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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

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Abstract

Background The reuse of health data is critical for advancing health research, yet it raises complex ethical, legal, and societal challenges. In the European Union, the recently adopted European Health Data Space (EHDS) aims to harmonize access to and reuse of health data for research and innovation, while safeguarding individual rights. However, questions remain about what patients value in data reuse and how their values can be embedded in governance frameworks. Belgium, with its strong research tradition and central role in EU policymaking, offers an important testbed for these questions.

Methods We conducted a qualitative study combining semi-structured interviews with 39 professionals (policy and governance representatives, researchers, physicians, industry, law and ethics experts, and supporting actors) and three focus groups with ten oncology patients and patient representatives. The interviews explored professional perspectives on data reuse and informed the design of the focus groups. Data were analyzed using the framework method, integrating inductive and deductive coding. Patient-researchers were involved throughout the study design, data collection, and interpretation.

Results Participants unanimously recognized the value of health data reuse at both individual (improved healthcare) and collective (advancing scientific research) levels. Patients emphasized the importance of transparency, feedback about research results, and opportunities for meaningful involvement in data governance. While patients were generally willing to share their data, they highlighted conditions such as trust in the system, strong data protection, and safeguards against misuse. Both professionals and patients considered the EHDS a positive step for facilitating research but expressed concerns about its practical implementation. All participants recognized the value of both individual and collective control over health data, though challenges of representation and resource constraints were noted when it came to patient involvement.

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Conclusions This study provides the first in-depth investigation in Belgium of what patients and professionals value in relation to health data reuse, particularly in the context of the EHDS. Findings underscore that the legitimacy of the EHDS will depend on embedding patient values into its implementation through transparency, participatory data governance, and legal and technical safeguards. The results provide actionable insights for policymakers, researchers, and practitioners to build a value-oriented and socially legitimate health data ecosystem at national and EU levels.

Keywords European Health Data Space, Secondary use of data, Patient value, Health research, Oncology research, Patient involvement, Data protection, EU health policy

Text box 1. Contributions to the literature

- Provides the first in-depth analysis in Belgium of what patients and diverse professionals value in the reuse of health data for research, in the context of the EHDS.
- Expands the literature on patient involvement in the secondary use of health data, showing how transparency, feedback, and opportunities for both individual and collective data control are central to the perceived legitimacy of data governance.
- Advances the understanding on how to operationalize the EHDS in practice by identifying concrete concerns and recommendations at societal, organizational, and individual levels.
- Shows how qualitative approaches are especially suited for investigating complex governance issues.

Background

The reuse of health data is widely recognized as critical for advancing biomedical and public health research. Data reuse enables larger sample sizes, facilitates studies in rare diseases, reduces duplication of efforts, and supports the development of data-intensive technologies such as artificial intelligence (AI) [1]. Oncology research illustrates the stakes of data reuse particularly well: cancer remains a leading cause of morbidity and mortality in the European Union (EU), with an estimated 2.7 million new cases annually [2]. Over the past two decades, the EU has invested substantially in cancer research and innovation, underpinned by strong political commitment through initiatives such as Europe's Beating Cancer Plan, which sets out comprehensive actions for prevention, early detection, treatment, and survivorship. At the same time, secondary use of health data raises important ethical, legal, and societal questions [3]. Finding the balance between enabling innovation and protecting individual rights remains at the core of the European debate on health data governance.

In the EU, the legal and ethical framework for health research is complex and highly divergent [4, 5]. In addition to the many specific rules governing research, a central role is played by the EU General Data Protection Regulation (GDPR), which established a legal regime for the processing of personal data for scientific research [6, 7]. However, the GDPR has also been criticized for creating legal uncertainty around the secondary use of health data, and divergent national interpretations have led to fragmentation and barriers for cross-border studies [8, 9].

To address these challenges, in 2025 the EU adopted the European Health Data Space (EHDS) Regulation [10]. The law is among the legislative initiatives that stemmed from the European Strategy for Data (other examples including e.g. the Data Governance Act and the Data Act) and which aim to ensure that more data is available for use in the economy and society, while control is maintained by the individuals and companies who generate the data. The EHDS builds on existing relevant legislation and it functions as a complementary, sector-specific governance layer to the GDPR. The goals of the EHDS in particular are to 1) improve individuals' access to and control over their personal electronic health data, 2) make more data available for research, innovation, and other legitimate purposes, and 3) establish a uniform legal and technical framework for electronic health systems[1]. It provides rules pertaining to both primary (healthcare) and secondary (e.g., research) use of data[2]. With respect to secondary use of data, the law puts in place new mechanisms, such as public bodies in each EU country responsible for providing permits for data reuse (so called health data access bodies[3] (HDABs)). At the time of writing of this paper, the HDABs are still under development in most Member States, and many questions foundational for their design remain to be addressed, such as transparency, communication towards society and the individual citizens, and patient involvement in the governance of data. In addition, each citizen would have the right to opt-out from secondary use of data at any time, without stating reasons, and their decision would be reversible[4]. EU countries must provide an accessible and easily understandable opt-out mechanism. The EHDS entered into force in March 2025 but the full implementation and operationalization of the regulation will take approximately ten years[5].

Research on health data reuse in general and the EHDS implementation in particular increasingly highlights the

[1] Article 1 EHDS

[2] Chapter II and Chapter IV EHDS

[3] Article 55 and following EHDS

[4] Article 71 EHDS

[5] Article 105 EHDS

importance of involving patients and other stakeholders in shaping data governance [11–14], and of identifying and embedding the values of patients and citizens in the new legal and policy frameworks [15–17], but such questions remain underexplored in practice. Belgium presents a particularly relevant setting to further explore these issues. With its strong biomedical research tradition, multilingual and multicultural population, and central role in EU policymaking, Belgium is an important testbed and microcosm of wider European challenges in health data governance and EHDS implementation [18].

Our study aimed to address these gaps by investigating what oncology patients value in relation to health data reuse for scientific research, with particular attention to dimensions such as perceived societal and individual benefit, transparency, and patient involvement in the governance of data. Using oncology research as a use case, our study specifically seeks to inform the implementation of the EHDS by exploring how key governance mechanisms introduced by the new law – such as opt-out – are understood by those most directly affected. In parallel, the study aimed to capture the perspectives of key professional stakeholders involved in health data reuse and governance, allowing for a comparative and integrative analysis of patient and professional viewpoints. By bringing these perspectives together, the study aims to identify points of convergence and tension that are relevant for organizing data reuse under the EHDS in a way that is ethically sound, socially legitimate, and aligned with the goals of European health policy.

