Universidad del País Vasco Euskal Herriko Unibertsitatea

RED CÁTEDRA DERECHO & GENOMA HUMANO

SECONDARY USE OF GENETIC DATA IN THE EHDS: IS THERE A WAY TO AVOID THE MISTAKES OF THE GDPR?

1st Interuniversity Workshop of Researchers in Biolaw (UPV/EHU – UniTrento)

Leioa

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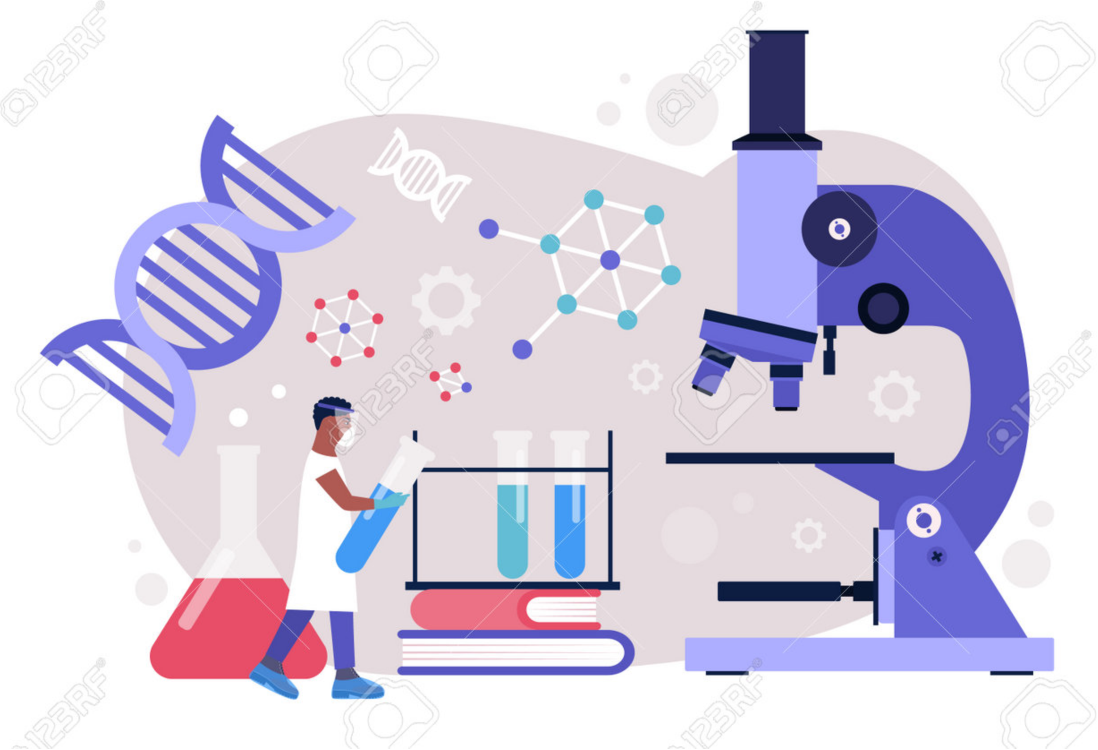
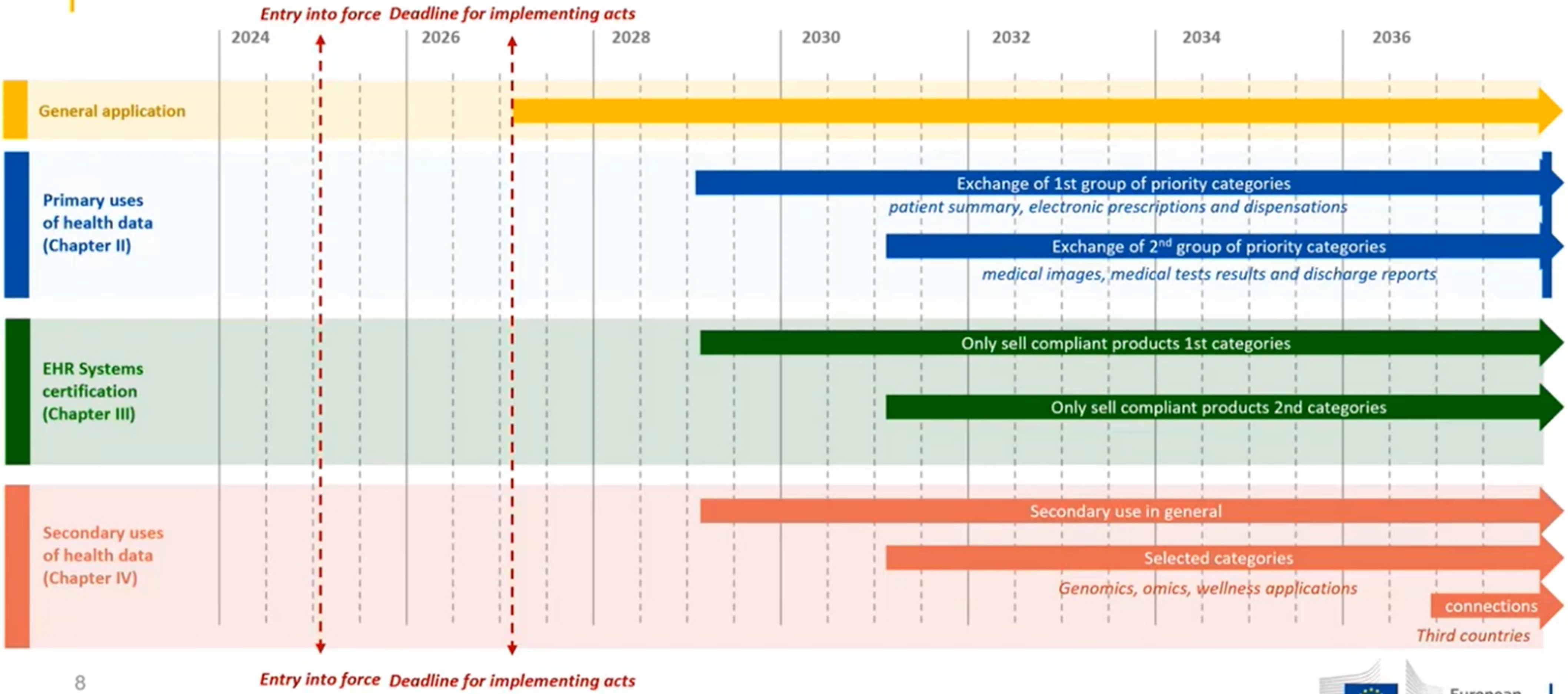
Some context on the secondary use of data in the EHDS



