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Introduction to GDPR in Pharma

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2 April 2019
Copenhagen, Denmark

Disclaimer

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Poll

Do you think that

Regulation (EU) 2016/679 Of The European Parliament And Of The Council of 27 April 2016
on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC

General Data Protection Regulation or (**"*GDPR*"**) is:

1) Good idea;
2) Bad idea;
3) Good idea, but badly implemented;
4) Bad idea, but good implemented;
5) I have no idea what are you talking about.

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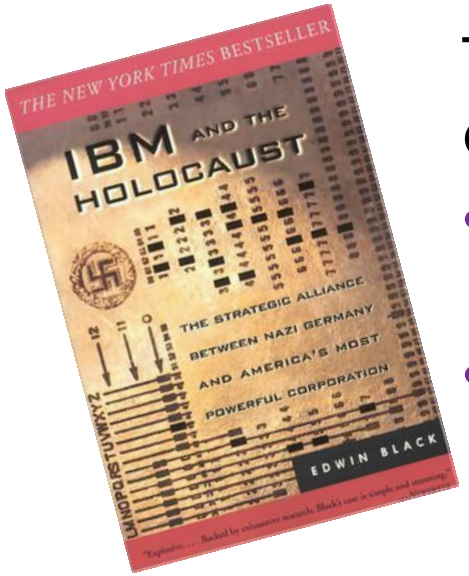
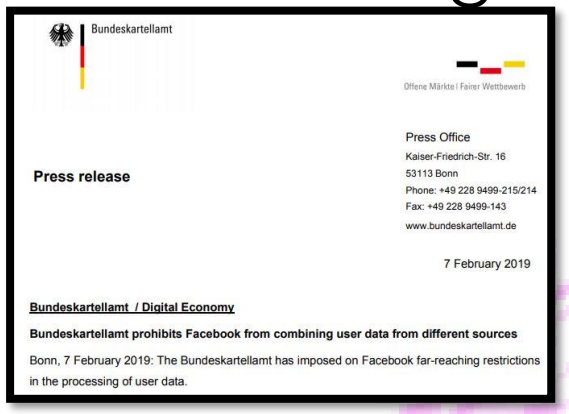
Raison d'etre for the GDPR



To prevent abuse of personal data, such as:

- Nationalities discrimination during World War II
- abuse of government power, particularly in respect to civil liberties, often specifically related to mass surveillance
- Recent cases of privacy abuse (Facebook, Google, e.a.)



Bundeskartellamt

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Press release

7 February 2019

Bundeskartellamt / Digital Economy

Bundeskartellamt prohibits Facebook from combining user data from different sources

Bonn, 7 February 2019: The Bundeskartellamt has imposed on Facebook far-reaching restrictions in the processing of user data.

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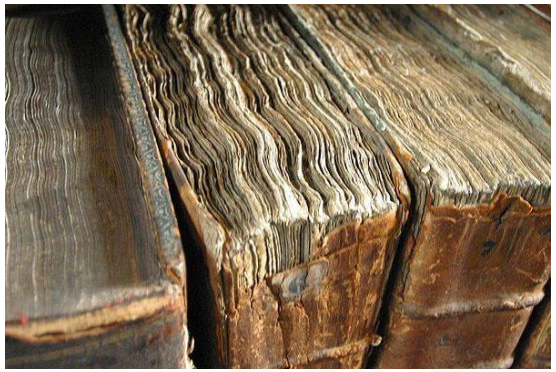
Goals of GDPR



- ✓ To ensure protection of the fundamental privacy rights
- ✓ To update the privacy laws (previous directive was issued more than 20 years ago); and
- ✓ To unify the 28 disparate privacy laws of the EU member states.

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GDPR: key boundaries

Source:https://upload.wikimedia.org/wikipedia/commons/1/11/European_Economic_Area_members.svg

- **Who**:

all companies processing the personal data of data subjects residing in the EEA have to comply

- **Where:**

European Union + EEA countries (Norway, Iceland, Lichtenstein)

- **When:**

effective date: EU countries- 25 May 2018,
EEA countries – 6 July 2018

- **If in breach:**

administrative fines up to 20 mln EUR, or up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher

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What is Personal Data?

"**Personal data**" means any information relating to an identified or identified natural person ("**Data subject**"); an identifiable natural person is one who can be identified, directly or indirectly[...](art.4 (1) GDPR).

