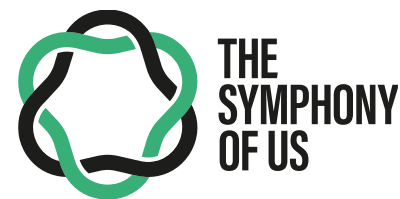


Additional file 6: Focus groups Introductory presentation

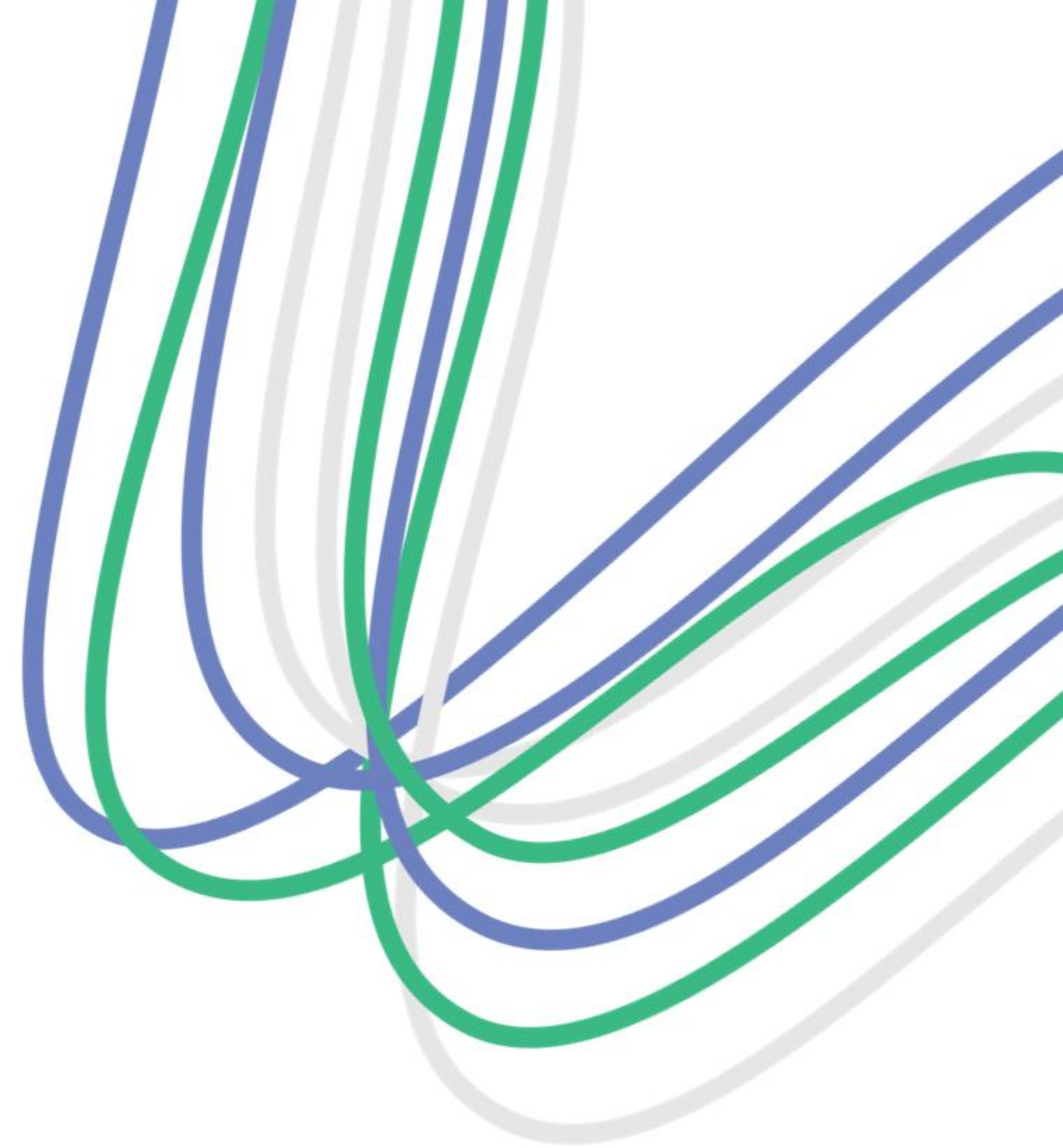
For the paper Lalova-Spinks et al., “ *What patients value in data reuse for oncology research: a multi-stakeholder qualitative study to inform the European Health Data Space implementation in Belgium and beyond*”, Archives of Public Health (2026), doi: 10.1186/s13690-026-01884-5

