sciensano

healthy all life long

Embedding opt-out in a democratic EHDS: rights first, trust through engagement

24th March 2026,

Online Conference: 3th International Conference EHDS 2026.

Secondary use of data and the subject rights

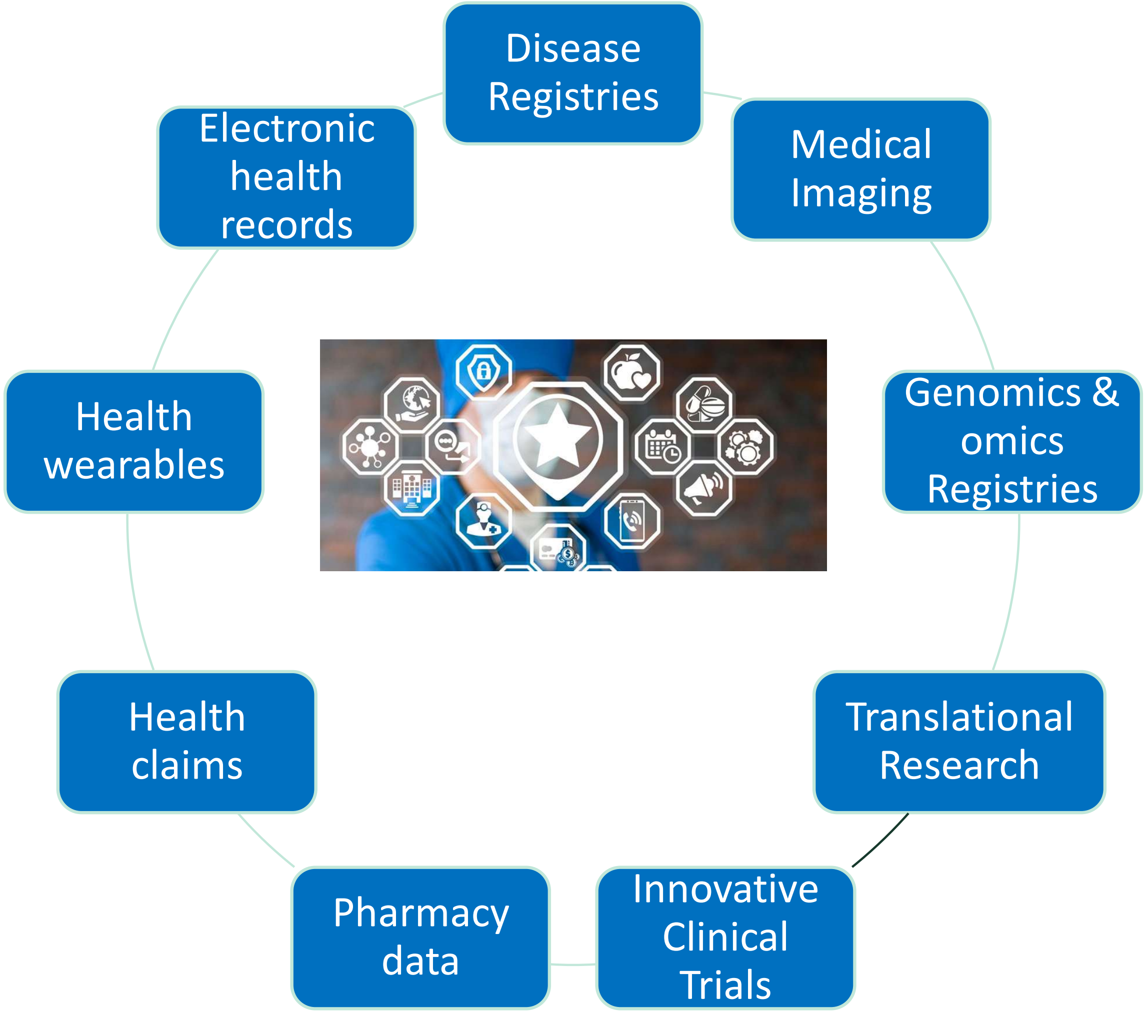
Roxana Albu,

Wannes Van Hoof,

Sciensano, ELSI team, Data Governance Directorate, Belgium

.be

1 single patient = 1 million gigabytes of health related data in their lifetime



Disease Registries

Medical Imaging

Genomics & omics Registries

Translational Research

Innovative Clinical Trials

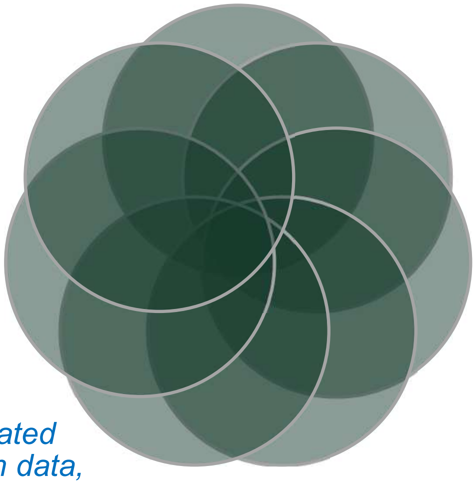
Pharmacy data

Health claims

Health wearables

Electronic health records

Minimum Categories of EHD to be made Available (Art. 51)



Electronic health records

Data impacting on health, including social, environmental behavioural determinants of health

Health-related administrative data, including claims and reimbursement data

Human genetic, genomic and proteomic data

Person generated electronic health data, including medical devices, wellness applications or other digital health applications

Population wide health data registries

Electronic health data from clinical trials

Secondary Use of Electronic Health Data: Unlocking Health Data for the Public Good (Art. 53)

Why it matters:

- **Protect public health** (combat cross-border health threats & enhance patient safety)
- **Empower policy & regulation** (support evidence-based decisions across EU institutions)
- **Drive health statistics** (enable robust national & EU-level health insights)
- **Advance education** (train future health professionals with real-world data)