Implementation of the EHDS Regulation

Timelines are indicative.



Entry into force *Deadline for implementing acts*

2024 2026 2028 2030 2032 2034 2036

General application

Primary uses of health data (Chapter II)

Exchange of 1st group of priority categories

patient summary, electronic prescriptions and dispensations

Exchange of 2nd group of priority categories

medical images, medical tests results and discharge reports

EHR Systems certification (Chapter III)

Only sell compliant products 1st categories

Only sell compliant products 2nd categories

Secondary uses of health data (Chapter IV)

Secondary use in general

Selected categories

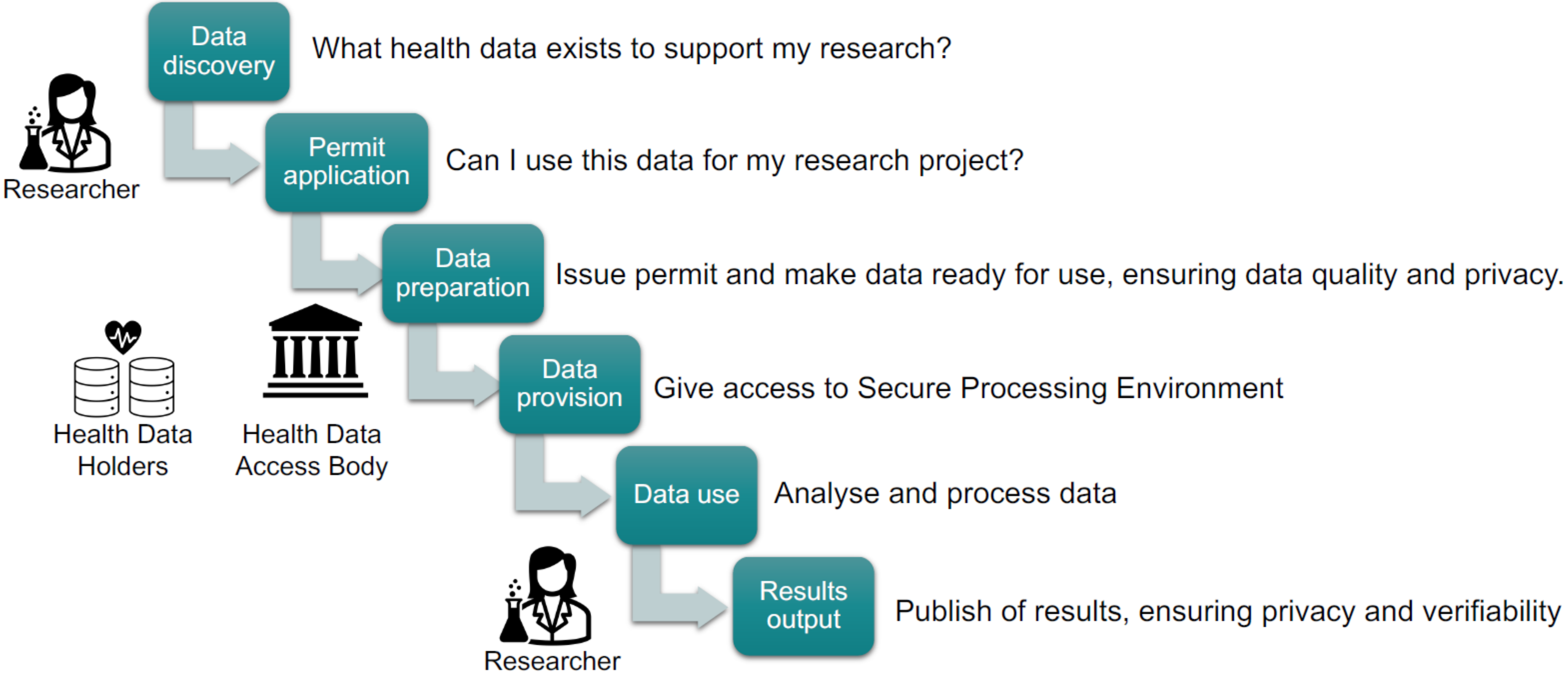
Genomics, omics, wellness applications

connections

Third countries

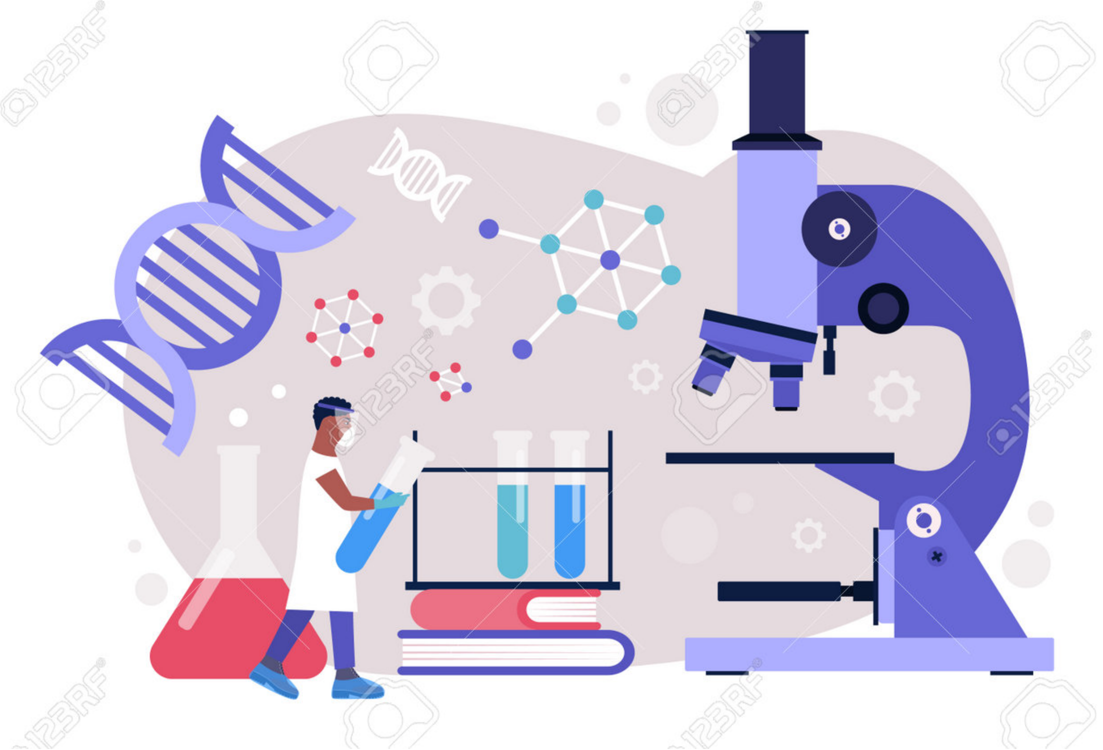
Entry into force *Deadline for implementing acts*

Overview of a generic data access approval process



Data discovery	What health data exists to support my research?
Permit application	Can I use this data for my research project?
Data preparation	Issue permit and make data ready for use, ensuring data quality and privacy.
Data provision	Give access to Secure Processing Environment
Data use	Analyse and process data
