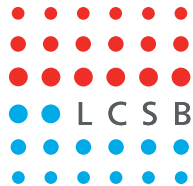




FAIR Human Data under GDPR

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ELIXIR All-Hands
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FAIR Human Data

— What to look out? Can it work?

F_{indable} A_{ccessible} I_{nteroperable} R_{eusable}




Health data



Genomics data



FAIR Human Data under GDPR

— F like Findable



- 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



FAIR Human Data under GDPR

— A like Accessible



- 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)



FAIR Human Data under GDPR

— A like Accessible



- 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)

FAIR Human Data under GDPR

— A like Accessible



- 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)



FAIR Human Data under GDPR

— I like Interoperable



- Not affected by GDPR



FAIR Human Data under GDPR

— R like Reusable



- 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

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