THE SYMPHONY OF US

Discussion group on Patient Value &
Health Data Use



YOUR HEALTH DATA & THE EUROPEAN HEALTH DATA SPACE



WHAT IS PERSONAL DATA?

- Any information that can be used to identify you.



Photo



National
registration
number



Address



Name



E-mail

- There is also special personal data -> it requires higher protection.



Health (diagnosis, treatments, medical images...)



Genetic information

WHAT IS PERSONAL DATA?

Important distinction

- . Sometimes your data is **pseudonymised** – your name is removed, but it can still be traced back to you using a code. => These data are still protected.
- . Other times it's **anonymised** – all identifiers are removed, and it's impossible to trace it back. => The law does not apply to such data.

EXAMPLE OF A PSEUDONYMISED DATA FILE

Raw Data file

Name	Gender	Test Score (0 - 20)
Marty McFly	M	18
Elwood Blues	M	19
Elsa Schneider	V	10
Walter Sobchak	M	15
Chris Shiherlis	M	13
Ellen Ripley	V	20

Pseudonymized Data file

Pseudonym	Gender	Test Score (0 - 20)
P085	M	18
P080	M	19
P089	V	10
P098	M	15
P095	M	13
P079	V	20

Keyfile:

Pseudonym	Name
P085	Marty McFly
P080	Elwood Blues
P089	Elsa Schneider
P098	Walter Sobchak
P095	Chris Shiherlis
P079	Ellen Ripley

HOW IS YOUR PERSONAL DATA PROTECTED?

Data protection is your fundamental right



- In the EU: the **General Data Protection Regulation** and **national data protection laws** (e.g., the Belgian Data Protection Act)
- Embodies a **willingness to work with and to share** personal data
- **Rights and obligations** are granted to and imposed **on all involved actors**: citizens, companies, hospitals, researchers...

HOW CAN DATA BE (RE)USED FOR RESEARCH?

Examples...



- You can **join a medical study** (e.g., a clinical trial) or another type of study (e.g., today's discussion group). **New data** will be collected and used.



- **Existing data from your medical history** could also be **re-used** to help researchers improve treatments, develop new medicines, or understand diseases.

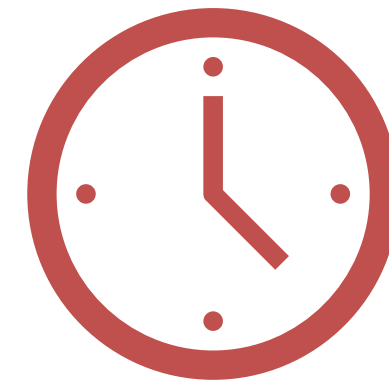
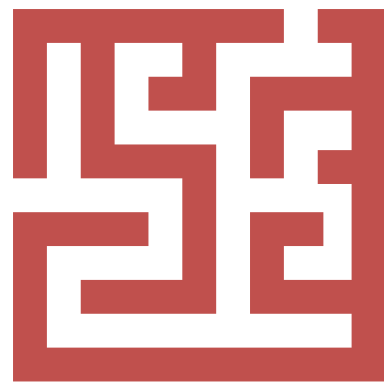
HOW CAN DATA BE (RE)USED FOR RESEARCH?

If re-using data from your medical history, today this usually happens:

- Inside the hospital or clinic where you were treated.
- With special approvals (e.g., from an ethics committee, from data protection officers).
- Sometimes, there are collaborations across hospitals (in Belgium, or abroad) – but this takes time and rules may vary.

HOW CAN DATA BE (RE)USED FOR RESEARCH?