Methods

Study design

Our study design was aimed at collecting so-called "thick" descriptions, reflecting the richness and diversity of professionals' and patients' views, priorities, and expectations, to identify what they regard as crucial in health data reuse practices. The study therefore employed a qualitative design consisting of two phases: 1) semi-structured interviews with health (research) professionals, followed by 2) focus groups with cancer patients and patient representatives. Expert interviews served to identify key themes and professional perspectives, which informed the development of the patient focus group guide. This design is consistent with established approaches to triangulation and progressive focusing in qualitative research [19]. It integrates professional knowledge with lived experience, thereby enhancing the contextual relevance, depth, and validity of the findings [20]. The research methodology and its reporting were in accordance with the Consolidated Criteria for Reporting Qualitative research (COREQ) guidelines (Additional file 1) [21].

Data collection and research team

The study was conducted in the scope of the Symphony of Us project, which aimed at better understanding and implementing patient value in oncology research[6]. The methodological approach aligned with the principles of transdisciplinary research, where study design, data collection, and interpretation are co-created by various academic disciplines and non-academic stakeholders [23]. Four academic researchers with diverse backgrounds (law, social sciences, biomedical sciences, nursing) were involved in the project. Moreover, the academic team sought to partner with patients in every aspect of the project (from study design to dissemination). Such partnership implies involving patients as co-researchers and co-authors, i.e., as patient-researchers[7]. The involvement of patient-researchers in the study is described following the Guidance for Reporting Involvement of Patients and the Public (GRIPP2) checklist (Additional file 2) [25]. In addition, the study benefited from collaboration with legal academics experienced in the topics of data governance and secondary use of data.

The interview questionnaire and focus group topic guide were informed by the literature (Additional files 3 and 4). Prior to the focus groups, patients were asked to complete a short survey (Additional file 5), which aimed at gathering information about their demographic characteristics and prior knowledge about health data reuse. At the start of each focus group, patients were given a short (10-min) presentation with key information about the current rules for reusing personal data for health research, and the main new rules for reuse of data established with the EHDS (Additional file 6). The goal was to equip all patients with the same knowledge on the topics of discussion.

All questionnaires and the introductory presentation were developed by a postdoctoral researcher with a legal educational background (TLS), specialized in the topic of data protection and data (re)use in health research, and experienced in empirical research. They were further discussed with academics with different disciplinary backgrounds (SL, FH, MS, PC) and patient-researchers (IVZ, LB, BC, WD), and were revised based on their feedback.

All discussions were organized either in person, or online (via Microsoft Teams). The interviews were conducted by one researcher (TLS) in English and French (July 2024—January 2025). Three focus groups were held in June—July 2025, and were facilitated by experts fluent in Dutch or French (IVZ and PC). The opportunity

[6] The project is a collaboration of three Belgian higher education institutions (Ghent University, AP Hogeschool Antwerpen and Université Libre de Bruxelles), and it is initiated and supported by the King Baudouin Foundation. For more information about the project, see reference [22].

[7] To learn more about our work with patient-researchers and the team's composition, see reference [24].

for a focus group in English was offered, to capture the insights of foreigners residing in Belgium, but no English-speaking participants registered. All patient-researchers participated in the interviews and focus groups as observers.

Participants and recruitment

The interviews targeted representatives of diverse professional stakeholder groups involved in the secondary use of health data, namely 1) policy and governance representatives (public bodies, health ministries, EU policy actors), 2) data users (pharmaceutical industry, academic researchers, and physicians), 3) law and ethics experts (lawyers and data protection officers working at hospitals, research institutes, companies, as well as ethics committee members), 4) experts in supporting roles (e.g., consultants, providers of digital solutions). While physicians were selected based on direct expertise in oncology, interviewees from the other stakeholder groups were recruited for their broader roles in health data governance and secondary use of health data, and were invited to reflect on these issues in relation to oncology. Interviewees were recruited via a combination of purposive and snowball sampling[8]. The aim was to purposively select experts who work primarily in Belgium, and to achieve representation across the three regions: Brussels-Capital Region, Flanders, and Wallonia. Considering the global nature of health research, participants who have experience at both Belgian and EU/global level, or who work in countries neighboring Belgium were also approached.

The focus groups targeted patients who have or have had cancer, as well as patient representatives active in the field of oncology who resided in Belgium. Participants were recruited through a self-selection sampling approach. The call to participate was broadly distributed via the professional networks of the research team, the website of the Symphony of Us project, as well as on social media. Interested patients could register to participate via an online form.

Analysis

The interviews and focus groups were recorded, transcribed ad verbatim and translated into English (where applicable) by a third party[9]. Data was analyzed following the framework method [26], using the NVivo© 15 software. A working analytical framework was prepared in three stages: 1) all academic and patient-researchers coded individually three transcripts, 2) the codes were compared, 3) the ambiguities and overlaps were cleared out by a joint discussion. All remaining transcripts were coded by one researcher (TLS), based on the working analytical framework. Reflexivity and consistency were further achieved via ongoing discussions between all team members. Data was analyzed using a combination of inductive and deductive approaches. Initially, transcripts were coded openly in a data-driven manner, allowing themes and patterns to emerge freely from the material. These codes were then grouped into broader categories, which facilitated the identification of recurring concepts across the dataset. In a subsequent step, the emergent categories were compared with the predefined categories from the topic guides, ensuring that both novel insights and anticipated themes were captured and systematically integrated. Final themes and subthemes were generated through iterative refinement of the analytical framework, whereby clustered codes were reviewed, merged, or split based on conceptual coherence and analytical relevance, resulting in the final coding tree (Additional file 7). In this paper, we report the themes that were discussed by both professionals and patients.

Results

Demographics

In total, 69 experts were invited for an interview, of which 39 participated[10]. Most of those who declined to join the study did not specify a reason; and among those who did, lack of time was the primary reason for non-participation. As shown in Table 1, all targeted stakeholder groups were represented, with the majority being data users ($n = 16$) and law and ethics experts ($n = 11$)[11]. Some professionals had dual functions (e.g., both an ethics committee representative and an academic researcher; or an academic researcher and a physician). In such cases, they were assigned to a stakeholder group based on the professional viewpoint they chose to primarily represent. Most worked in Belgium (Fig. 1), of which more than half had expertise at EU level (either by working at an EU institution, or as senior experts in cross-border research projects), and the majority were based in the Brussels-Capital region ($n = 21/35$, Fig. 2).

[8] Further interviewees were invited based on responses and recommendations made in earlier interviews. This technique was chosen as it is particularly useful for investigating sensitive topics which require the knowledge of insiders to identify study participants.

[9] Transcriptions and translations were done by a professional translation company with which a non-disclosure agreement was signed. The company performed internal quality checks on the transcriptions and translations.

[10] Thirty-five interviews were performed, however some organizations were represented by two or more employees with different expertise, hence the total number of individual experts is thirty-nine.

[11] Although interviewing patient representatives was not originally planned in the first phase of the project, one such participant was referred during snowball sampling. Given the relevance of their insights to the research question, we included this interview in the analysis. This adaptation reflects the flexibility of qualitative sampling strategies, which can evolve as the study progresses.

