Legal aspects of research data sharing

Dilza Campos, PhD

22/10/2024

Sharing sensitive data in practice

- Bob is a researcher working with genomic data in Ugent, he does a collaboration with Alice, also from UGent

Conditions

•Sufficient technical and organisational measures such as pseudonymisation, limitation of access to the data, encryption, …

•Data minimisation must be respected (do not collect more personal data than necessary and do not transmit more personal data than necessary).

• If the data was originally collected on the basis of consent, consent must also be requested for reuse.
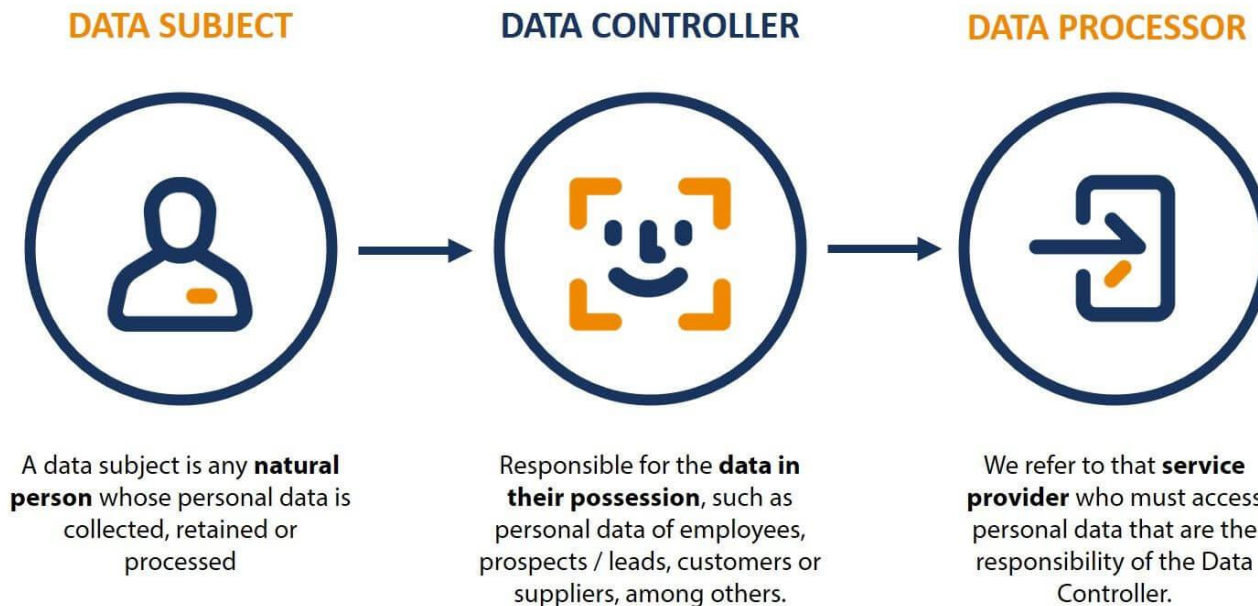
Document and justify this transfer of data in UGent GDPR register
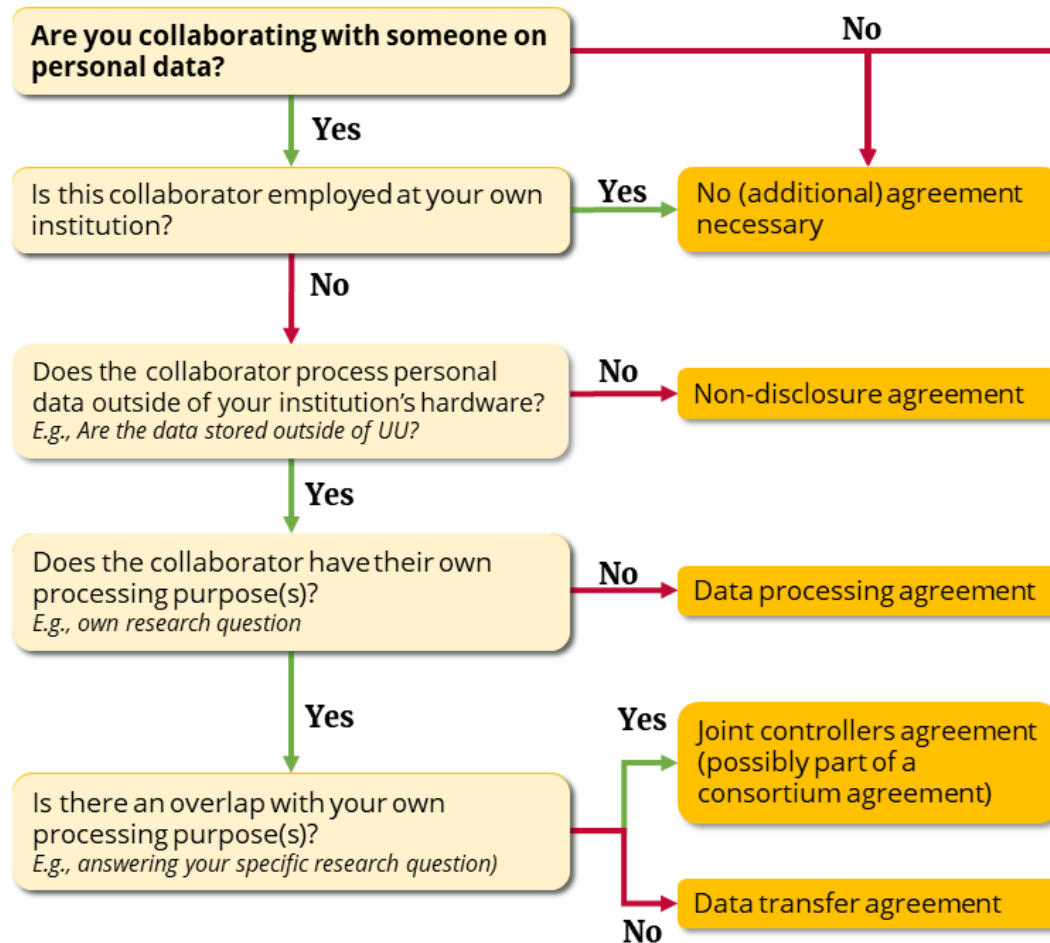
Sharing sensitive data in practice