Key challenges for data re-use today:

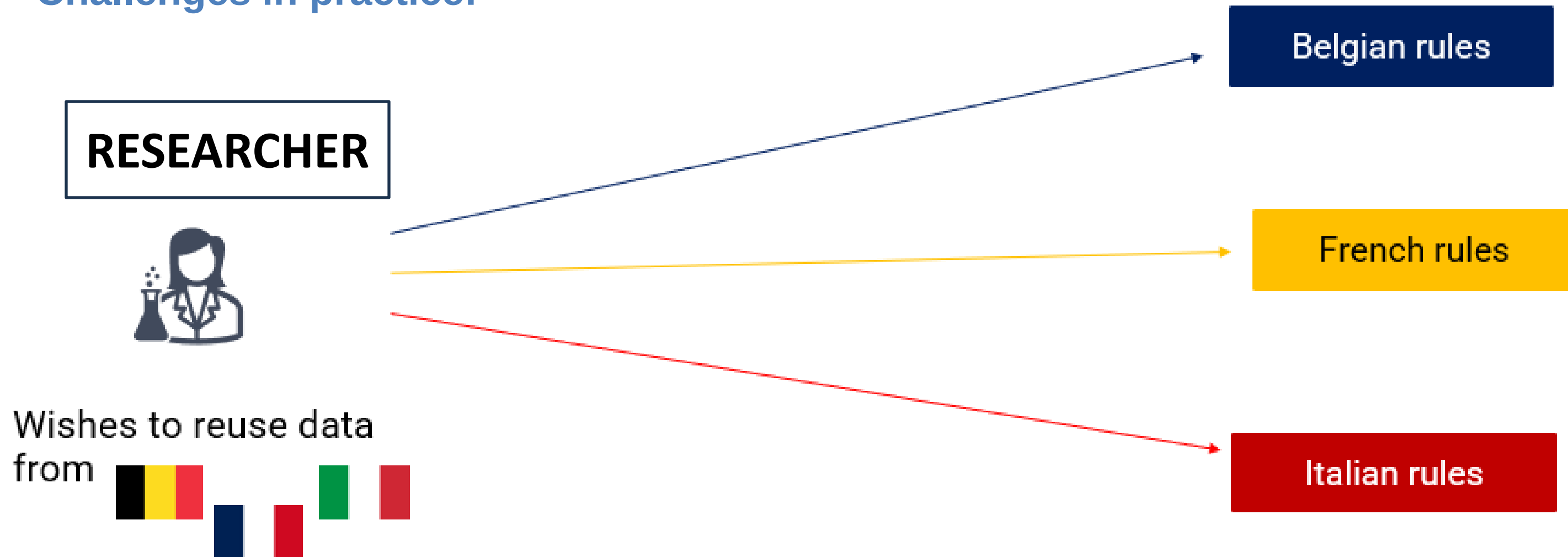


- **Too much fragmentation:** rules can be different across countries, and sometimes even across regions in the same country. This makes sharing data across countries difficult.

- **Complex approvals:** researchers often wait months or even years to access data.

HOW CAN DATA BE (RE)USED FOR RESEARCH?

Example – Challenges in practice:

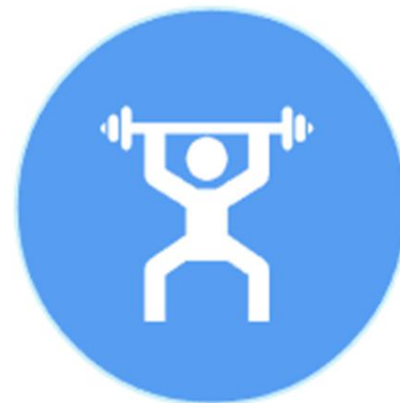


WHAT IS THE EUROPEAN HEALTH DATA SPACE?



New EU law - Adopted March 2025; it will take around 10 years to see it fully working.

Goals of the EHDS:



Improve **individuals' access to and control** over their personal electronic health data



Make more data available for research, innovation, personalized medicine...



Uniform legal and technical framework for the development, marketing and use of **electronic health record systems**

WHAT IS THE EUROPEAN HEALTH DATA SPACE?

Provides rules about:



PRIMARY USE

- The use of electronic health data **for the provision of healthcare...** (diagnosis, treatment...)