Table 1 Interviews: representation of stakeholders

Stakeholder groups	Sub-groups	Number of interviewees
Policy and governance		5
	Public authorities	2
	Health ministries	2
	EU policy actors	1
Data users		16
(Representatives of actors who generate, manage, or use health data for health research purposes)	*Pharmaceutical industry*	4
	Academic researchers	7
	Physicians	5
Law and ethics		11
(Experts who ensure compliance, ethics, and responsible use of health data)	*Legal/DPO*	9
	Ethics committees	2
Supporters		6
(Expert in supporting roles, such as coordination, consultancy, providers of digital health solutions)		
Patient representatives		1

Twenty-six individuals registered to participate in the focus groups, of whom ten joined. Two registrants were excluded by the research team because they were not patients or patient representatives, and fourteen did not ultimately join the focus groups; where reasons were provided, these related mainly to personal circumstances. The majority were both patient representatives and cancer patients ($n=7$), female ($n=7$), and above 55 years old ($n=8$) (Table 2). Their past experience and knowledge about health data re-use varied (Table 3). Most patients knew about the GDPR, but only four had heard about the EHDS.

In the presentation of results below (Sects. 3.2–3.4), insights shared by experts who participated in the interviews are attributed to "professionals" or by using a code (e.g., I20, referring to interviewee number 20). Opinions of focus group participants are attributed to "patients", or by using a code (e.g., P3, referring to patient/patient representative number 3). When speaking about views expressed by both groups, "participants" is used. Table 4 presents a high level summary of all results.

The value of data reuse for patients

Stakeholders' understanding

All participants understood the value of data reuse at both individual and collective levels. At individual level, they considered most important 1) the opportunity to receive better care (which included e.g., saving the patient's life, better health, better interaction with physicians, improved quality of life) and 2) feeling satisfaction from being able to contribute to society by sharing their data.

> *"It gives me a good feeling, a joyful feeling that we are a small fish in that big bowl, or that swimming pool, and that we can make a contribution." (P4).*

At a collective level, every participant recognized the importance of data reuse for enabling more scientific research, especially in rare diseases.

> *"You have to be able to reuse data because the patient pools are so small that if you have to restart each time you want to add an additional component to a study, you don't have the patient population to power the study and particularly in oncology, where you have to take invasive measures to collect samples from the patients, that harms the patient and can be painful." (I8).*

Several professionals commented that individual and collective value could also be directly linked, in the case of personalized medicine (PM). In a PM approach, patient data collected for clinical care are continuously reused to generate new knowledge, that, in turn, directly informs individualized treatment decisions.

The importance of balancing individual and collective value was highlighted by legal experts and pharmaceutical companies' representatives. Related to this, around a quarter of the professionals (mainly law and ethics, academic researchers, and policy representatives) discussed a third dimension to understand the value of data reuse, namely the fundamental rights of individuals, e.g. data protection, privacy, and non-discrimination. They cautioned against the risk of overriding individual rights for the collective interest and emphasized that balancing between the two, as provided by the law, is key. Patients rarely commented on legal issues, with one notable exception: they focused on the necessity for strong law enforcement of their rights and the other relevant rules established in the applicable legal frameworks.

How to realize value in practice?

Both professionals and patients opined that although the main way to realize value was by using the data, simple use in itself was insufficient. According to most professionals, it was important that 1) accurate and complete data is 2) made available, 3) used for the specified purposes (scientific research), and 4) the results of the data reuse – even if there were no significant findings—are peer reviewed (e.g., via publications in scientific journals). Additionally, patients emphasized that change in clinical practice based on data reuse needs to be demonstrated. They expressed strongly that value can be further brought when patients have access to data themselves (to do own research, or to be able to e.g., compare between services provided at hospitals), and by involving patients