Mobile device ID

Email address

Marital status

Job title

Signature

Attendance Records

Photographic and video images (CCTV)

Patient Data

Next of kin

Date of birth

Travel booking details

Healthcare Professional Profiles

Telephone number

Employee ID

Name

IP address

Smoking History

Staff

Vendors

Identification documents

Health Data

Patents

Medical history

Prescribing history

Dietary requirements

Nationality

Bank account details

Adverse effects

Biometrics

Genetic

Lifestyle factors

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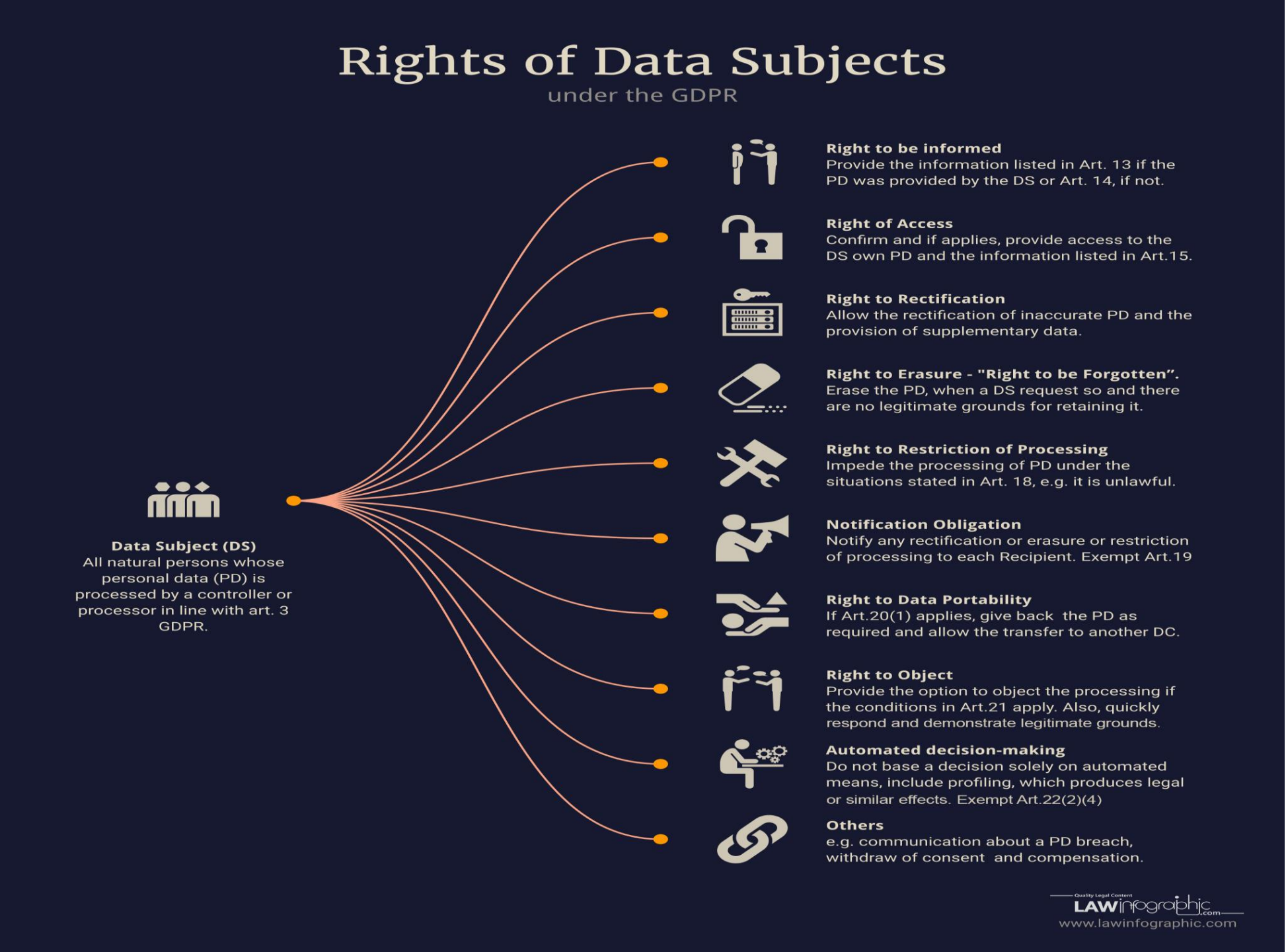
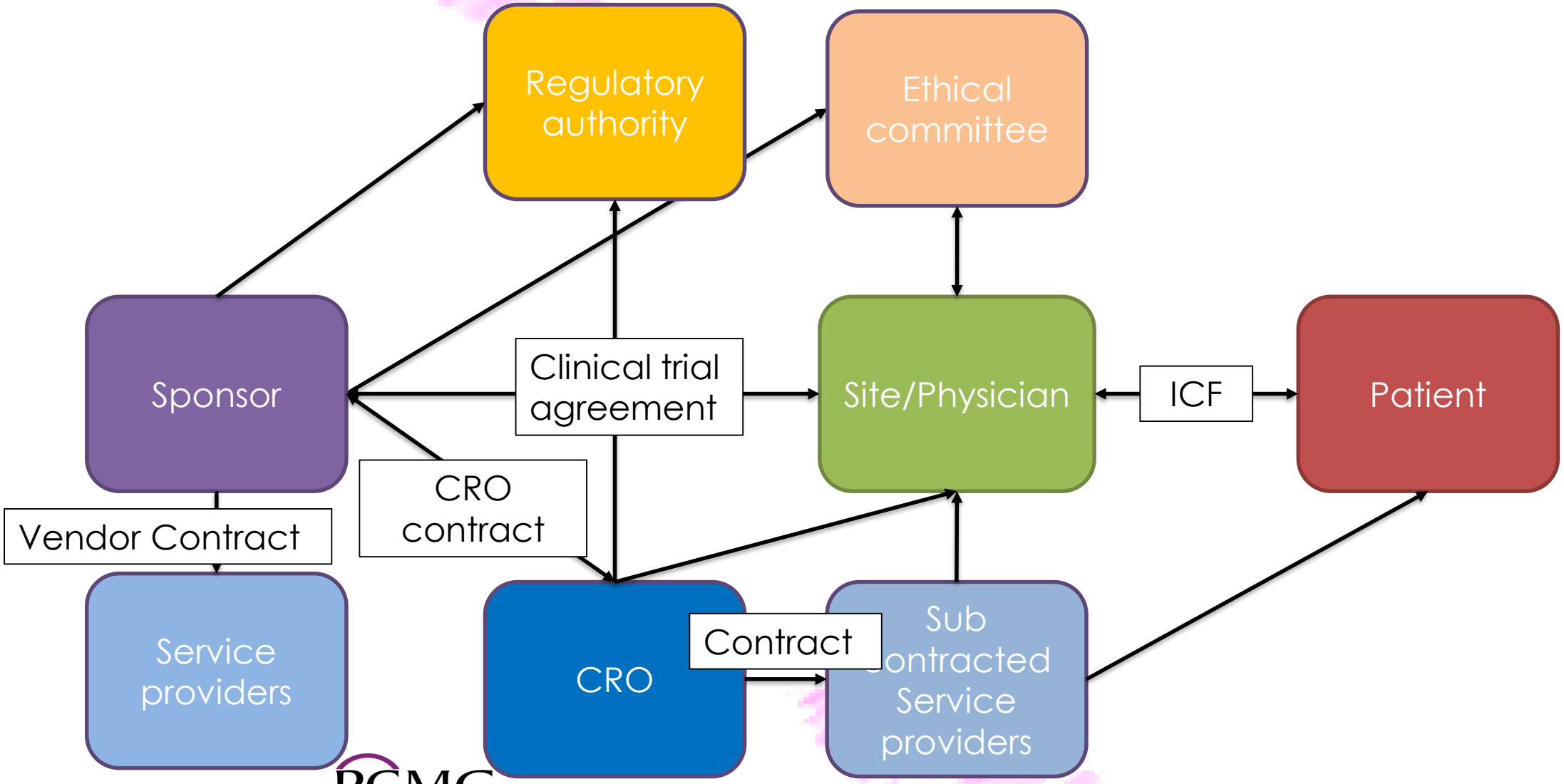