Results output	Publish of results, ensuring privacy and verifiability

The emergence of the problem in the legislative procedure



Genetic data in the EHDS

EU legislators are happy with the GDPR's definition

- **Art. 2(1)(a) EHDS** the definitions of (…) 'genetic data' laid down in Article 4, points (…), (15) (…), respectively, of Regulation (EU) 2016/679;
- **Art. 4(13) GDPR**: 'genetic data' means personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question;

Genetic data appeared to be like other kinds of personal electronic health data in the initial proposal but… not anymore

- Discussions on the particular status of genetic data opened the door to consider stricter measures for secondary use.

Against opt-in for the sharing of human genetic, genomic, and proteomic data

The integration of genetic data into clinical practices is increasingly commonplace, particularly in areas such as oncology and rare disease diagnosis.

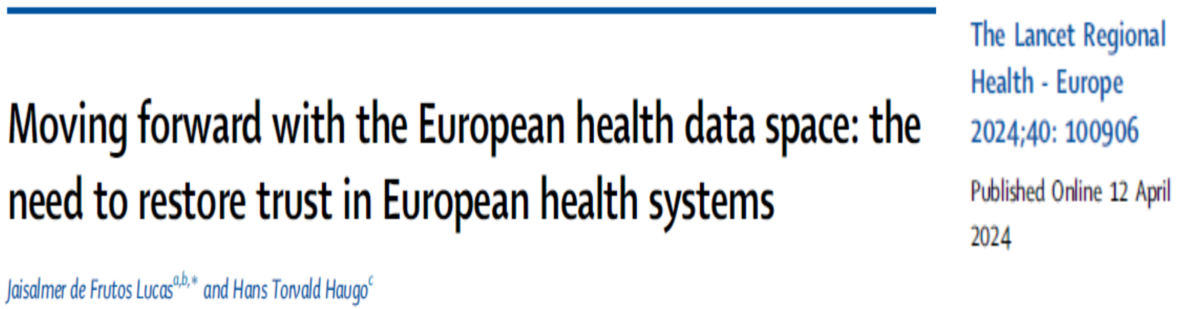
An opt-in requirement will negatively affect the use of such data in research and will prevent patients, **particularly those with rare diseases, from obtaining the significant benefits that may result from it**.