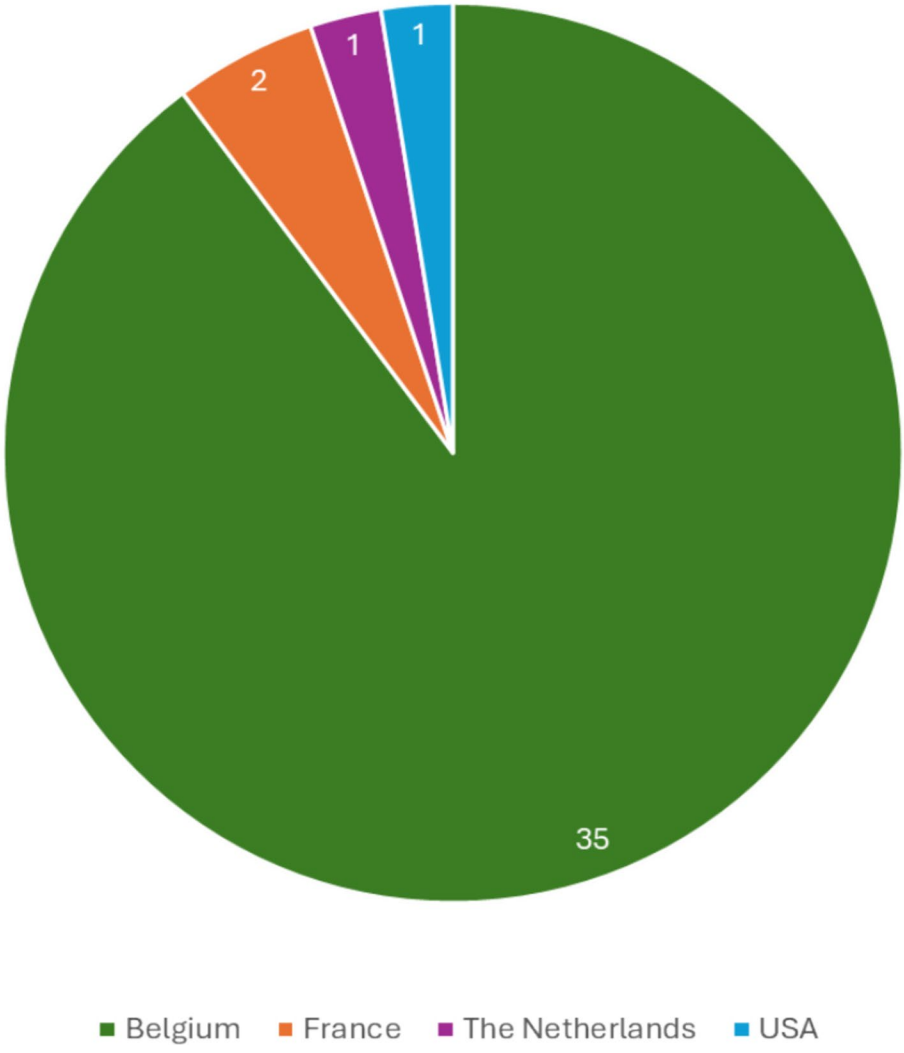

Fig. 1 Interviews: representation per country

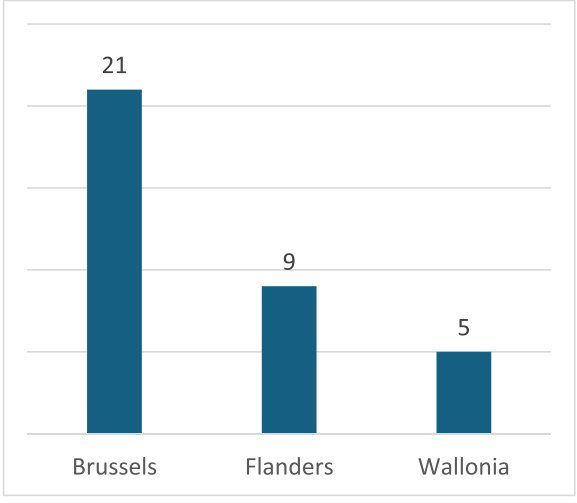

Fig. 2 Interviews: representation per Belgian regions

in the prioritization of areas where data should be collected and/or used.

> *"We as patients have completely different questions about the use of data and what data is actually needed (…)." (P1).*

The majority of study participants agreed that collaboration between all stakeholders, with the patients at the center, was a prerequisite for realizing value and stimulating more data sharing. Moreover, a legal expert, working at a pharmaceutical company, emphasized the need to build trust not only between patients and other stakeholders, but also between organizations themselves (e.g. between commercial and academic entities).

All considered crucial that stakeholders reach alignment on the purposes for which data is reused, especially in relation to the upcoming implementation of the EHDS. Transparent communication, collaboration, as

Table 2 Focus groups: demographic characteristics

Stakeholder group	Number of participants
Patient representatives who are also themselves patients	7
Patient representatives who are not themselves patients	2
Patients	1
Gender representation	
Female	7
Male	3
Age	
25–34	2
55–64	3
65–74	4
75 or older	1
Highest level of completed education	
Secondary education	2
Bachelor's degree or equivalent	4
Master's degree or equivalent	4
Have followed courses on the topics of medicines development, clinical or biomedical research, or patient engagement	
Yes	6
No	4
Native language	
Dutch	6
French	4
Total number of participants: ***n*** = 10	

Table 3 Focus groups: Past knowledge and experience regarding health data (re)use

Participated in a clinical trial or another biomedical study	Number of participants
Yes	2
No	8
Allowed the re-use of their personal health data for biomedical research	
Yes	5
No	1
Don't know	4
Collaborated with researchers or other stakeholders in decisions whether or how health data from patients other than themselves should be re-used for research	
Yes	5
No	5
Have previously heard about the GDPR	
Yes	9
No	1
Have previously heard about the EHDS	
Yes	4
No	6
Total number of participants: ***n*** = 10	

well as providing education to patients *"to make sure that they understand the impact of their decision"* (I34) were seen as the basis required for alignment at the micro, meso and macro levels of health care and research. Organizing a societal debate (macro level) about the purposes of data reuse was discussed by several professionals, with diverse backgrounds (academic researchers, law, policy, and consultancy experts). Such debates could take the form of e.g., citizen forums at regular intervals or a dedicated platform that provides space for inter-stakeholder dialogue. Additionally, as highlighted by a policy expert, it would be important to start by mapping the interests of all stakeholders and trying to solve potential tensions between the different purposes desired for data reuse: *"Here the purpose limitation principle would play a key role"* (I1).

Can value be measured?

All participants found this question the most difficult. Most patients focused on quantitative measurements related to treatment or interventional research settings (e.g., patient-reported outcome measures). They opined that, in contrast, qualitative measurements might be more relevant for secondary use of data, but could not provide concrete examples.

Most professionals agreed that value can be measured after projects are completed. In this respect, peer review and publishing research results was again cited as important, as well as the demonstration of either implementation of results in clinical practice, or that conclusions (positive or negative) were reached faster thanks to the reuse of data.

Specifically related to the operationalization of the EHDS, the majority of all participants concurred that it would be beneficial to have a system or a tool that could help HDABs prioritize addressing data requests related to research projects. Pharmaceutical industry representatives opined that the measurement should be done based on the scientific merit of the proposed study *("is it a research question that can improve patient outcome or healthcare in general?"*, I9) and on whether the project answers unmet medical needs. Law and ethics experts reminded that prioritizing might be easy in a global crisis (e.g. COVID-19), but warned about the ethical challenges of prioritization in general, e.g.: *"You may say, well if it's a larger patient pool then that should go first, but unfortunately, I think it's actually the smaller patient pools that have the highest priority because the impact for that small group can be highest"* (I8). Most professionals found an existing tool that measures the public value of data (re) use (PLUTO)[12] to be a possible way forward for prioritization, but only two had already explored it in practice. All participants agreed that patients should be involved in the development of any value measurement tools.

[12] PLUTO is a tool for assessing the benefits and risks of specific instances of data use. The weighing of risks and benefits results in a score that indicates the public value of data use. It was created by a team of researchers at the University of Vienna, for more information see reference [27].

Table 4 High level summary of the study's results

Main themes	Subthemes	Patients' and professionals' perspectives
The value of data reuse	*Stakeholders' understanding*	- Value was recognized at both 1) individual (e.g. better care) and 2) collective (e.g. enabling scientific research) levels - Importance of balancing individual and collective value through respect for fundamental rights was emphasized
	How to realize value in practice	- Through the use of data - Through collaboration among all stakeholders, with the patients' at the center - By reaching alignment among all stakeholders on the purposes for data reuse (e.g., via societal debate)
	How value can be measured	- Identified as the most difficult question for all participants - In relation to the EHDS, the majority agreed that a system or a tool to support the HDABs in prioritizing data access requests would be beneficial, and that patients must be involved in the development of any value-measurement tools
Expectations and perceptions about the EHDS	/	- The majority had positive expectations, including that the EHDS would facilitate the conduct of research and help address existing legal, regulatory and technical barriers to data sharing and cross-border collaboration - Professionals highlighted possible implementation challenges, such as the anticipated high workload for HDABs - Patients expressed concerns about risks of data misuse or breaches of fundamental rights if law enforcement and security measures were insufficient
How to put the EHDS into practice	*Willingness of patients to share data*	- A general willingness among patients to share data for research purposes was noted
	Transparency	- Transparency was considered essential for the EHDS implementation and discussed at both societal and individual levels - Societal level: there was consensus on the need for a national information campaign and education of all levels of society about health data reuse. Key roles were identified for national and local authorities (particularly HDABs), hospitals, health insurance funds, patient organizations, and media - Individual level: participants noted the importance of providing understandable, tailored information and capturing individual preferences regarding whether to receive information, at what level of granularity, and in which format. Several ideas how information should be provided were discussed: 1) digital means (e.g. portals), 2) non-digital means (e.g. letters by post), 3) with the support of intermediaries (e.g. hospital desks), and 4) via the HDABs (e.g. awebsite)
	Patient involvement in data-driven research	- All participants valued patient involvement in research, although professionals generally attributed a more limited role to patients in the secondary use of data - In the EHDS context, involvement was discussed at two levels: individual and collective - Opt-out from the secondary use of data was considered the main mechanism for exercising individual control. The importance of informing society about opt-out and its consequences was emphasized. Three approaches to offering opt-out were discussed: 1) digital (e.g. an app), 2) non-digital (e.g. orally via an intermediary), and 3) hybrid (e.g. to allow people to choose between digital and non-digital ways). Most patients strongly supported granular opt-out - Avenues for collective patient control included: 1) participation in data governance (i.e., collaboration of patient representatives with the HDABs), 2) access to data for patient-led research; and 3) involvement in information and communication activities about use of data and the EHDS. Challenges and risks were identified, e.g. the fragmented landscape of patient organizations and the limited time and financial resources

