

Secondary use of Health Electronic Data

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Chapter 4 sets rules for the cross-border sharing, i.e. between the different Member States of the European Union, of health data for their secondary use.





Primary use of
electronic health data
MyHealth@EU



Secondary use of
electronic health data
HealthData@EU

Definition of *secondary use of electronic health data*

secondary use of electronic health data means the processing of electronic health data for purposes set out in Chapter IV of this Regulation. The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data collected for the purpose of the secondary use



Secondary use or reuse of electronic health data corresponds to the further processing of electronic health data initially collected for other purposes for



public statistics in the health sector



public interest health activities, such as protection against cross-border threats or public health surveillance;

scientific research relating to the health sectors


development and innovation activities for products or services contributing to public health or the safety of health care, medicines or medical devices or educational activities in the health sector.




The new regulation must provide a coherent and effective framework for the secondary use of health data for the purposes of research, innovation, policy development, official statistics, patient safety or activities. regulations.


Users of health data, namely researchers, innovators, policy makers and regulators, should benefit from a more efficient secondary use of health data.

Concrets Use Cases


1 

monitoring of antimicrobial resistance


mené par 

2 


identify the risks of bleeding disorders in Covid patients


mené par 

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH


3 

adherence to vaccination and testing among vulnerable people


mené par 

4 


project intended to anticipate the course of care in heart disease thanks to AI

mené par 

HEALTH DATA HUB

5 

identify genomic signatures in colorectal cancers

mené par 

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In France, the example of a national infrastructure for sharing health data for secondary use is the “Health Data Hub”.



At European level, no common infrastructure project for cross-border sharing of health data for secondary use has yet been deployed. In July 2022, a consortium led by the Health Data Hub was commissioned by the European Commission to prefigure such an infrastructure and its operating methods.

It is mandatory to submit electronic data
even data of private operators protected by
trade secret and IP rights.

Specify the authorized purposes

Development of public policies



Research



AI for innovation and development of health products.



Provide for prohibited purposes



Any discriminatory practice against persons

Any purpose of commercial advertising or insurance



Any development of hazardous products

Set up organizations to access data for secondary use (art 36)



- Create an health data access body
- Cooperate with stakeholders : representatives of patients/data holders/data users

Set the missions and obligations of these organizations (Art.37, 38, 39)

in particular to decide on access requests and process data for their provision;

Specify the modalities for implementing the notion of altruism of health data (Art.40)

- Voluntary sharing of data based on the consent of data subjects or the authorization granted by data holders;
- without receiving compensation that goes beyond compensation for the costs incurred for the provision of the data
- for purposes of general interest.



Set the missions and obligations of data holders and users (Art.41)

- Cooperation in good faith
- General description of the database
- Disposal of the health data base access body within 2 months
- Update of the HDB

Provide a transparency framework and the methods for calculating royalties (Art.42)



1. Issues from the data governance regulation

2. Taking into account the costs related to the processing of the request

3, And can take into account the costs of human and technical resources used to enrich electronic health data.



