

Robots need data

**Healthcare robots
need health data**

(and that is a problem in the
EU)

The kind of data

- Personal data: any information related to an identified or identifiable natural person (Article 4(1) GDPR)
- ‘Data concerning health’: personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status (Article 4(15) GDPR) –SENSITIVE DATA (Article 9 GDPR)

Legal grounds

Article 6(1) GDPR

Article 9(2) GDPR

The GDPR was made for the internet...

not for AI

The kind of technology

Can I use data that is... simple there?

Article 5(1)(b) GDPR- *‘Personal data shall be: collected for specified, explicit and legitimate purposes...’*

- Use of data collected by another player, for a different purpose

Exceptions to the principle of purpose limitation:

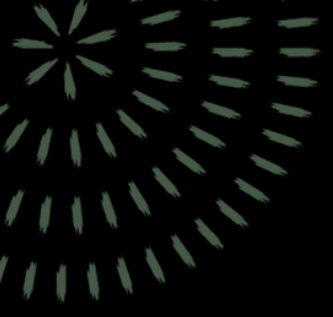
- ✓ Data subject's consent (Recital 50 and Art. 6(4) GDPR)
- ✓ Authorised by Union or Member State law (Recital 50 and Art. 6(4) GDPR)
- ✓ Research exception (Arts 5(1)(b) and 89(1) GDPR)

Compatibility test (Article 6(4) GDPR)

Article 5(1)(b) GDPR: '*Personal data shall be collected for specified, explicit and legitimate purposes and not further processed in a manner that is **incompatible** with those purposes...*'

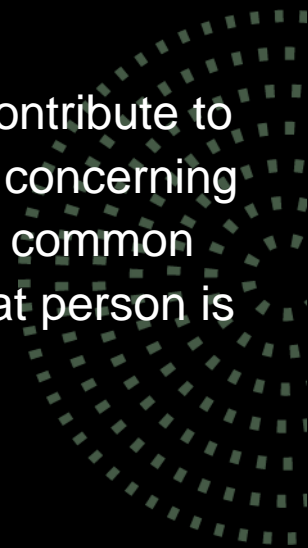
Recital 50 and Article 6(4) GDPR

- ✓ the distance between the new purpose and the original purpose
- ✓ the alignment of the new purpose with the data subjects' expectations,
- ✓ the nature of the data
- ✓ their impact on the data subjects' interests
- ✓ the safeguards adopted by the controller to ensure fair processing and prevent undue impacts



Personal data in a training set

Compatibility test


- Data misuse: the information about the person must be anonymised or deleted once the model is constructed.
 - Inferences about the group: contribute to enabling the system's inference concerning a group of people and affect the common interest of the group in which that person is included
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Personal data to personalize a medical robot

For AI personalization we need:

- To use lots of data about the individual
- To do some profiling (Article 22 GDPR) and individual inferences

Consent is a legal ground for data processing (Articles 6 and 9 GDPR)

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- Tricky
 - Complex
 - Uncertain
 - Bureaucratic
 - Lengthy
 - Expensive

The European Health Data Space (EHDS) based on the DGA

Harmonized framework for the legal groundwork for the secondary use of health data in the EU, which aims to ensure the free movement, sharing and reuse of electronic healthcare data for the benefit of patients, businesses, researchers and/or public administrations.

Key terms in the EHDS (Article 2)

- **Data holder:** ‘any natural or legal person, which is an entity or a body in the health or care sector, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law, or in the case of non-personal data, through control of the technical design of a product and related services, the **ability to make available, including to register, provide, restrict access or exchange certain data**’;
- **Data user:** ‘a natural or legal person **who has lawful access to personal or non-personal electronic health data for secondary use**’;
- **Personal electronic health data:** ‘**data concerning health and genetic data as defined in Regulation (EU) 2016/679, as well as data referring to determinants of health, or data processed in relation to the provision of healthcare services, processed in an electronic form**’

Article 34(1) of the Proposal on EHDS

- (f) and innovation activities for products or services contributing to public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices;
- (g) training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices;
- (h) providing personalised healthcare consisting in assessing, maintaining or restoring the state of health of natural persons, based on the health data of other natural persons.