- **Fuel research & innovation** (boost development of safer treatments, AI tools & medical devices)
- **Improve care delivery** (optimize treatments & healthcare systems for all)

Operationalising Opt-Out for Secondary Health-Data Use

- **Direct EHDS right:** individuals may opt-out of secondary use without given reason
- **Individuals can say no:** to your health data being used *(research, innovation, AI training, policymaking)*
- **Effect:** data excluded from new permits/requests after opt-out date
- The choice is **reversible:** you can change your mind
- **Not impacted** public health reporting duties (e.g. notifiable diseases, adverse reactions)
- Primary care opt-out ≠ secondary use opt-out

Role of Health Data Access Bodies:

- Clearly inform citizens of their opt-out rights = **Informed choice & Public trust (Element of suprise!)**
- HDABs shall provide public info on:

Legal basis for data access

Safeguards protecting personal data

Who accessed which datasets and why

Outcomes of secondary use (e.g. research results)

Citizens must be empowered with full, accessible & understandable information

«Member States shall provide for an accessible and easily understandable opt-out mechanism… »
EHDS Art. 71(2)

Transparency is not optional = it's a legal obligation

« Health data access bodies shall make information… publicly available, easily searchable… and accessible for natural persons. »

EHDS Art. 58(1)

Opt-out in the EHDS: exceptions (<u>all</u> conditions met)

Public sector body / office/agency mandated to carry public tasks

Emerging health threats/ Research Public Health Tasks / Interest

Process is Necessary & Purposeful & Justified

Data cannot be obtained by alternative means (timely & effectively)

MANDATORY:

