Additional file 3: Interview questionnaire

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

Opening questions:

- Can you tell me a little bit about yourself - your background and current role?
- What is your experience with oncology research and secondary use of health data?

Research-specific questions:

Topic I. Data governance, public value, patient value	
Q1	The success of new frameworks for data re-use, such as the European Health Data Space, will depend on the establishment of a strong data governance mechanism, fully compliant with the GDPR and that provides for sufficient assurances of a lawful, responsible, ethical management anchored in EU values, including respect for fundamental rights. One of the approaches to data governance in health research that has gained the interest of scholars in recent years is data solidarity. Solidarity is defined as a practice that comprises people's commitments to supporting others with whom they recognize similarity in a relevant aspect. Solidarity-based data governance is one which ensures that the benefits and costs of data use are borne collectively and fairly. Data solidarity's focal points are harm prevention and the creation of public value by specific instances of data use. Public value is created when the use of data benefits people without posing heavy risks. Under a data solidarity framework, uses that are likely to benefit the public considerably, and which pose no heavy risk, should be supported, whereas data uses that pose grave risks while creating little or no public value, should be prohibited. **What do you think about the possibility to rely on a data solidarity approach when re-using personal data for oncology research?** **Please discuss from the point of view of 1) your current work, and 2) the future, when we will be implementing the EHDS?** *[for participants who might not know about the EHDS, a short description of its objectives will be provided:* *The EHDS is a new EU law that aims to empower individuals to take control of their health data, facilitate the exchange of data for healthcare across the EU (primary use of data), and provide a trustworthy system for research, innovation, policymaking, and regulatory activities (secondary use of data).*

Q2	In our project, we aim to conceptualize the notion of "*patient* value" in oncology research, including data-driven research. **When you hear the notion of "*patient* value", how would you personally define it in relation to the use of personal data for oncology research?** Supporting questions, in case the interviewee finds this question challenging: - What elements do you think could be important part of the concept "patient value"? - How do you think the use of data can bring more value to patients? And how can we measure value?
Q3	**How could we achieve an alignment between the public/patient value(s) and the values of other stakeholders (e.g. commercial actors) when it comes to use of personal data for scientific health research?** Follow-up question: - How can we assure that the patients' interests prevail?
Q4	**In your current role, what do you do (alone and/or in collaboration with other stakeholders) that in your view contributes to patient value?**
Topic II. Lawful (re)-using personal data for oncology research	
Q5	The EU General Data Protection Regulation and the Belgian Data Protection Act provide a list of legal bases and special conditions that legitimize the use of personal data. For example, consent of the individuals, public interest, or the legitimate interests of the entity which will be using the data. **In your experience, do you (or your institution) have a preference for a specific legal basis and why?**
Q6	**What is your understanding of the concept "public interest", for instance conducting scientific health research in the public interest?** Clarifying and follow-up questions: - What do you think should be considered as public interest? - How do you think public interest has been interpreted so far in practice?
Q7	**What is your understanding of the concept "scientific health research"?**
Q8	The Joint Action Towards a European Health Data Space (TEHDAS) reported that citizens' values should inform what constitutes the common good when health data is used for secondary purposes, such as oncology research. **In your view, how can this be achieved, for instance in the future implementation of the European Health Data Space (EHDS)?** *[for participants who might not know about the EHDS, a short description of its objectives will be provided:* *The EHDS is a new EU law that aims to empower individuals to take control of their health data, facilitate the exchange of data for healthcare across the EU (primary use of data), and provide a trustworthy system for research, innovation, policymaking, and regulatory activities (secondary use of data).*
Topic III. Role of research ethics committees	
Q9	Research ethics committees play a meaningful role in ensuring that the respect of human rights and underpinning values, including the right to data protection, is embedded in research projects from the early stages. One of their main