SECONDARY USE

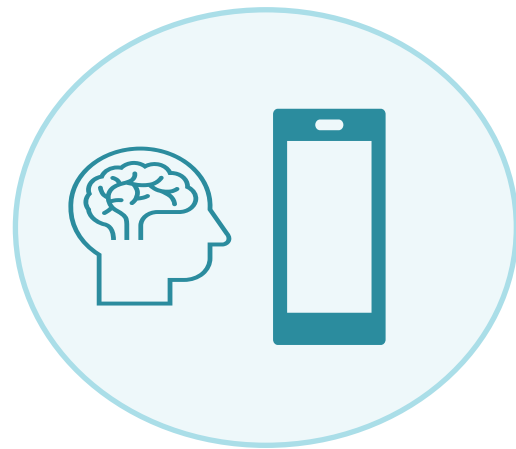
- The use of electronic health data **for research, innovation, policy making...**

SECONDARY USE UNDER EHDS: DATA FROM WHERE?

For example...



Electronic health
records



Wellness applications



Clinical trials



Health data registries



Biobanks



Medical devices

SECONDARY USE UNDER EHDS: HOW?

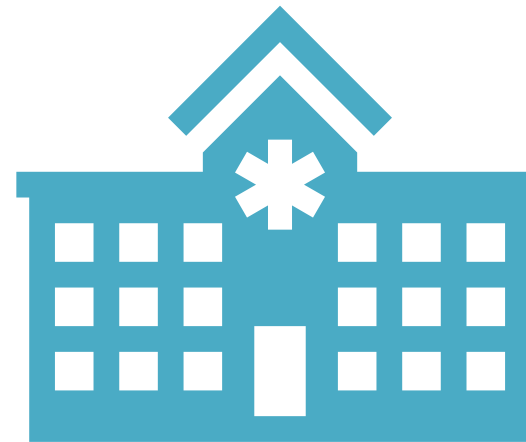
HEALTH DATA USER

(researchers,
government...)



HEALTH DATA ACCESS BODY

In
Belgium:



Data permit



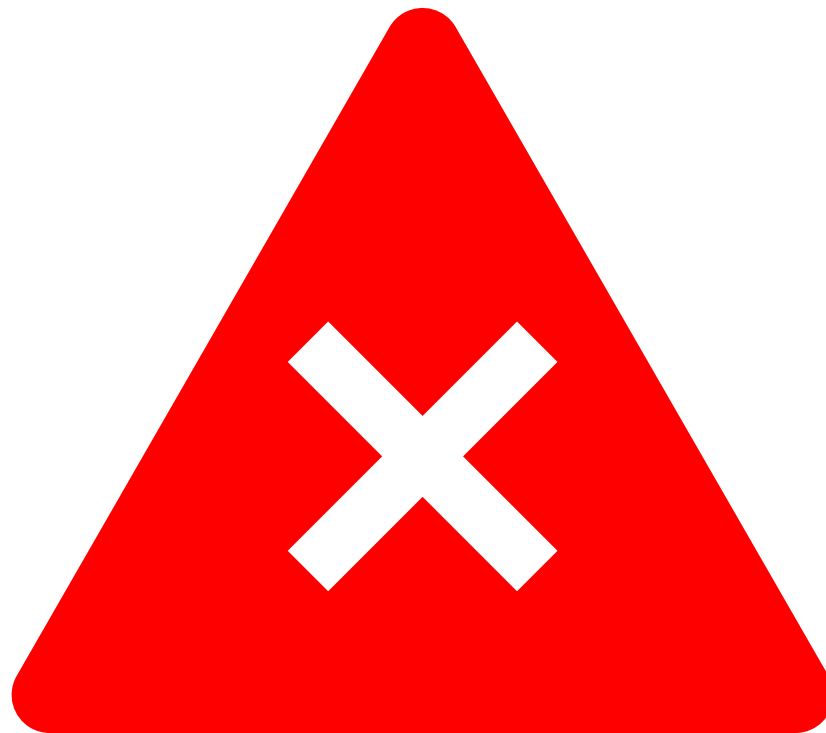
HEALTH DATA
HOLDERS (hospitals,
companies...)