Expectations and perceptions about the EHDS

All participants expected that the EHDS implementation would bring positive changes in the field of research. The majority were enthusiastic about the new law, and several saw it as recognition of the value of data reuse by the EU legislator. The general expectation was that the EHDS will facilitate the conduct of more research, and that it will help solve existing legal, regulatory, and technical barriers to data sharing and cross-country collaborations.

Professionals discussed possible challenges for the implementation of the regulation. Namely, 1) for HDABs: the high workload they may experience, and related to it, the possible difficulties in addressing and prioritizing data access applications; 2) for data holders: difficulties in providing individual level information to patients about the use of their data. One legal expert was critical about the current detachment between the rules regulating data reuse (such as EHDS) and the rules governing access to medicines: *"People don't have access to the medicines they need. So, what do we need to do? First create a European health data area or ensure that everyone has access to the essential medicines they need?"* (I26).

Patients shared their fears related to the new law, namely risks of data misuse and breaches of their fundamental rights if strong law enforcement mechanisms and robust security measures are not ensured. As one patient emphasized, the EHDS "*creates many advantages, but at the same time you have to be aware of it and deal with it critically, and continue to do so in the long term.*" (P5).

How to put the EHDS into practice

Willingness of patients to share data

All patients were positive about their data being shared and used for research that could benefit society, provided that sufficient safeguards are put in place to protect their rights. They also believed most other patients

would share the same view but showed understanding and respect towards individuals who might have differing opinions (e.g., too scared to share data). Most patients opined that the willingness to share data is influenced by factors such as trust in the system overall, transparency about data reuse, patient involvement in the governance of data, strong law enforcement, and the personal desire for solidarity.

> *"There is a real desire on the part of patients to contribute, and yes, there are fears, but that doesn't necessarily prevent them from wanting to contribute. There is a real desire for solidarity, which ties in with what we said about information, the importance of information and involvement." (P10).*

Whether the research was conducted by academic or commercial entities was not an influencing factor in itself for patients. They were supportive of commercial research, but only if conducted under certain conditions: 1) it is done to benefit society, and not solely for the profit of the company, 2) the privacy of the patients is well protected (e.g., companies should use pseudonymized or aggregated data), and 3) that there is ethical oversight.

Some patients also voiced opinions on whether the country where the research takes place could influence their willingness to share data. They mostly reported trust in the Belgian system, but believed that other countries might not have the same protections.

> *"I think Belgium is well protected (…) but that's not always the case in other countries, even in Europe, and there's still work to be done there." (P4).*

Similar to patients, all professionals believed that there is a general willingness to share data. A few had personally experienced that patients are less willing to share with commercial entities, but explained this and other fears with a possible lack of understanding of how research is conducted.

Transparency

Both professionals and patients unanimously considered transparency as key for putting the EHDS into practice, but also acknowledged it is a challenging task due to the different levels of digital and health literacy in society.

All participants discussed transparency at two levels: 1) how to provide information about the new law to society as a whole, and 2) how to provide information to individuals about data reuse occurring via the EHDS mechanisms.

Societal level At societal level, participants aligned on the need for a national information campaign that should reach people from all types of backgrounds and age, both patients and healthy citizens, and including children. Some of the patients in our focus groups had already been involved in efforts to bring awareness to society about the EHDS, e.g. through the creation of educational materials. Patients were conscious that the topic of data reuse was likely distant for many citizens.

> *"I can also imagine that for many people it's [EHDS and data re-use] really far removed from their lives. And that they're not immediately interested in it. It remains unknown to a large proportion of patients. I do think that those who have metastases will be more interested in it and pay more attention to it." (P1).*

Varied proposals on who should be responsible for this campaign, and how it should be organized were discussed. Key roles were identified for 1) the national and local authorities, and particularly the health data access body, 2) hospitals and healthcare providers, 3) health insurance funds, 4) pharmacies, 5) patient organizations, and 6) media (national and local TV, radio, newspapers, social media). All information channels were considered of equal importance, and a combination between different approaches was agreed as optimal, recognizing the important role of doctors as first point of contact, as well as of patient organizations: *"they could keep you informed about what's happening and about new European or Belgian regulations,* etc. *They might be better placed to do this than the mainstream press or social media, as they're really on the ground."* (P1) Most participants considered that the HDAB and other authorities should support patient organizations in fulfilling their transparency mission.

The use of flyers, videos, infographics, and movies, including fictional scenarios that deal with the topic of data reuse in an everyday setting, was frequently mentioned. With respect to the content of the information campaign, patients strongly emphasized the need for concrete, real-life examples of how the EHDS impacts citizens, what rights it provides them, and how they can be involved in the new system. Most professionals focused on the necessity to inform about the benefits and risks of data reuse, the purposes for its use, how data would be protected, and the patients' rights. A few law and ethics experts stressed the importance of organizing a multilingual information campaign – in the three national languages of Belgium (French, Dutch, German), but also in English: *"(…) so that* [it reaches] *individuals not only from the three linguistic areas of the country but those that are coming through from other Member States, that would actually facilitate the free movement of persons within the countries (…) and it's also consistent with the efforts to revise the medicine's legislation to allow*

electronic package leaflets available in any of the languages within the EU for the individual." (I8).

In parallel to a campaign, long-term efforts towards educating all levels of society about the reuse of health data were highlighted as crucial by both professionals and patients. Particularly, education targeting citizens and physicians, as well as children and young adults in school.

Individual level At an individual level, the majority of patients warned again about accessibility and literacy constraints among some population groups and highlighted the importance of giving information that is understandable and adapted to the needs of individuals.