The decision to differentiate genomic data from other electronic health record information is not only **arbitrary** but also poses the **risk of unfairly disadvantaging genomic medicine diagnostics and research**.

Serious and negative impact on work to develop **personalised treatments and cures**, particularly in rare diseases **where international collaboration and data-sharing are the only way forward**.

ESHG

The European Society
of Human Genetics



The Lancet Regional Health - Europe
2024;40: 100906
Published Online 12 April 2024

Moving forward with the European health data space: the need to restore trust in European health systems

Jaisalmer de Frutos Lucas[a,b,*] and Hans Torvald Haugo[c]

Genetic = more sensitive?

1. The level of constraint to fully **deidentify** health data
2. Linked to **stigma and risk of discrimination** or victimization

- Other kinds of health data also seem to be as sensitive as genetic data
- **Opt-in**: The burden of responsibility should not be simply transferred from the institutions to patients
- **Transparency, security and equity should be at the bases of the design of the EHDS** and at the core of the current conversations. Empowering citizens goes beyond enabling consent

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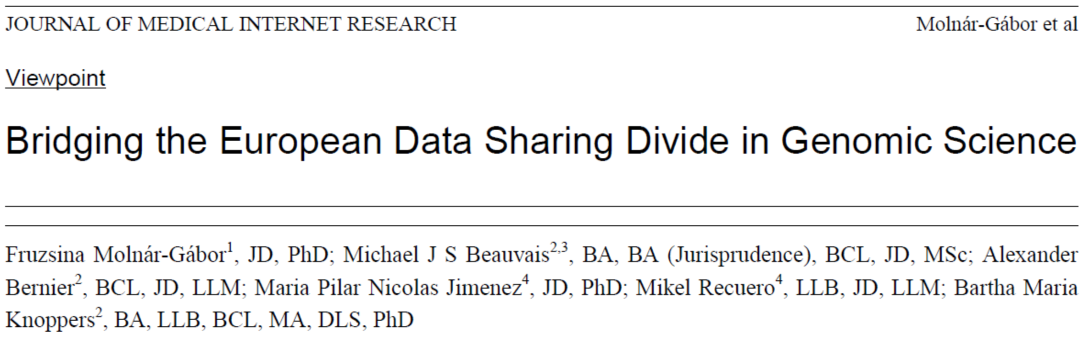