Data request

- Data must be provided through a **secure processing environment**,
- in **anonymised format** or,
- where the purpose of the processing cannot be achieved – in **pseudonymised format**.

SECONDARY USE UNDER EHDS: PROHIBITED PURPOSES



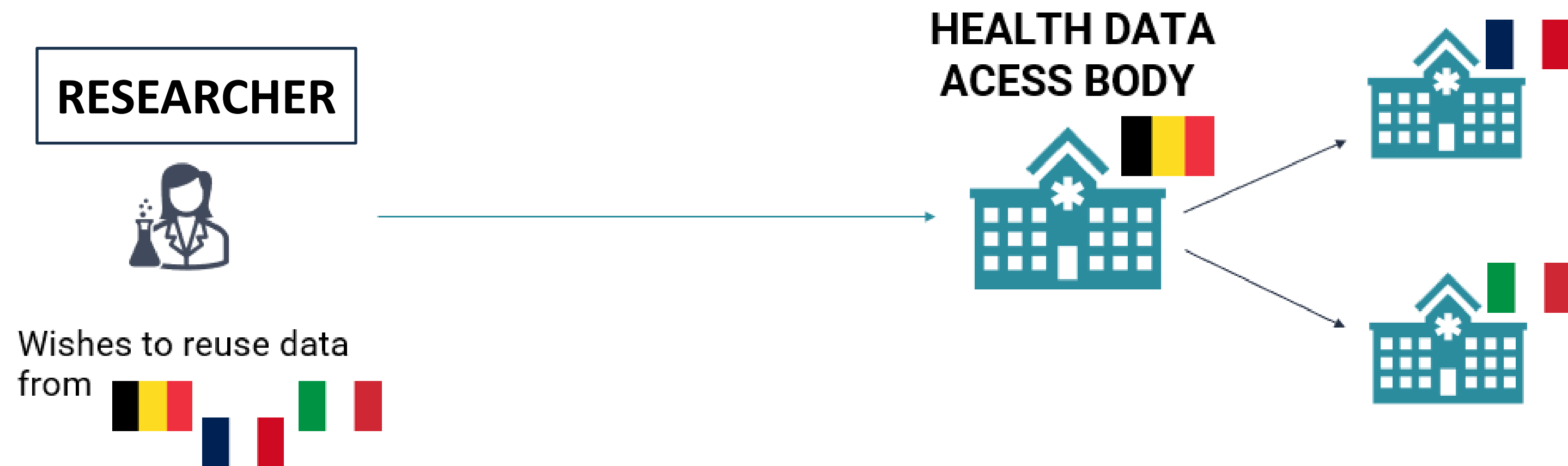
The law prohibits the use of data for goals, such as:

- Taking decisions detrimental to an individual based on their health data (e.g., discriminate against them)
- Advertising or marketing activities
- Developing harmful products or services (e.g. drugs, alcohol, weapons...)

And health data access bodies can issue fines for the misuse of health data.

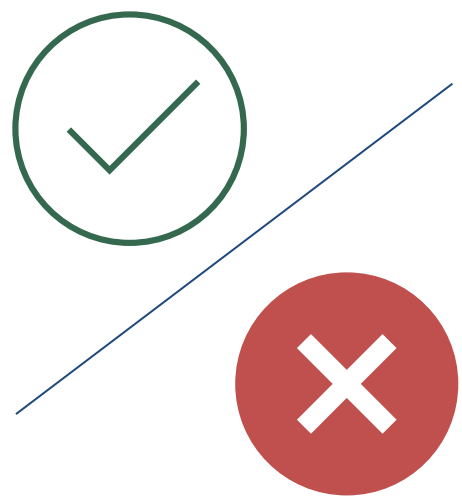
SECONDARY USE UNDER EHDS

Example – How can EHDS help:



SECONDARY USE: WHAT CAN YOU DO?

You can opt-out:



- Individuals will have the **right to opt-out**:
 - At **any time**
 - **Without stating reasons**
 - The decision is **reversible** (they can change their mind)
- EU countries shall provide for an **accessible and easily understandable opt-out mechanism**.