> *"(…) there is still this problem of understanding. I'm a self-confessed dunce when it comes to science. You tell me that you're using my data to see because I have a certain type of cell or God knows what… Once again, I don't understand. So if I receive a notification that my data is being used for a certain type of research, I would expect a very simplified explanation so that I can understand what it's for. Otherwise, we receive a notification… Frankly, it wouldn't be of much use to me." (P8).*

The majority of participants noted that the preferences of individuals on whether, or not to receive information about the reuse of their data, at what level of granularity, and in what format, are important to capture, as they might vary. This was reflected in our sample: e.g., whereas some of the patients found it very important to receive feedback about each project that uses their data, others saw such an approach as too overwhelming. Moreover, around half of the patients wanted to know not only that their data is used, by whom and for what type of project, but also whether value had been created thanks to the data reuse: e.g., whether a new medication had been developed, or whether the study had consequences for the treatment of the patients who contributed data.

The variation in patients' preferences was explained both with personality, as well as with the stage of treatment a patient might be in. For example, in the words of P7: *"when you're dealing with cancer and treatment, you're mainly focused on saving your life and managing the side effects. Would I have wanted to worry about what my data was being used for?"* However, most participants acknowledged that capturing preferences (which may also change over time) might be difficult due to a lack of human and financial resources, and technology constrains. A legal expert working at a hospital provided an example from their own experience with a portal to inform patients: their hospital provides granular information in the portal, but leaves it up to the patient to decide whether they want to know all details.

With respect to how the information should be provided, participants had several main ideas, which ideally should be available as complimentary: 1) via digital means—e.g., portals (either existing ones such as the Belgian Ma Santé and Cozo; or specifically created); 2) via non-digital means – e.g., a letter by standard post, 3) with the support of intermediaries – e.g., at newly created hospital desks, with the information explained by paid or volunteering individuals, specifically trained on the topic, in collaboration between hospitals and patient organizations, 4) via the HDAB (e.g., website, newsletter)—particularly in the case of informing about the benefits achieved by using the data.

Most representatives of the pharmaceutical industry, policy, law, and consultancy discussed the importance of balancing how much information to provide, so that patients are sufficiently informed without being overburdened. In this respect, a policy representative made the following comparison: *"I often give the metaphor or rather the comparison with the aviation industry: as the individual person who is the passenger on the plane, I don't understand how the plane operates, I don't understand how it can fly, it's magic for me, even if I was taught at school it was theoretically possible. But at the same time stepping into the plane, I understand that there is a governance structure which makes this secure, which makes this safe for me, because there are the regulators, there are the institutions which are assessing the industry itself and also the aviation companies. So, (…) with health research, we should have the information which is given to the patient, which is understandable for him or her, but we should also have the transparency understood as the larger process of delivering the data to the assessment authorities, even if sometimes these data can contain the information which shall be confidential."* (I1).

Patient involvement in data-driven research

In general, all participants valued patient involvement in research, but held different opinions with respect to its application in primary versus secondary use of data. For around half of the professionals, involvement was particularly important in primary use (e.g., in the design of clinical trials, the prioritization of what interventional research to be conducted, or in the provision of health care) due to the higher perceived risks for patients as study subjects. However, they were less in favor of it when it came to secondary use of data—some expressed the view that there might not be a need for it as the data has already been collected and the risks for the patients from its reuse are minimal. Nevertheless, patients found involvement equally important for both primary and secondary use of data.

Related to secondary use under the EHDS specifically, patient involvement was discussed at two levels: 1) individual (i.e., control over the use of a patient's own personal data by exercising the rights afforded to them by the GDPR), and 2) collective (i.e., involvement of patient representatives in the governance of data).

Individual control and Opt-out According to most professionals' experience, prior to the EHDS, patients rarely exercised individual control over their data in a research setting. If they did, it was mostly to have access to their data, or to request its deletion. Some explained it with the patients' priorities during treatment: *"once you're at a point that you're only thinking of getting out of a certain situation, I don't think control is still your first worry".* (I24).

Patients in our study reported that they valued individual control. They linked it to two tools particularly: 1) being well informed, and 2) consent. For some, individual control was equated entirely to consent. Several reported feeling out of control due to insufficient transparency or difficult communication, e.g. according to P8 some doctors *"don't explain things clearly enough"*.

In the context of the EHDS, all participants considered opt-out the main mechanism for exercising individual control for secondary use of data, and supported the choice of the legislator to offer opt-out. Patients didn't personally plan to use it, but some appeared to not fully understand what opt-out meant and confused it with consent. Around half of the professionals were concerned whether patients in general would understand the impact of opting-out from research (e.g., mass opt-out could lead to less representative datasets), and most participants emphasized the importance of informing society about opt-out and its consequences: *"Patients need to be properly informed so that they don't become mistrustful, which is understandable. When we don't know what's happening with our data, we're afraid, and that's when we want to opt-out without necessarily realizing all the benefits it can bring."* (P10).

With respect to how opt-out should be offered in practice, patients suggested three main approaches: 1) digital – e.g., as part of existing systems, or in a new app; 2) non-digital (oral via an intermediary, or in paper) – e.g., at hospitals or at the general practitioners, and 3) a hybrid approach: *"I think you have to (…) let the people involved choose which option they want. They can choose digital or just a paper form. The choice should be up to the participant, not the government."* (P1).

Most patients strongly supported granular opt-out. Namely, they would value the possibility to opt-out e.g., per type of research, per type of stakeholder using the data (e.g., academic or commercial), or per country which would have access to the data. Some professionals agreed, particularly for offering the option to opt-out per type of data use. However, the majority of experts were in favor of general opt-out, as they perceived it less burdensome technically and easier to organize.

Collective control All participants valued collective patient control over data (i.e., patient representatives' participation in data governance), and considered it one of the ways to realize the value of data reuse for patients (Sect. 3.2.2). Moreover, some believed that collective control could help stimulate less use of opt-out from the secondary use of data within the EHDS. However, none of the professionals had previously involved patient representatives in decisions about the reuse of data. Only in the experience of one legal expert, several life sciences companies who they worked with had engaged patients in the conduct of data protection impact assessments, prior to the start of research projects. For patients, collective control helped increase their willingness to share data (Sect. 3.4.1) and was considered particularly important in view of the fact that when one is dealing with disease, sometimes individual control might be difficult or burdensome.

With respect to the EHDS, participants found avenues for collective patient control in: 1) data governance (i.e., collaboration of patient representatives with the HDAB), 2) data access and use, i.e., for patient organizations themselves to have the opportunity to conduct research on data they consider relevant; and 3) involvement in organizing and providing information to individuals and society about use of data and the EHDS (Sect. 3.4.2).

The majority of professionals believed that involvement of patients in the HDAB should be only high level—related to strategic decisions, setting up goals, or the prioritization of purposes for which data must be made available—but not at granular level (e.g., involvement in the assessment whether a data permit should be issued, or not).

