SEMINAR

HEALTH RESEARCH: EUROPEAN HEALTH DATA SPACE CHALLENGES

Wednesday, 16th November 2022, 9:30 to 14:30 CEST

Representation in Spain of European Commission

Organize

Càtedra Microsoft
Universitat de València
Privacitat &
Transformació Digital

Goals and impact

1. European Union healthcare research environment.

Our countries are looking for the foundations for a functional model that enhances research and the use of data for the common good in the field of health and biomedical research. In this regard, the director of the Chair has collaborated with core initiatives leaded by our regional healthcare system hospitals.

Furthermore, over the last years research on COVID-19 has shown the importance of using the data for the common good. In addition, the European debate on mobile applications has highlighted the essential value of data from sources outside the healthcare system, such as location and mobility data, Smart Cities, Smart Houses and many other sensors that are essential for population-based and predictive medicine.

Finally, the provision of data protection compliance requirements in health research projects is a highly demanding challenge. At this regard, the European Data Protection Supervisor published the document "A Preliminary Opinion on data protection and scientific research". This document shows that there are no corresponding data protection laws in the various countries, due to several factors:

- The Regulation leaves part of the legislative development to the Member States.
- Legislative asymmetries may exist and these also occur in the criteria provided by national data protection authorities.
- In healthcare research the requirements for data processing with consent, pseudonymisation and anonymisation are higher than in other areas.
- Projects that apply data analytics and artificial intelligence techniques must be guided by constantly evolving ethical principles.

Certain common patterns could be identified:

1. Most national laws facilitate retrospective research with data by providing exceptions to the patient consent rule and certain facilitations to comply with the transparency duties.
2. Regulations are stricter and more demanding for prospective research with data that usually requires patient consent.
3. The position of data protection authorities makes it literally impossible to generate open data environments that do not meet specific characteristics. The reason for this lies in the fact that while recital (26) of the GDPR defines anonymization as a process that results in no third party being able to re-identify with "reasonable effort", data protection authorities require an "irreversible anonymization equivalent to erasure" that should consider future technological risks.

4. Only Spain (Additional Provision XVII of LO 3/2018) has defined a technique with controlled environments, provided with security and traceability.

2. Common European Data Spaces[1]

The European strategy for data aims at creating a single market for data that will ensure Europe's global competitiveness and data sovereignty.

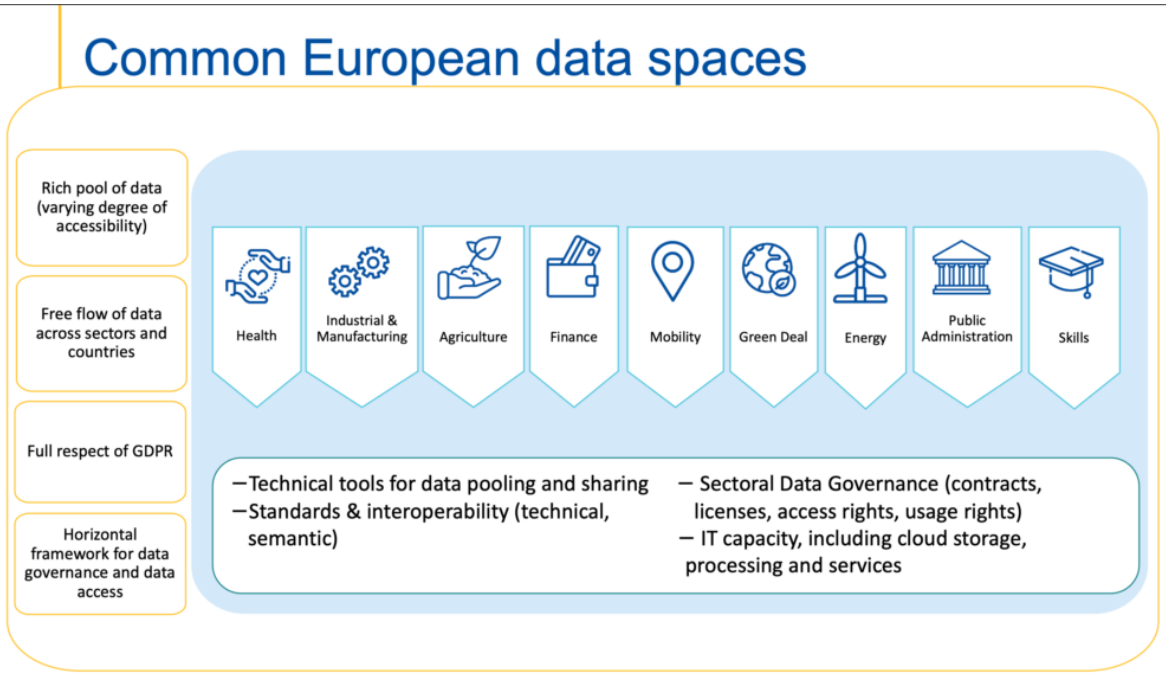

Figure 1. Common European Data Spaces. Source: European Commission.