- Alice is a researcher working with genomic data in Ugent, she does a collaboration with Maria, from another institute in EEA
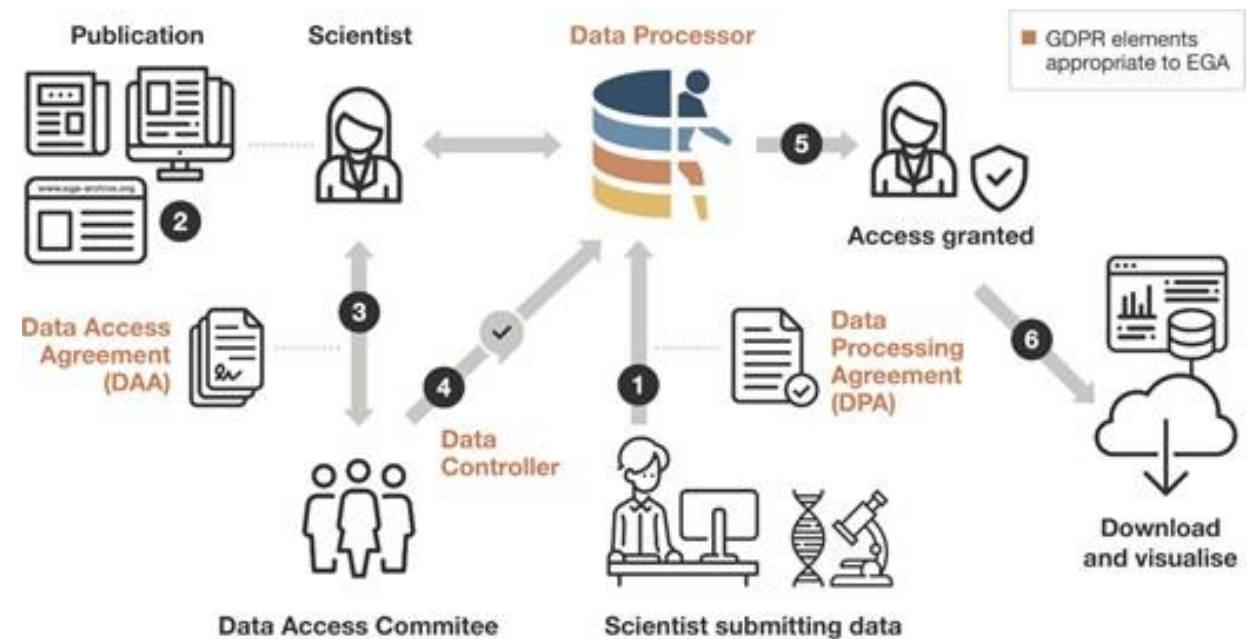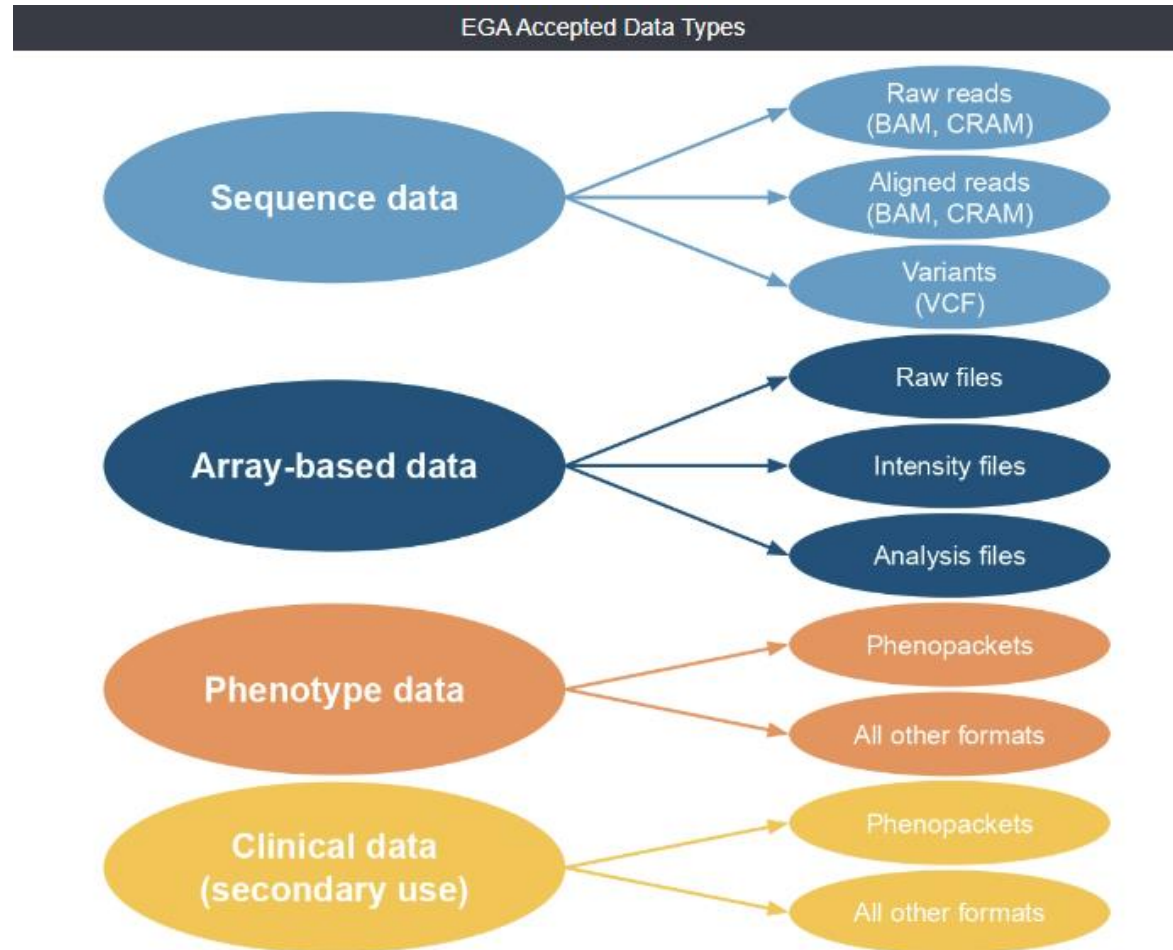
FURTHER LEGAL REQUIREMENTS