JOURNAL OF MEDICAL INTERNET RESEARCH Molnár-Gábor et al

Viewpoint

Bridging the European Data Sharing Divide in Genomic Science

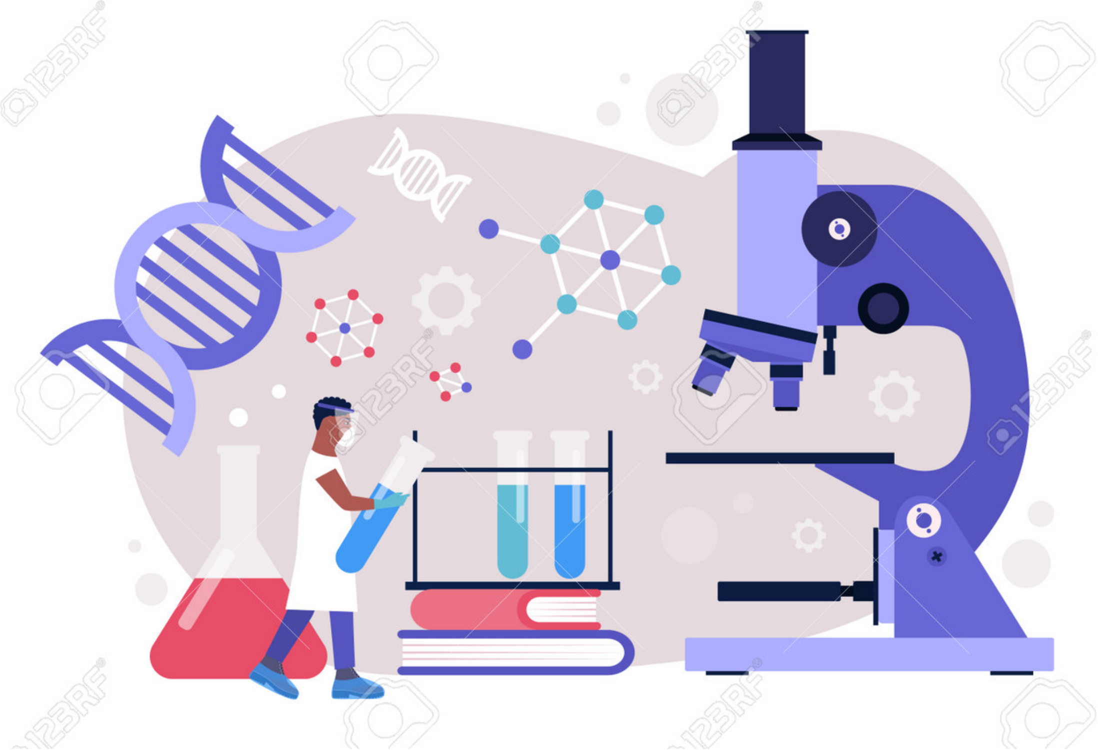
Fruzsina Molnár-Gábor[1], JD, PhD; Michael J S Beauvais[2,3], BA, BA (Jurisprudence), BCL, JD, MSc; Alexander Bernier[2], BCL, JD, LLM; Maria Pilar Nicolas Jimenez[4], JD, PhD; Mikel Recuero[4], LLB, JD, LLM; Bartha Maria Knoppers[2], BA, LLB, BCL, MA, DLS, PhD

In summary, the legislation creating **the EHDS "reprises" (amplifies?) numerous restrictive and limitative elements of the GDPR** that will continue to impede the potential to make plentiful use of data for genomic research supporting health research and care.

Among the proposed **ways of improving the EHDS**:

- Acknowledge its security and organization as data sharing that is adequate for the genomic sector
- Foster public interest in genomic science through participation, information, and transparency

The worst possible outcome?



The return to the spirit of Art. 9(4) GDPR

Recital 52 EHDS: (…) Consequently, Member States should **no longer be able to maintain or introduce under Article 9(4)** of Regulation (EU) 2016/679 further conditions, **including limitations and specific provisions requesting the consent of natural persons**, with regard to the processing for secondary use of personal electronic health data under this Regulation, **with the exception of the introduction of stricter measures and additional safeguards at national level aimed at safeguarding the sensitivity and value of certain data as laid down in this Regulation**.

Article 51(4)

Member States may introduce **stricter measures and additional safeguards at national level aimed at safeguarding the sensitivity and value of the data that fall under paragraph 1, points (f), (g), (i) and (q)**. Member States shall notify the Commission of those measures and safeguards and, without delay, of any subsequent amendment affecting them.

Article 51(1)

(f) human genetic, epigenomic and genomic data;

(g) other human molecular data such as proteomic, transcriptomic, metabolomic, lipidomic and other omic data;

(q) health data from biobanks and associated databases.

