transfer) to the data from outside the EU is prohibited unless there is:

- **Adequacy** decision by EU per country (CH, NO, IL) Art. 45
- **Explicit** consent by data subject (Art. 49)
- Important reason of **public interest** (Art. 49)
- **Contractual** safeguards through standard clauses by EC or data protection authority approved clauses (Art. 46)
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• Access restriction required
  • Only necessary people should have access (Art. 25)

• Data minimisation is required
  • Serve only relevant data for processing (Art. 25)

• Security measures need to be in place (Art. 32)
  • Only 2 specific measures
    • pseudonymisation & encryption
    • (2-FA) authentication
    • Encrypted transfers, ...

• Keep track of all data shared
  • data subject has reach-through right (Art 15, Art 19)
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• Not affected by GDPR
Data subject needs to be informed before any further processing beyond original purpose (Art. 13)

GDPR allows for broad consent where consent is legal basis (Recital 33)

Where consent is not the legal basis not all countries in Europe may be allowed to process your data different national provisions for processing health and genetic data are possible under GDPR (Art. 9.4)

GDPR allows for not too limiting retention time (Art. 5)
Thank you
References

— For images and materials

• http://couponloots.com/Categories
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• http://www.davidfroud.com/vendor-due-diligence-assessing-cloud-service-providers/
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