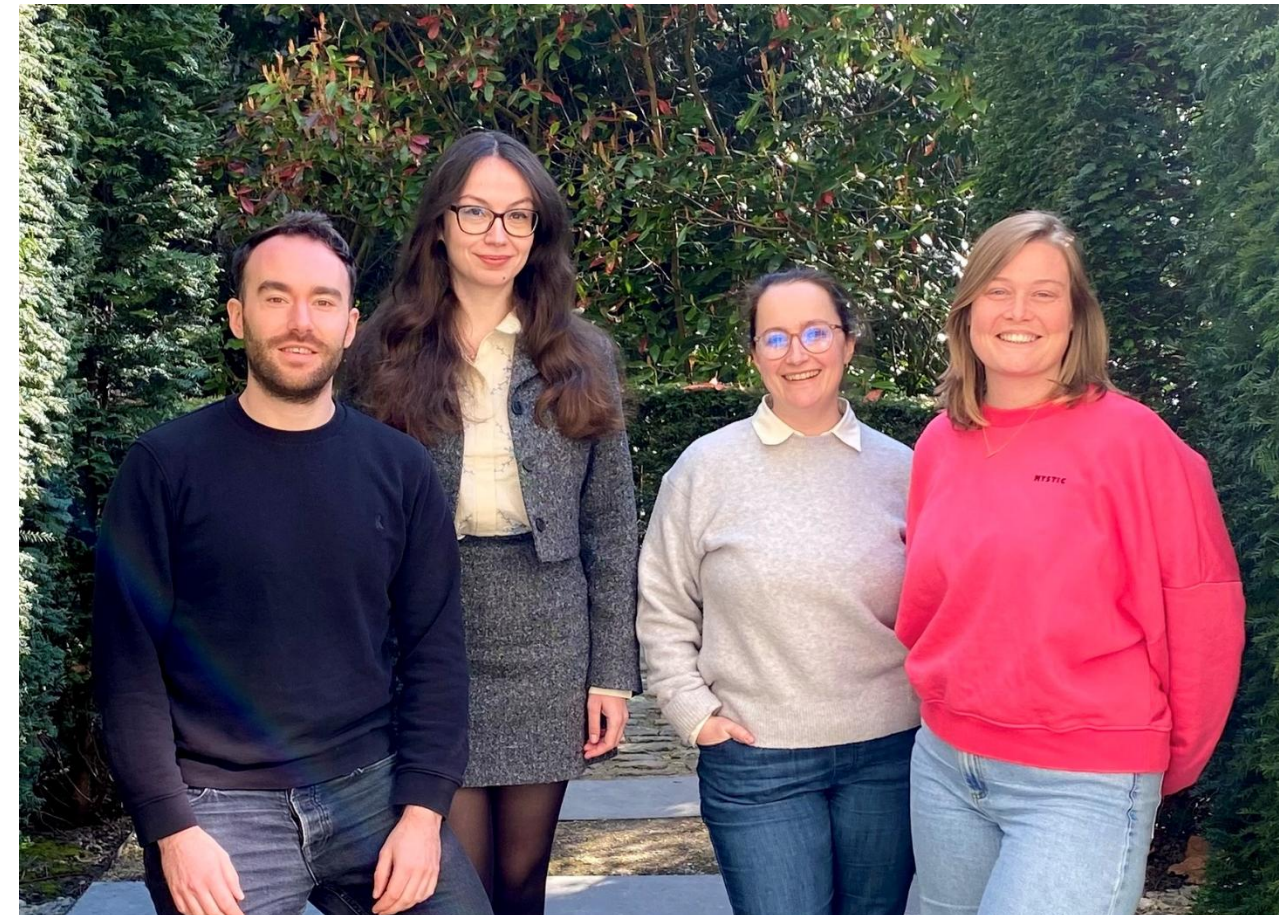
SECONDARY USE: ROLE FOR PATIENT REPRESENTATIVES?



- In the performance of their tasks, **health data access bodies shall actively cooperate with** representatives of relevant stakeholders, **especially with representatives of patients.**

THANK YOU!

The Symphony of Us Team



<https://www.symphonyofus.be>



info@symphonyofus.be