The questions and the risks

- Member States adopting the opt-in (or other stricter measures) vs. Member States maintaining the opt-out (and the rest of the EHDS measures): **A two-speed Europe on genetic data sharing?**

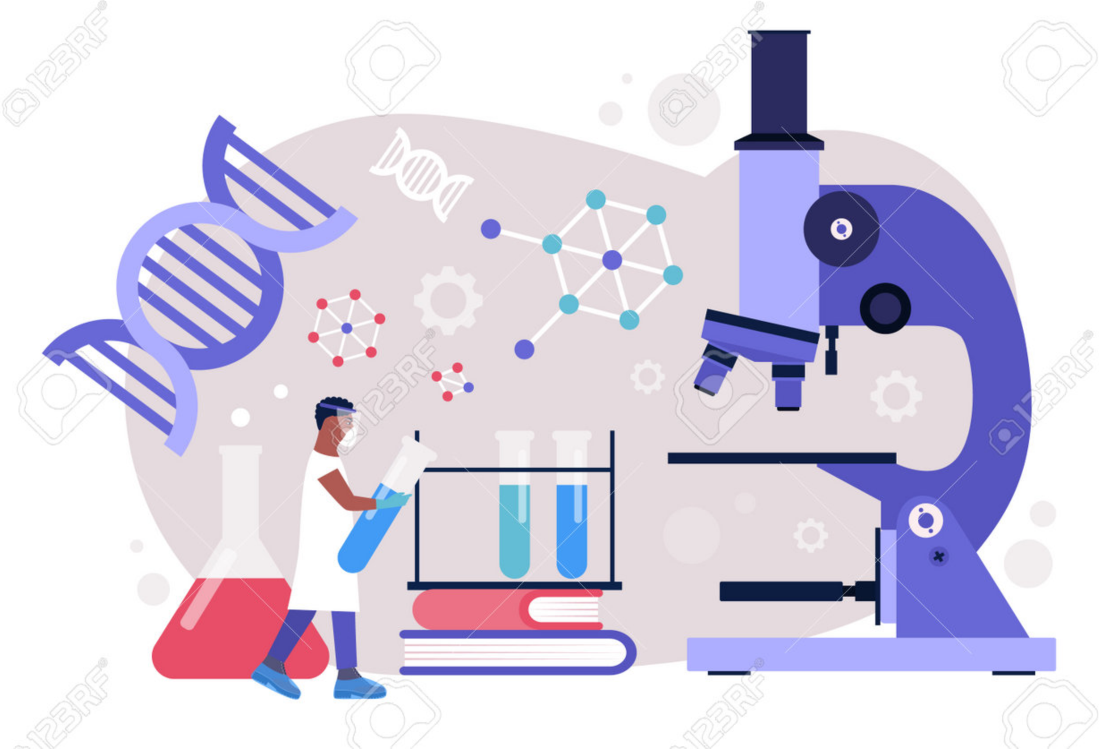
- The risk of infection: **Will I openly share my data with you, if you don’t allow me to do so?**

- **Will the EHDS become an alternative route, but not the main highway for genomic research?** For instance, this is not what is planned for the 1+MG initiative.

What is the point?

- **The economic rationale**. Genetic research discriminated compared to other areas of research. What about all the money invested?
- **The scientific rationale.** The literature indicates that representativeness is significantly different in opt-out vs. opt-in. It carries a risk of bias, as well as under-representation of populations most in need (rare diseases).
- **The patients' rights protection rationale.** Autonomy is already there as opt-out. If indeed the sharing of genetic data generates risks not adequately foreseen in the EHDS and we require stricter measures, are we going to leave it up to individuals (opt-in)?

A comparative exercise: secondary use of genetic data in the Member States



How is it already regulated secondary use of genetic data in the different Member States: Spain

Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales:

Disposición Adicional 17ª.2

The possibilities:

(1) Broad consent (1ary)

(2) Healthcare authorities for public health reasons under exceptional circumstances

(3) Reuse of consent for related areas -2dary-

(4) 2dary use of pseudonymised data

The measures (4):

- Strict pseudonymization
- Data protection impact assessment
- Subject scientific research to appropriate quality standards
- Designate a legal representative established in the EU
- Prior approval of the research ethics committee provided for in the sectoral regulations

How is it already regulated secondary use of genetic data in the different Member States: Italy*

Codice della Privacy Decreto Legislativo n. 196/2003

Articoli 110 + 110bis (2024)