The European Health Data Space proposes in our view several key challenges:

1. To form an interoperability framework that ensures appropriate use of health data for primary purposes and facilitates the necessary and functional health care services to a European area without borders.
2. To promote a broad list of uses for secondary data.
3. To have a strong impact on all actors involved by promoting rights as well as processing opportunities.
4. Ensure effective control over data subjects' data and provide certainty and guarantees of their rights.
5. Encourage the involvement of data holders and data intermediaries in the development of reusable datasets,

[1] See http://dataspaces.info/common-european-data-spaces/#page-content

6. Promote the creation of secure and traceable environment for the use of health data.

3. Action

The Chair is committed to spread the use of big data and artificial intelligence techniques in the health sector will improve the prevention, diagnosis, and treatment of diseases. At the same time, these technologies enable the optimization of processes to reduce healthcare times and costs thus contributing to the sustainability of health systems in Europe. Therefore, it is expected to produce academic content and possible follow-up seminars around the issue.

This seminar aims to discuss the requirements for healthcare research repositories. This event should include experts from all the sectors involved and, above all, researchers, governments, and data protection authorities. The profile of the experts should include the areas of privacy, artificial intelligence, security, data science, ethics, and governance, among others. Within this framework, a seminar is designed with the following objectives 1:

1. To define the requirements that data lakes for health research should meet, considering, the current legislation and the developing framework.

2. To reflect on the strategic definition of data governance frameworks.

3. To consider the state of progress of the European standards proposed by the Commission.

The reference framework in this area is made up of:

Area	Law	State
Open data	Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information	In force
	Regulation (EU) 2018/1807 of the European Parliament and of the Council of 14 November 2018 on a framework for the free flow of non-personal data in the European Union	In force
Data Governance	Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act)	In force
	Proposal for a Regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act)	L. Procedure
Research	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space	L. Procedure

Artificial Intelligence	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS	L. Procedure
e-Health technology	Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU	In force
	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.)	In force
Healthcare Services	Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare	In force
Security & Interoperability	Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format (Text with EEA relevance.)	In force
	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on horizontal cybersecurity requirements for products with digital elements and amending Regulation (EU) 2019/1020	L. Procedure
Digital identity verification	Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC	In force

Table 1. Present and future legal frameworks.

Event

Date

Wednesday, 16th November 2022, 9:30 to 14:30 CEST

Location

Sede de la Representación en España de la Comisión Europea, Sala Europa

Paseo de la Castellana, 46, E-28046, Madrid, España [Maps]

+34 91 423 80 00

ec.europa.eu/spain

Registration

The seminar is going to be organized as a hybrid event (physical and virtual participation). All sessions will have simultaneous English-Spanish translation.

Participation is free of charge.

For attendees who want to participate on site please register here esdeveniments.uv.es/go/Health-Research-2022-Seminar

There is a limited capacity of seats available on site (max. 100). If this number is reached, you might be asked to participate remotely.

Website https://www.uv.es/microsoft-chair/en/conferences-health-research/2022-conference/introduction.html

Speaker profiles
Legal experts, representatives of data protection authorities.

Program

9:30 Opening session

- Joaquín Aldás-Manzano, Vice-Principal for Planning, Quality and Information Technologies, Universitat de València.

- Ms. Mar España Martí, Director of the Spanish Data Protection Agency.

- Ms. Elena M. Grimme, General Manager and Associate General Counsel, Western Europe, Microsoft.

10:00 The future of healthcare research: An overview on governance and requirements

- Dr. Ricard Martínez Martínez, Director of the Privacy and Digital Transformation chair.

10:45 European Health Data Space requirements: Building data repositories (the researchers point of view)

- Dr. Enrique Bernal-Delgado, Senior Scientist. Head of the Data Science for Health Services and Policy Research Group Institute for Health Sciences.

- Dr. Luís Marti Bonmati, Head of the medical imaging department of Instituto de Investigación Universitaria La Fe and chairs the CHAIMELEON consortium.

Coffee Break

11:30 European Health Data Space requirements: Security and interoperability

- Mr. Miguel Ángel Benito Tovar, representative of the Sociedad Española de Informática de la Salud representative and Data Protection Officer of the Balearic Islands Regional Healthcare System.

12:00 European Health Data Space requirements: Ethics

- Dr. Federico de Montalvo Jaaskelainen, Director of the Centre for Innovation in Law (CID-ICADE) and former President of the Spanish Bioethics Committee.

12:30 European Health Data Space requirements: And data protection

- Ms. Magdalena Kogut–Czarkowska, Attorney-at-law at TIMELEX and ELSI Group Member.

- Mr. Jesús Rubí Navarrete, Head of the Institutional Relations of the Spanish Data Protection Agency.

- Mr. Leonardo Cervera Navas, Director at European Data Protection Supervisor (EDPS).

13:30 European Health Data Space: Digital transformation and common good opportunities

- Mr. Andrea Pescino, Member of Microsoft European Cloud in Health Advisory Council.

- Mr. Gabriel Lopez Serrano, Government Affairs Director Microsoft Iberica.

14:15 Closing Session

14:30 Lunch

Seminar

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