Includes secure environment & no re-identification

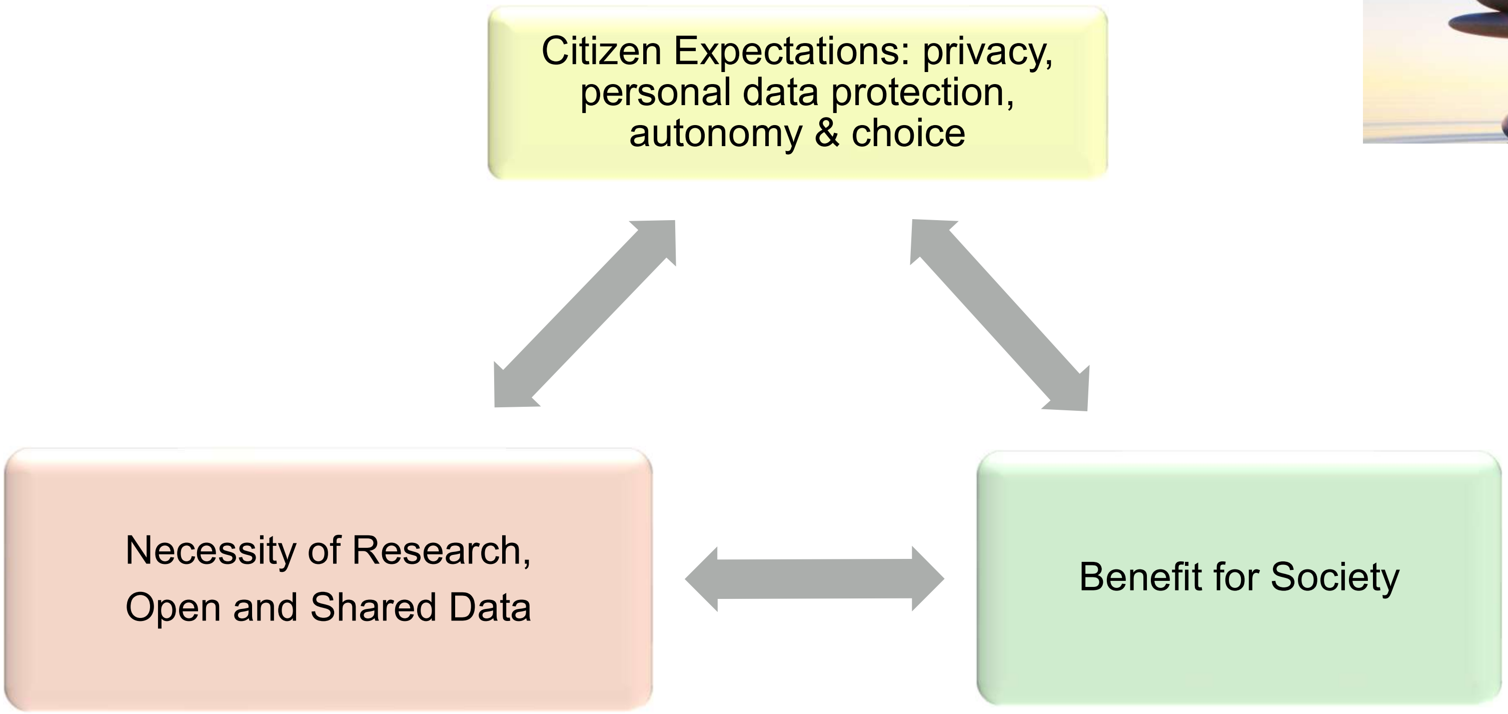
National law only

Law enforcement excluded from EHDS secondary use

In a Nutshell: What it Means for You as a Citizen

- ☐ Primary care opt-out ≠ secondary use opt-out
- ☐ You can **say no** to your health data being used *(research, innovation, AI training, policymaking)*
- ☐ The choice is **reversible**: you can change your mind
- ☐ Once opted out, **future projects** cannot use your data
- ☐ **Past projects** (already approved) may still use it
- ☐ In emergencies, doctors may still need access.
- ☐ For the public good, some data may be used despite opt-out: **mind the national law**

Opt-Out in the EHDS: balancing societal benefits and individual autonomy in secondary use of health data under the EHDS framework



Citizen Expectations: privacy, personal data protection, autonomy & choice

Necessity of Research, Open and Shared Data

Benefit for Society

Law and ethics: Trust

Operationalising public trust for health policymakers - A qualitative study in the EU, France, Italy, and Switzerland

Federica Zavattaro[a,b,*], Viktor von Wyl[a,b,c,d], Felix Gille[a,b]

Pilot Study: Digital Trust

Felix Gille, Markos Mpadanes, Federica Zavattaro

Unlocking the Power of Health Data by Ensuring the Public Can Trust the EHDS

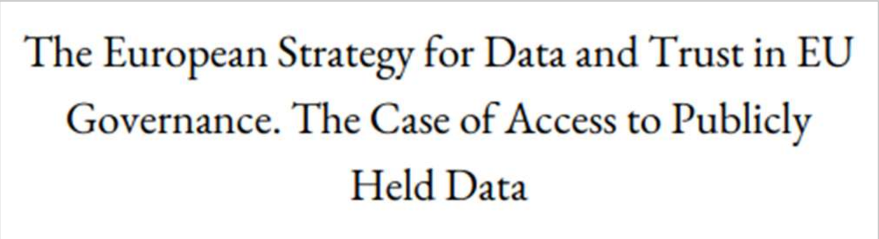
Dipak Kalra[a]

[a]The European Institute for Innovation through Health Data, Ghent, Belgium

DOI: 10.25929/wgxbmf28

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]*



The European Strategy for Data and Trust in EU Governance. The Case of Access to Publicly Held Data

Jane Reichel

Trust is critical to EU health data success, says WHO

As the EU enacts its landmark health data law, officials warn that public trust, not just infrastructure, will determine its success, citing past misuse cases, such as 23andMe, as a cautionary tale.