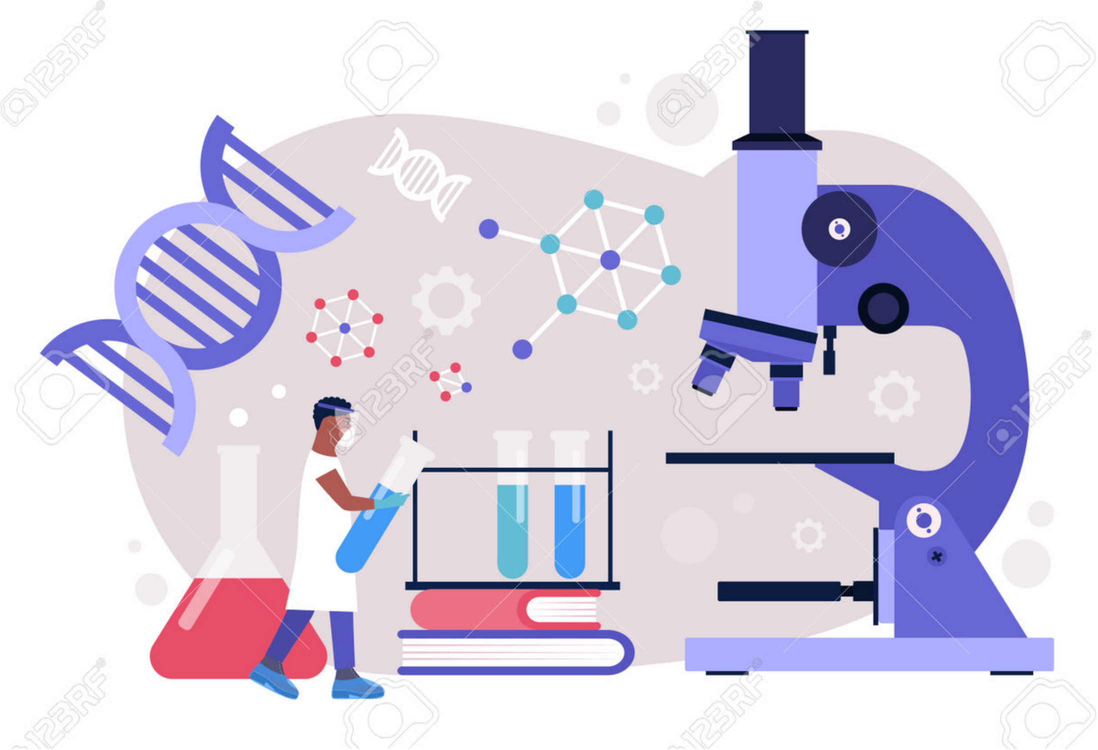
*Acknowledgements: Francesca Gennari & Andrea Parziale

The possibilities:	**The measures:**
(1) Consent is not necessary due to a EU or national law implementing Art. 9(2)(j) GDPR (e.g.: Art.110 bis (4) for the IRCSS)	(1) Each law regulates its own measures + public DPIA
(2.1) Contexts where consent is not «possible» (same controller)	(2.1) Justification + appropriate measures + REC assessment
(2.2) Consent is not possible + third party	(2.2) Justification + appropriate measures + Authorisation by the Garante
(3) Secondary use allowed by the Garante in a provvedimenti generali published in the Gazzetta Ufficiale	(3) Specific categories of data controllers and processing operations + specific measures in the provvedimenti

Results of the comparative analysis

- While Spain has a general regulation for secondary use of data without consent, Italy is more restrictive.
- In both cases secondary use requires the adoption of measures to safeguard the rights of data subjects.
- The regulations **do not introduce specific measures in relation to secondary use of genetic data** (although they both do have particularities in relation to primary use).
- **What should we expect from them?**

So now… What do we do? Looking for a constructive approach



What should Member States do?

Avoid opt-in

If further measures are deemed necessary:

1. As compatible as possible with the governance structure of the EHDS
2. Cooperative efforts should be made between Member States

Muchas gracias, Eskerrik asko.

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