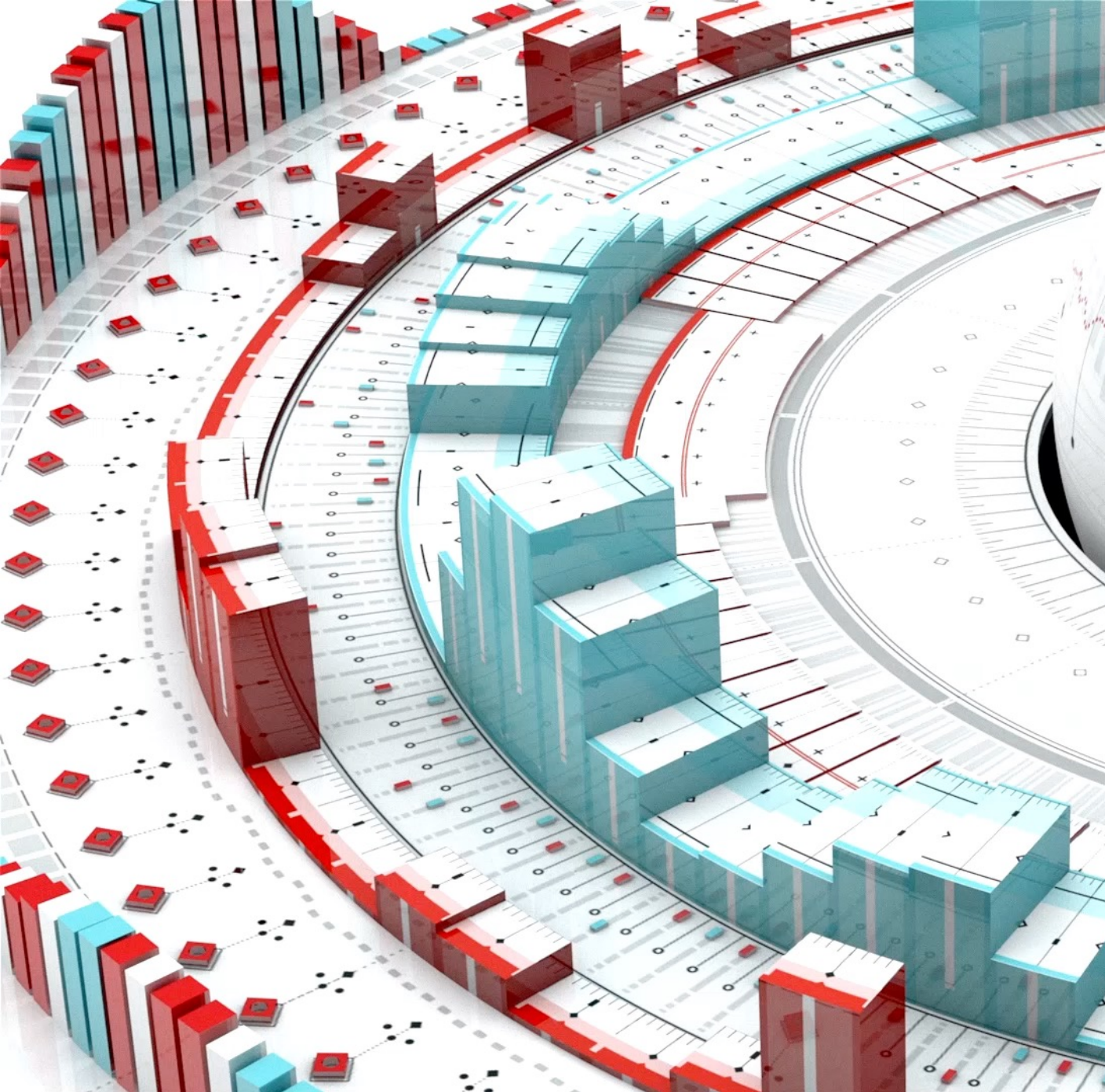
Specify the sanctioning power of data access organizations (Art.43)

- To revoke the data permit
- To exclude the data user from any access of the HDB for a periode of up to 5 years
- Fines established by the health data access body



Set the criteria for granting a permit for the secondary use of data including in particular commitments on data minimization, access to data, secure processing environment including access to data for public and European institutions (Art. .44–51);

Ex . When the purpose can be achieved with anonymised data = health data body provide data in pseudonymised format



Describe the development of the new decentralized infrastructure for secondary use HealthData@EU (Art.52)

- National contact point for secondary use of HDB
- List of authorised participants of HealthData@EU
- Participation of third countries or international organisations
- Criteria for the platform, the secure processing ..



Specify the procedures for setting up cross-border access to data (Art.53, 54)

- Organise the cross border registries and data base
- Case of single network of registries or data bases
- Mutual recognition



Provide the modalities for describing the datasets and their quality for the establishment of the catalog of EU datasets (Art.55, 56, 57)



**Focus of reuse
from data private
operators
protected by
trade secret and
IP rights.**

1 Preserve intellectual property and company trade secrets

Favor the provision of data on a voluntary basis



provide effective safeguards for the protection of industrial property rights and trade secrets

Provide an adapted economic model



Take into account the specificities of clinical trials

lay down the conditions for the reuse of data in an agreement



consult data holders on reuse projects



2 . Secure the management of personal data

Clarify the role of actors within the GDPR



Indicate the possible legal bases in the context of the reuse of data



provide the methods of informing the persons concerned by the re-use of their data

3. Ensure a unified system within the EU

Precisely establish the rules for granting data access authorizations



Do not open the way to national derogations