BUILDING AND MAINTAINING PUBLIC TRUST TO SUPPORT THE **SECONDARY USE OF PERSONAL HEALTH DATA**

By: Gemma A Williams and Nick Fahy

08 DEC 2021 | EVENT REPORTS

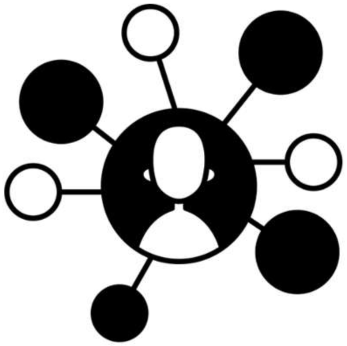
The European Health Data Space will not work without trust from healthcare communities, warn officials and patient associations

Speaking the Same Words, Not the Same Language

One concept = different stakeholders = different meanings

“My Data”

Citizen	GDPR	Researcher	Company
Belongs to me	Processor/ Controller	Responsibility	Economic value
A part of me	Consent	Right to use	Transaction

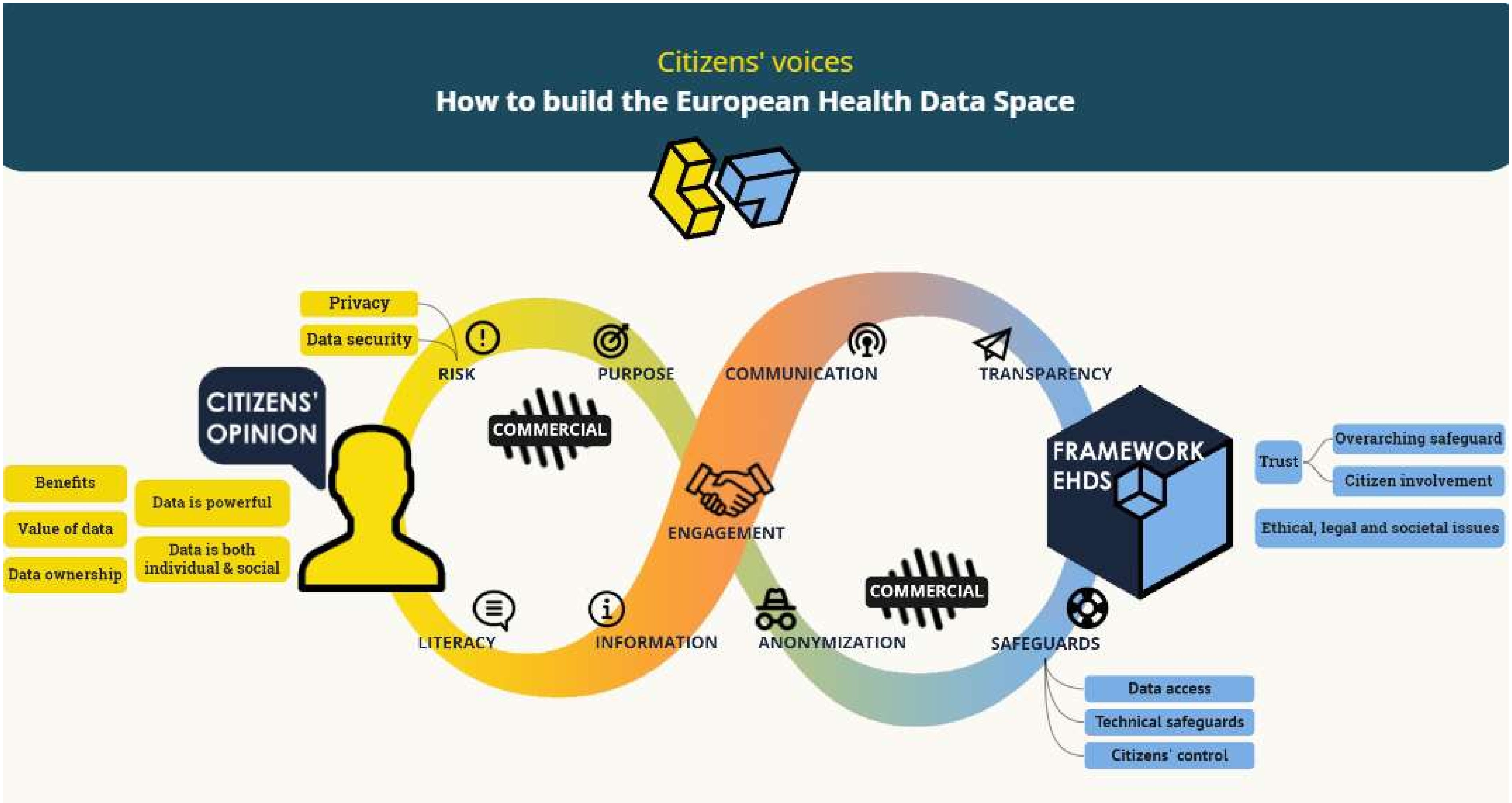


Public interest
PRIVACY
COMMON GOOD
REUSE
TRANSPARENCY
RISK
DATA OWNERSHIP
INFORMATION
COMMERCIAL
PURPOSE
BENEFIT
CONSENT