DATA SUBJECT	DATA CONTROLLER	DATA PROCESSOR
A data subject is any **natural person** whose personal data is collected, retained or processed	Responsible for the **data in their possession**, such as personal data of employees, prospects / leads, customers or suppliers, among others.	We refer to that **service provider** who must access personal data that are the responsibility of the Data Controller.

Sharing sensitive data in practice

https://utrechtuniversity.github.io/dataprivacyhandbook/

EGA submission process

1. Submission after a Data Processing Agreement
2. A scientist discovers the dataset (e.g. through a publication or by navigating the EGA)
3. The DAC is contacted and a DA is defined
4. EGA is informed of access permission
5. Scientist can access the data
6. Data is downloaded and re-used

Data types at EGA

Beyond EGA: FEGA and GDI (2026)

		Federated European Genome-phenome Archive	**European Genomic Data Infrastructure**
	DIFFERENCES		
🏛️	**Governance model**	FEGA nodes are Data Processors. The DACs are Data Controllers for their own datasets.	The EDIC legal entity (part of the EHDS) will be the data controller for all the hosted datasets.
📄	**Data inclusion criteria**	Almost any omics in need of control access.	Initially, WES and WGS produced for the Genome of Europe and 1+ Million Genomes initiatives.
💻	**Software stack maturity**	FEGA provides a software solution for data and metadata submission, storage, and permissions management.	GDI is building open source reference implementation for the 5 functionalities covering the full data life cycle.

VIB

EGA is not the only repository

Generic versus domain-specific repositories

- **Disciplinary and domain-specific repositories**
    - Should be commonly used and endorsed by the research communities.
    - Should be recognized internationally.

Guidelines on finding a repository

• A **persistent identifier (PID)** should be assigned to each dataset.

• Rich and **standardized metadata** should be present.

• **License** or **terms of use information** about the reuse of the data is available or can be determined on the dataset level.

• The repository provides broad, equitable and ideally **open infrastructure** to access content on the platform.

• The platform **ensures the preservation and continued availability** and access to the data and metadata entrusted to it by the users.

• Information about the **mission, scope, preservation policies and plans is available** and transparent.

https://www.kuleuven.be/rdm/en/guidance/data-sharing
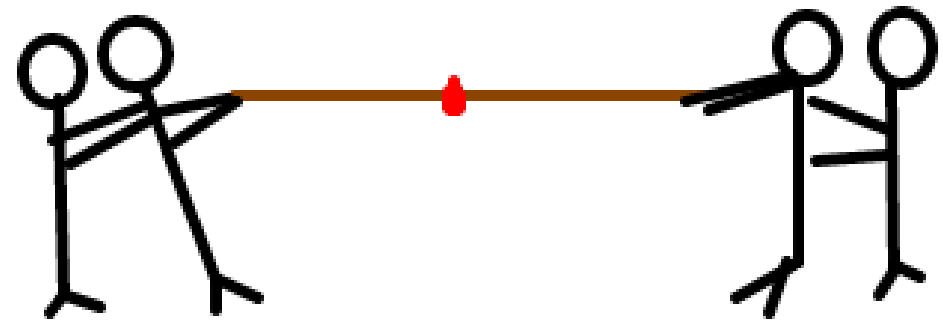
Sharing sensitive data in practice

- Maria is a researcher working with genomic data in Ugent, she does a Collaboration with Stewart, from the US

Cross-border data transfer

Movement of personal data to a country outside the European Economic Area (EEA)

Protection X Free movement

Non-EEA

Only allowed if the country or organisation can guarantee an "adequate level of protection" for the processing of personal data.

Who decides on adequacy levels? European Commision

Andorra, Argentina, Canada (commercial organisations), Faroe Islands, Guernsey, Israel, Isle of Man, Japan, Jersey, New Zealand, Republic of Korea, Switzerland , the United Kingdom under the GDPR and the LED, the United States (commercial organisations participating in the EU-US Data Privacy Framework) and Uruguay

https://commission.europa.eu/law/law-topic/data-protection/international-dimension-data-protection/adequacy-decisions_en

Ask help from your institution: DPO, TechTransfer, Legal team to assist and draw the legal documents

Thank you

VIB