	responsibilities is also to assess the proportionality of potential risks against benefits of research for the citizens. **What could be the biggest challenges and opportunities related to the role of ethics committees in: 1) data protection, and related to this** **2) capturing what is of value for patients when personal data is (re)-used for oncology research?**
Q10	**When it comes to capturing patients' and citizens' values for informing the notion of "public interest", what role do you think ethics committees could play?**
Question only for stakeholders involved in the implementation of the EHDS	**What role will be foreseen for ethics committees in the Belgian implementation of the EHDS?**
Topic IV. Transparency about (re)-using personal data in oncology research	
Q11	Being informed about the processing of one's personal data is crucial for enabling individual data control. **What do you think are the key challenges when it comes to informing patients and citizens about the (re)use of their health data for oncology research, both at present and in the future within the EHDS framework?**
Q12	**In your view, what could be the ideal way to keep patients informed about the (re)use of their personal data for scientific research, including in the scope of the EHDS framework?**
Q13	Some patients might not want to be informed about the re-use of their data, for instance in order not to be reminded about their disease pathway. **To respect the diverse preferences and sensibilities of patients, could we think in the future of a right not to know about the processing of personal data related to health, similar for instance to the right not to be informed of the results of genetic examinations*?** Follow-up question: - In which ways it would be possible to determine patients' interest in being informed about the re-use of their health data? * reference if asked: UNESCO Universal Declaration on the Human Genome and Human Rights, Article 5c
Topic V. Data control and patient empowerment (involvement/engagement)	
Q14	The notion of data control is central to the fundamental right of data protection and to the GDPR. According to literature, control can be achieved through tools to decide at a granular level about what is done with the individual's personal data. Such tools could be understood to be individual (e.g., consent, individual data subject rights) or collective (e.g., enriching individual tools with collective actions, data intermediaries, patient representatives engagement in decision-making…).

	What is your view on data control (both individual and collective) in the context of oncology research?
Q15	**In your view, how could data control contribute to orienting the oncology research system towards more patient value and patient empowerment?** Follow-up question: - What about the patients who refuse to be in control?
Q16	There is an ongoing discourse in literature about the importance and pitfalls of individual vs collective data control tools. The patients' awareness, knowledge, and preferences about data control also significantly vary. While some may wish to be involved at a very granular level with whom their data is shared, and for what types of research it is used, others might prefer to have no involvement at all, or to delegate control to others (such as data stewards or patient representatives). **What could be an (ideal) way forward to navigate individual and collective control, while respecting patients' preferences and values during the implementation of the EHDS?**
Only for hospitals	**Are patients represented in the board of directors of the hospital, or in other decision-making bodies?**
Topic VI. Guiding frameworks for research and technology development: the 8 caring technology principles	
Q17	The EHDS regulation stresses the importance of adhering to ethical principles in the application of the new law. In particular, the law mentions the examples of the European ethical principles for digital health adopted by the eHealth Network and the principle of health professional-patient confidentiality. **What factors would you deem important when selecting which guiding principles-based frameworks would be best to follow when (re)using personal data for oncology research?**
Q17	**Which ethical guidelines or principles-based frameworks do you follow in practice?** Follow-up question: - Who decides on this? Your institution, an ethics committee, or other?
Q18	We shared with you the text of a novel framework originating in Belgium – the 8 caring technology principles (8CTPS) – that strengthen responsible health technology innovation through prioritization of the needs of users and society, data security, equity, participatory governance, and quality control. The principles are built on three central overarching values: autonomy, justice, and trust. **What is your view on the 8CTPS framework in general, but also with respect to the EHDS?** Follow-up/clarifying question: - What role do you think the 8CTPS could play in strengthening individual and collective data control in the context of oncology research and re-use of health data?
Q19	**What role do you think the 8CTPS could play in orienting the oncology research system towards more patient value?**

	Follow-up/clarifying question: - What role do you think the 8CTPS could play for fostering alignment between patients'/citizens and other stakeholders' values when it comes to (re)using data?

Closing questions:

- Do you have any further comments or issues which you think may be relevant for this study?
- Do you have recommendations for other experts to interview on these topics?
- Do you have any questions for me?