Potential Ethical–Legal Tensions Around Opt-Out Systems

Trust is a verb: it demands effort, not assumptions

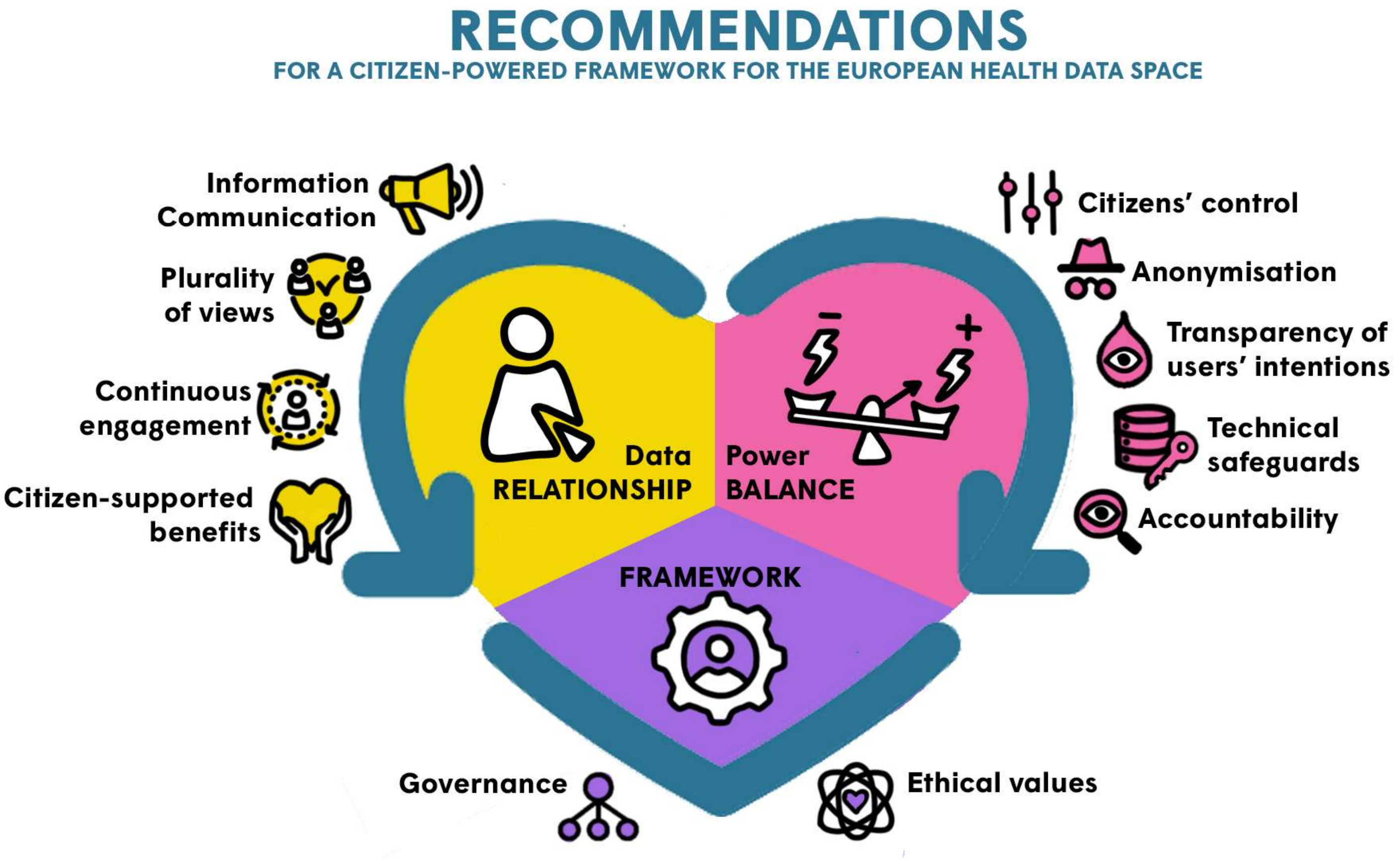
The elements of trust