EHDS and GDPR: The elephant in the room

Art. 6 GDPR

Art. 6(1)(c) (compliance with a legal obligation to which the controller is subject) for data holders to release the data

Arts. 6(1)(e) (public interest) or 6(1)(f) (legitimate interest) for data applicants (data users) to have access to the data

Art. 9 GDPR

Art. 9(2)(g) substantial public interest;

Art. 9(2)(h) individual treatments;

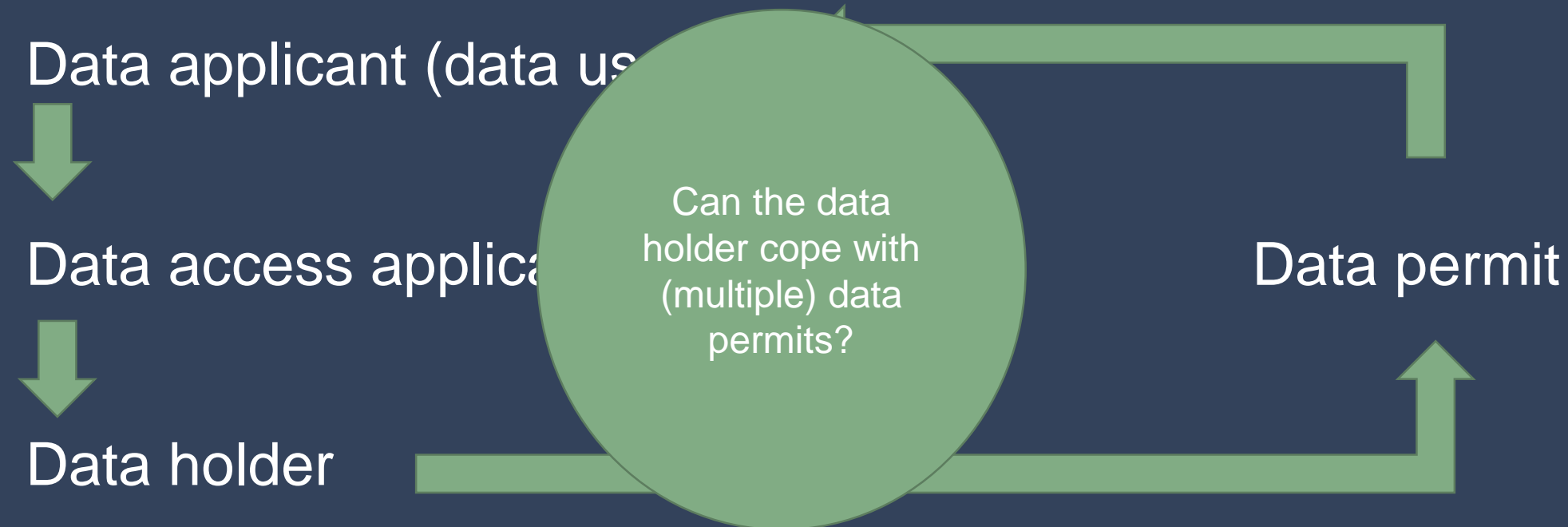
Art. 9(2)(i) public interest in public health;

Art. 9(2)(j) scientific research exemption.

Requirements for data access: Data protection by design and data security (Articles 44 and 45 EHDS)

- Data shall be provided in an anonymised format, unless the purposes of the processing cannot be achieved with anonymised data
- Pseudonymised data, but reidentification is forbidden.
- Data can only be accessed and processed in closed secure environments with clear standards for cyber security

Access to electronic health data from a single data holder (article 49 EHDS)



Now it gets complicated (Article 45-46 of the Proposal on the EHDA)

Data applicant (data user)



Data access application



National health data access bodies: *'support the development of AI systems, the training, testing and validating of AI systems and the development of harmonized standards and guidelines under Regulation [...] [AI Act COM/2021/206 final] for the training, testing and validation of AI systems in health'* (Art. 37(1)(i) Proposal on the EHDA).



Data permit



Data holder

How efficient will it be?

Risk-based approach (instead of the permit-based approach)

Self-assessment

Standards by the European Health Data Space Board



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