Challenges and risks of collective control were identified. Some patients acknowledged that at present, the landscape of patient organizations in Belgium is very fragmented. However, others expressed concerns that even with an umbrella organization, it would be *"difficult to speak on behalf of the entire population"* (P1), a general worry about representation also shared by most professionals. Moreover, it was also emphasized that patient representatives need to be trusted: *"it still means trusting people who we need to be sure won't make random decisions about our data, who are objective and who aren't influenced by other people"* (P7).

Patients and professionals also opined that the current approach to patient involvement, which is often voluntary, on top of other personal and professional commitments, and frequently without or with minimal remuneration, makes it difficult for patients to contribute.

Therefore, patients found it crucial that patient organizations are given sufficient means (time- and budget-wise) to be involved in the EHDS mechanisms, and that there are guarantees to ensure that the voice of the patients is considered in practice, not merely heard.

Discussion

This multi-stakeholder qualitative study unveiled a broad consensus around the value of data reuse in health research, while also illuminating what patients value with respect to how data reuse is conducted and organized, inter alia: transparency about the reuse and feedback on the results of data-driven research, collaboration between all stakeholders, and patient involvement in data governance. Furthermore, the study offered the first in-depth investigation into expectations and perceptions about the EHDS implementation in Belgium, as well as concrete ideas how patients' values could be embedded in the new framework.

The core values and preferences expressed by patients regarding health data reuse (Table 4) map onto foundational bioethical principles, including human dignity, autonomy, justice, and fairness. They also echo recent empirical work, which emphasized the importance of embedding citizens' values and participatory governance into the implementation of the EHDS [11, 16, 28]. In this regard, our study provides starting points on what values are at play and how they could be incorporated into the new data sharing ecosystem.

The participants' recognition of the value of data reuse at both individual and collective levels, as well as across levels (e.g., precision medicine)[13], aligns with existing literature and EU policy discourse [30–32]. However, legal and pharmaceutical industry experts stressed the importance of balancing individual and collective interests, alongside the protection of patients' fundamental rights, echoing broader academic and policy discussions on the EHDS [13, 31, 33, 34].

Defining and measuring value has been difficult to articulate, both for participants in our study, and for the academic community at large. In one conceptualization, Prainsack et al. coined the notion of "public value", which is created when the use of data benefits people without posing heavy risks [35]. Under their proposed framework, data uses that are likely to benefit the public considerably but pose no heavy risks should be supported, whereas data uses that pose grave risks while creating little or no public value, should be prohibited. Others have sought to capture the multifaceted nature of value creation in the health data ecosystem by e.g., describing a typology of what data enable us to do (diagnose, predict, aggregate, intervene), arguing that these functional dimensions may help guide evaluations of data use [36]. As in our study, where participants struggled to identify clear metrics, past empirical attempts have encountered similar difficulties [37, 38]. Considering this, our participants' call for transparency about reuse outcomes and participatory evaluation resonates with efforts to move beyond narrow metrics toward broader, socially grounded notions of value creation.

Study participants mostly expressed optimism towards the EHDS and what it could mean for advancing health research, but remained vigilant and critical about its practical implementation and possible limitations, thus supporting the findings of other studies conducted across the EU, or nationally (e.g. Ireland) [12, 39]. The patients' high willingness to share data, as well as the factors influencing it – e.g., trust in the system, transparency, patient involvement, strong law enforcement – corresponds with past results about public support for data sharing as outlined in a recent meta-analysis on worldwide tendencies by Olsen et al., and with EU and national surveys [40–43]. In contrast to attitudes demonstrated elsewhere [41], patients in our project were not negative towards data reuse for research conducted by commercial entities per se. They supported it, but under certain conditions (benefit for society, well-protected privacy, ethical oversight). Additionally, sufficient understanding about the conduct of research was emphasized by professionals as a possibly decisive factor, which links with other scholars' findings about the importance of education as well as digital and health literacy [42].

Zooming in on building the EHDS in practice, participants focused on how to operationalize transparency and patient involvement. Feedback about the research results was highlighted as crucial and a way to both demonstrate the value of data reuse, and bring value to patients themselves, something which the EU legislator has considered in the EHDS and established among the obligations of the HDABs[14]. The need for an inclusive communication strategy, involving various stakeholders in its execution, has been highlighted in literature in e.g., the studies and recent guidelines prepared by the Towards the European Health Data Space (TEHDAS) project [44, 45].

Additionally, patients recognized transparency as a prerequisite to and part of being in control of their personal data at both individual and collective levels, in alignment with the scholarly understanding of the concept

[13] Precision medicine benefits from embedding a learning loop in which real-world care outcomes inform hypothesis generation and model refinement, and newly derived insights are then translated back into clinical practice, shortening the bench-to-bedside cycle. See, for example, reference [29].

[14] Article 58(f) and (g) EHDS prescribe that HDABs should provide information on "who has been granted access to datasets of electronic health data and to which datasets they were granted access and details of the data permits regarding the purposes for processing such data as referred to in Article 53(1)" and "*the results or outcomes of projects* for which the electronic health data were used." [authors' emphasis]

[13, 46]. Patient control over data was valued by all participants, although individual control was demonstrated to be rarely exercised, confirming past studies among patients and consumers in the EU [13, 47, 48]. Such rare occurrence has been explained elsewhere with e.g. lack of awareness about the rights, insufficient transparency about the use of data, and the unique and vulnerable moment at which reuse of data occurs for patients – when their priority is to receive care and treatment [9, 49, 50].

Under the EHDS framework, participants discussed opt-out as the only way to exercise individual control for data reuse and largely supported the choice of the legislator in establishing the mechanism. The tensions highlighted (e.g. granular versus general opt-out) and the recommendations made by participants have been recognized in the TEHDAS2 draft guidelines on opt-out [45]. The guidelines confirm that under the EHDS provisions, granular opt-out is possible, although not required – leaving the choice to each EU Member State and emphasizing the need to weigh its usability and cross-border interoperability. Importantly, TEHDAS2 has underscored that opt-out is not a mechanism to engage patients, but a "fundamental safeguard to protect autonomy".

Among the participants, collective patient control over data was demonstrated to rarely occur in practice: none of the professionals engaged with patients in the governance of data reuse, unlike established practices for patient involvement in interventional research. Under the EHDS, the value of patient involvement has been recognized and the HDABs are prescribed to "actively cooperate with relevant stakeholders' representatives, especially with representatives of patients (…)".[15] However, the formulation of the provision lacks further specification, which might jeopardize its implementation in practice. The Belgian HDAB - the Health Data Agency – has already recognized the importance of citizen participation at individual and societal levels [51]. It involves representatives of all stakeholders in their working groups, taking their perspectives on the high-level implementation of the law [52], similar to what was the preference expressed by most participants in our study. In their patient consensus on Data and AI, the Melanoma Patient Network Europe (MPNE) also recently advocated for the broadest possible stakeholder engagement, involving patients, healthcare providers, researchers, innovators, the commercial sector, policymakers and other relevant actors to ensure legitimacy of the system [53]. Similarly, Bedenik et al. found that patients support involvement but need clearer infrastructures to make participation meaningful [11]. Best practice requires remuneration, capacity-building, evaluation of influence, and transparent feedback loops.