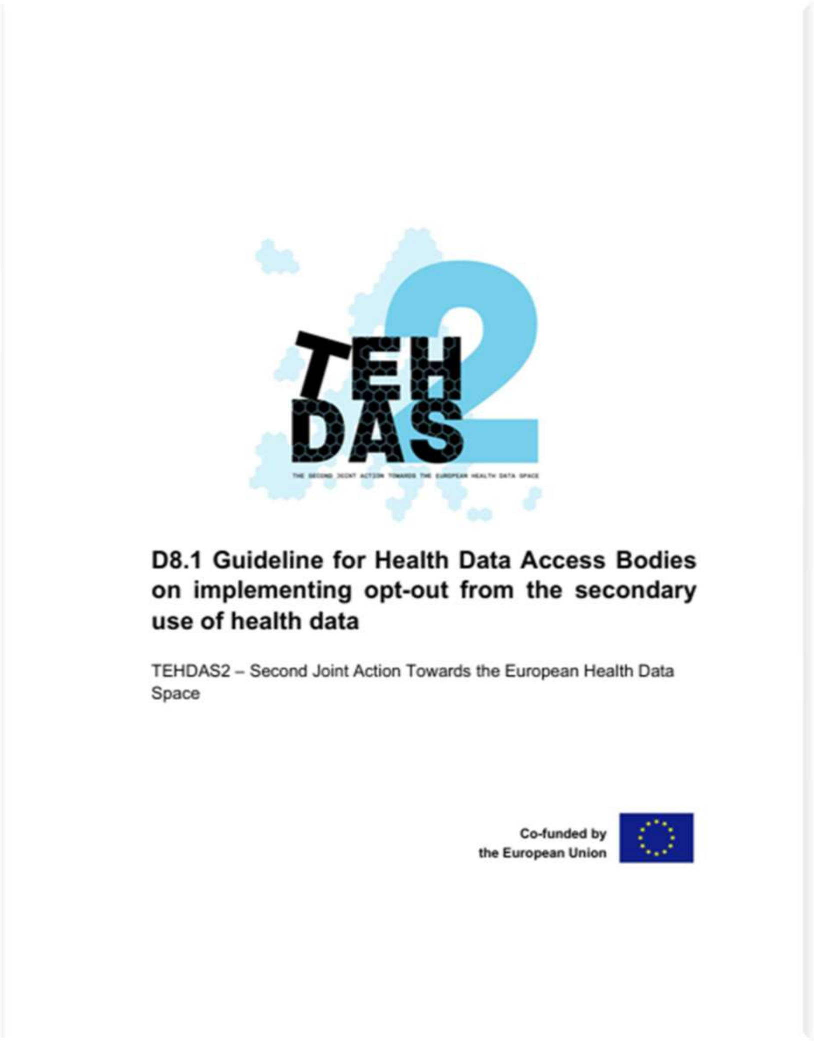
[Healthy Data, an online citizen consultation about health data reuse – intermediate report | sciensano.be]()