Source: http://www.lawinfographic.com/rights-data-subjects-gdpr/

Data flow in clinical trials



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Who is responsible: controller and processor

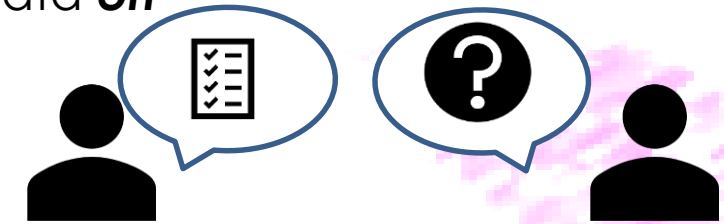
- Art.1 GDPR:

(8)"**controller**" means the natural or legal person, public authority, agency or other body which, alone or jointly with others, ***determines the purposes and means of the processing*** of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law;

(9)"**processor**" means a natural or legal person, public authority, agency or other body which processes personal data ***on behalf of*** the controller.

Where it becomes difficult:

- Sponsor vs Site
- Multiple sponsors
- Collaborative industry projects
- Real world evidence studies



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Risk management of outsourcing

Privacy by design:

- Role of Data Protection Officer;
- Conduct Data Privacy Assessment;
- Implementation of security measures;
- Know your sub-contractors;
- Appointment data protection representative;
- Communication and reporting obligations.

Source: https://www.slideshare.net/PECBCERTIFICATION/outsourcing-risk-management-59879323

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Source: https://work-work.no/keep-calm-and-gdpr/

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Backup slides

GDPR LAWFULNESS PERSONAL DATA PROCESSING

Legal grounds and lawful basis - processing lawful if at least one of legal bases below

Consent

The consent of a data subject to the processing of his/her personal data

Legitimate interests

There is a weighed & balanced legitimate interest where processing is needed and the interest is not overridden by others

Public interest

Public authorities and organizations in the scope of public duties and interest

Contractual necessity

Processing is needed in order to enter into or perform a contract

Legal obligations

The controller is obliged to process personal data for a legal obligation

Vital interests

It is vital that specific data are processed for matters of life and death

Source://www.i-scoop.eu/gdpr/legal-grounds-lawful-processing-personal-data/

Biological samples

- Recital 34 in the Regulation "Genetic data should be defined as personal data relating to the inherited or acquired genetic characteristics of a natural person **which result from the analysis of a biological sample** from the natural person in question, in particular chromosomal, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis, or from the analysis of another element enabling equivalent information to be obtained."

- Human tissue ≠ personal data?

- Scientific research of human tissue could be subject to national derogations introduced by Member State law.

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