Previous research has demonstrated that responsible governance with respect to data reuse—and the EHDS in particular—hinges on the recognition of different and at times competing goals, interests, and requirements, and that considering contested notions of value is essential [15]. An ongoing societal debate, as proposed by some of the participants in this study, is key in this regard and urgently needed. National deliberative experiences provide practical models. For instance, in France, the bioethics debates organized by the Comité consultatif national d'éthique have demonstrated how large-scale public consultation can shape sensitive biomedical policies [54]. More recently, France organized a citizen committee of 30 participants randomly selected across the country, who convened to examine how the EHDS could be best implemented [55]. The committee set out a wide range of recommendations (52 in total), including such aligned with the views of the participants in this study: e.g., related to transparency, information and education; user-centric control mechanisms, and citizen role in governance and ethics. Another example pertains to social licensing and its practical toolkit for implementation, as proposed by Verhulst et al. [56]. It provides a participatory framework through which communities can define, document and – where possible – enforce conditions for how data about them is reused, thus shifting data practices towards community-centered governance.

If pursued seriously, such deliberative infrastructures can reconcile the strong enthusiasm for data reuse we observed with the equally strong demand for rights-respecting, trustworthy governance. Building a multi-layer patient and citizen involvement framework, while also investing in multi-stakeholder engagement at a societal level, would be crucial for realizing the promises of the EHDS.

Patient-researchers' involvement in this study

Patient-researchers were substantively involved across all phases of the study and played a concrete role in shaping its design, analysis, and interpretation. Their input led to revisions of interview guides and focus group materials, helping ensure that questions were meaningful and accessible to patients with varying levels of experience and knowledge about health data reuse. During data collection and analysis, patient-researchers contributed through observation, co-facilitation, pilot coding, and structured debriefings, which sharpened the interpretation of findings and helped surface insights that may have been overlooked by academic researchers alone. At the same time, barriers were encountered, including varying levels of comfort with leading discussions on a technically complex topic and the voluntary nature of

[15] Article 55(4) EHDS

involvement, which limited sustained engagement for some of the patient-researchers. Overall, the integration of lived experience with academic and professional perspectives enhanced the credibility, relevance, and interpretative depth of the study.

Strengths and limitations

The main strength of this study is that, to our knowledge, it is the first to investigate how the EHDS implementation is prepared within the Belgian health research system and what oncology patients in Belgium value with respect to data reuse. It is also among the first studies at EU level to involve patients on the EHDS topic. The study addresses topics that are key for the design and development of new structures introduced by the EHDS, such as the HDABs, and new mechanisms, such as the right to opt-out from the secondary use of data. It is further strengthened by the diverse representation of stakeholder groups, as well as by the transdisciplinary methodological approach, i.e. the conduct of the study in collaboration with patient-researchers and experts with various disciplinary backgrounds, and the employment of a sequential qualitative design.

While this study is situated in Belgium, it offers insights that are transferable to other European contexts. The findings highlight common tensions—such as balancing individual control and collective benefit, operationalizing transparency, and embedding patient involvement—that are likely to recur across Member States. As such, the study provides a methodological and conceptual template for comparative research on EHDS implementation and health data governance across Europe.

However, the study reached a smaller patient sample in comparison to the interviewed professionals. This could be explained with the chosen sampling strategy, but may also reflect the differing levels of awareness and interest among patients in the topic of data reuse and the EHDS. More than half of the focus group participants were experienced on the topics of data reuse and patient involvement, which may not reflect the general cancer population. In addition, while cancer patients are a group with a high interest in health data reuse, the perspectives of patients with other diseases, particularly chronic diseases, may differ significantly. Moreover, no foreign patients residing in Belgium joined the focus groups.

This study provides a basis for future research that should bring all stakeholders together in a dialogue (e.g., in mixed focus groups), targeting patients from diverse disease areas as well as healthy citizens, and by employing quantitative approaches to reach a representative sample of the population. Investigations into how the increasing use of AI tools in health research could impact the topics discussed would also be crucial.

Conclusions

This qualitative study offers the first in-depth analysis of what patients and professionals in Belgium value with respect to the reuse of health data, with a specific focus on oncology research and the implementation of the EHDS. The interviews and focus groups unveiled a broad consensus around the value of data reuse in health research, recognized at both individual and collective levels, while highlighting the importance of safeguarding patients' fundamental rights and interests. The results also illuminated what patients' value with respect to how data reuse is conducted and organized, and offered an investigation on the expectations and perceptions about the EHDS implementation in Belgium, as well as concrete ideas how patients' values could be recognized in the new framework. The findings underscore that the legitimacy of the EHDS will depend on embedding patient values into its design and implementation. This requires a multi-layered approach: strengthening education and communication at a societal level, respecting individual preferences regarding information and control, and enabling collective patient involvement in data governance. The study provides insights that could support policymakers, practitioners and researchers with the implementation of the EHDS at national and EU levels in a value-oriented manner, and offers ground for comparative research and collaborations within the EU and globally.

Abbreviations

AI	Artificial intelligence
DPO	Data Protection Officer
EDPS	European Data Protection Board
EHDS	European Health Data Space
EU	European Union
GDPR	General Data Protection Regulation
HDAB	Health data access body
TEHDAS	Towards the European Health Data Space

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13690-026-01884-5.

Additional file 1: Completed COREQ checklist.

Additional file 2: Completed GRIPP2 checklist.

Additional file 3: Interview guide.

Additional file 4: Focus group questionnaire.

Additional file 5: Focus groups demographic survey.

Additional file 6: Focus groups introductory presentation.

Additional file 7: Coding tree.

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Authors' contributions

TLS conceived the idea for this study and designed it, with feedback on materials from SL, FH, MS, PC, IVZ, LB, BC, WD, BT. Data collection: TLS, IVZ, PC. Data analysis: TLS. TLS wrote the first draft of the manuscript. All authors reviewed and agreed with the manuscript.

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Data availability

The datasets generated and/or analyzed during the current study are not publicly available due to legal and ethical constraints. Study participants did not provide consent for the sharing of interview and focus group transcripts with parties other than the researchers. The transcripts cannot be made available, to make sure that the confidentiality and privacy of participants are preserved.

Declarations

Ethics approval and consent to participate

The study, part of the Symphony of Us project, received ethical approval from the University of Antwerp, Ethics Committee for the Social Sciences and Humanities, file ex_SHW_2023_48_1. The study was conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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