sciensano

A relationship based on trust



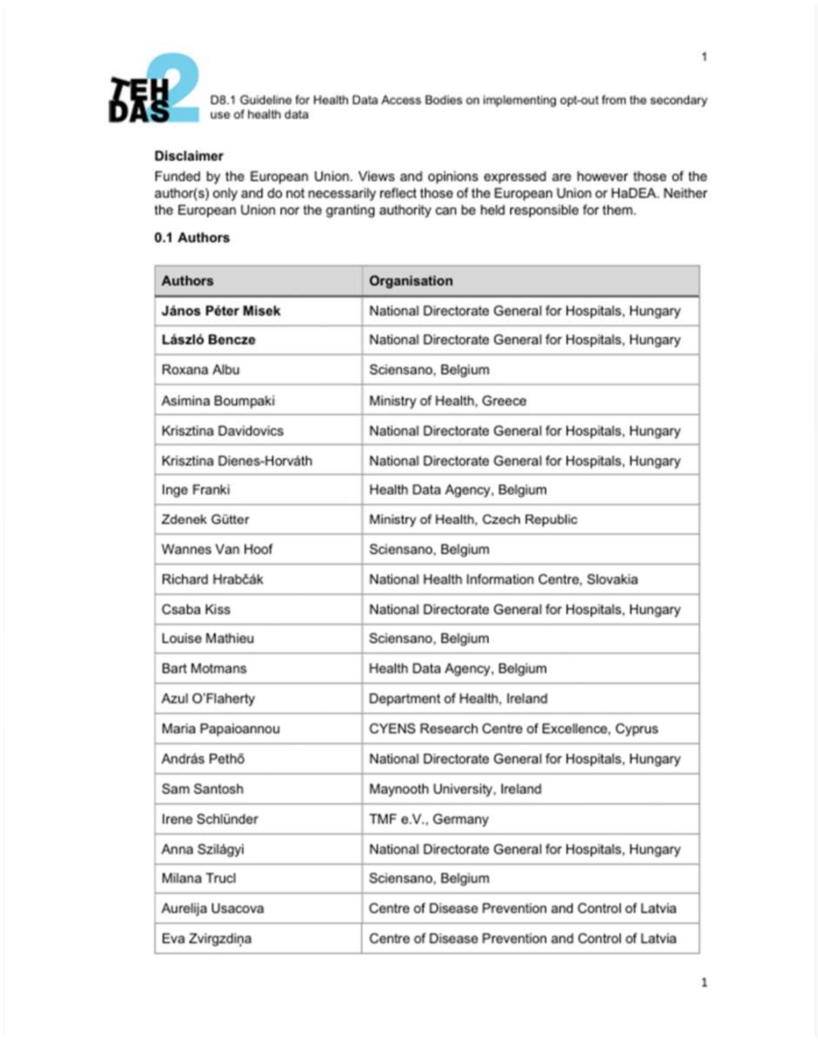
[Recommendations on how to engage citizens in the European Health Data Space | sciensano.be]



D8.1 Guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data

TEHDAS2 – Second Joint Action Towards the European Health Data Space

Co-funded by
the European Union



Disclaimer

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or HaDEA. Neither the European Union nor the granting authority can be held responsible for them.

0.1 Authors

Authors	Organisation
János Péter Misek	National Directorate General for Hospitals, Hungary
László Bencze	National Directorate General for Hospitals, Hungary
Roxana Albu	Sciensano, Belgium
Asimina Boumpaki	Ministry of Health, Greece
Krisztina Davidovics	National Directorate General for Hospitals, Hungary
Krisztina Dienes-Horváth	National Directorate General for Hospitals, Hungary
Inge Franki	Health Data Agency, Belgium
Zdenek Gütter	Ministry of Health, Czech Republic
Wannes Van Hoof	Sciensano, Belgium
Richard Hrabčák	National Health Information Centre, Slovakia
Csaba Kiss	National Directorate General for Hospitals, Hungary
Louise Mathieu	Sciensano, Belgium
Bart Motmans	Health Data Agency, Belgium
Azul O'Flaherty	Department of Health, Ireland
Maria Papaioannou	CYENS Research Centre of Excellence, Cyprus
András Pethő	National Directorate General for Hospitals, Hungary
Sam Santosh	Maynooth University, Ireland
Irene Schlünder	TMF e.V., Germany
Anna Szilágyi	National Directorate General for Hospitals, Hungary
Milana Trucl	Sciensano, Belgium
Aurelija Usacova	Centre of Disease Prevention and Control of Latvia
Eva Zvirgzdiņa	Centre of Disease Prevention and Control of Latvia

sciensano

CONNECTS HEALTH, SCIENCE AND SOCIETY

Thank you for your time; glad to answer any questions!

Roxana.albu@sciensano.be

Wannes.VanHoof@sciensano.be

www.sciensano.be

.be