Additional file 4: Focus group 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

Part 1: Data re-use

1. **How do you feel about your health data (e.g. data collected in the hospital when you were receiving treatment) being used in research?**
   Follow-ups:
   - *1.1.* Do you feel different depending on the people or countries using your data? For example, imagine you were treated in Belgium, and researchers in Germany or Spain wanted to use your data to improve treatment. Would that feel different from your hospital using it? Or what about a private pharma company versus an academic researcher versus a developer of a medical device?
   - *1.2.* *If participants feel different* - What about it makes you feel differently?

2. **What do you see as potential benefits and risks when your data is used for research?**

   Follow-ups:
   - 2.1. Do you feel differently about your data being shared for research in the existing ways (e.g., researchers have to apply to each individual institution to get access to data) versus what the European Health Data Space promises (researchers need to apply only to one institution – the health data access body, who then makes possible the access to data)?
   - 2.2. What (if anything) makes you excited about your health data being re-used under the EHDS? What opportunities (e.g. for research) do you see?
   - 2.3. What are your fears about data sharing and data re-use? (*could be both about currently, and about the future with EHDS*). If any, do these fears differ when talking about data (re)use by academic and private company researchers?

Part 2: Patient value

3. **When people talk about the use of health data in research creating "value" for patients, what does that mean to you personally? What would make you feel that sharing your data was truly worth it?**
   Follow-ups:
   4.1 How do you think the use of data in research can bring more value to patients individually, and to society as a whole?
   4.2 Do you associate "value for patients"/"patient value" also with your fundamental rights – e.g., right to privacy or right to data protection? How do you understand these rights, what do they mean to you besides the legal rules?
   4.3 How would you know (or how would you like to know) if your data is used in a way that created value for patients?

4. **When data is re-used in oncology research, how do you think the values (or interests) of patients and other stakeholders (e.g., pharma, hospitals, academic researchers, government…) could be aligned?**
   Follow-ups:
   5.1 What would make you feel confident that your data is being used appropriately?
   5.2 Can private companies (e.g., pharma, digital technology developers…) bring value to patients and how?

5. **How do you think value for patients can be assessed (or measured) when health data is used for research, especially via the European Health Data Space? For instance, who should make the assessment, how can this assessment be made, what the decision should be based on?**

   Follow-ups:
   6.1 For instance, imagine that before allowing access to data, the Health Data Agency starts using a questionnaire/tool to discover whether the benefits of the planned research by a company are more than the risks it could pose to patients (e.g., the data will be protected from being leaked to insurers who can discriminate against the patients). Are there elements you would like to see in such a questionnaire? On what conditions would you trust such a tool for assessment?
   6.2 Or, imagine that any researcher who wants to apply to the Health Data Agency for access to data has to first show and promise that when conducting their research project, they will follow a set of special principles that guarantee that the development and use of technologies improve health, well-being, and overall quality of life. Could this help, and how?

6.3 Imagine that the Health Data Agency will be receiving many requests for all types of different projects. Do you think there is a way for them to prioritize which projects get approved first or faster? And how?

<u>Part 3: Transparency & Patient empowerment/involvement/engagement</u>

6. **In 10 years, the European Health Data Space will be fully functioning. How would you ideally want to see, hear about, or check what is happening with your pseudonymized health data when it is re-used through EHDS ? What could be an ideal way to inform all patients about the use of their data?**

   Follow-ups:

   7.1 For instance, would it be useful if an electronic portal provided an overview of all the projects who received access to your pseudonymized data under EHDS? Or maybe all the therapies that were made thanks to your data?

   7.2 Is there a possibility that you'd prefer to not receive information each time? Why?

7. **The EHDS is now here and in the coming years it is going to gradually bring a lot of changes. What do you think would be the best way to inform all of society about the EHDS itself (not only the use of data, but how EHDS works and what it brings to society and researchers)?**

   Follow-ups:

   8.1 For instance, would you like to see a national campaign about it? What would be the key elements that this campaign should have – should it be on TV, on social media, in the schools…?

8. **As an <u>individual</u>, there are certain ways to control how or whether your data that has been collected for treatment is re-used for research. In the EHDS, the main way to do so is by opting-out of the new system.**

How do you feel about this opt-out model? What risks do you see if people opt-out? Could opt-out bring patient value/value for patients, or the opposite?

Follow-ups:

9.1 What kind of information do you need before making a decision to opt-out or not?

9.2 If you had to decide today, would you opt-out? Why yes/no? What could make you change your decision?

9.3 Would you prefer a general opt-out (you do it once and your data cannot be used for any type of research and by any type of stakeholder – academic, commercial…) or a more granular opt-out (e.g., you will be able to opt-out only from some types of research, but still allow your data to be used for others)?

9.4 Is there an ideal way this opt-out can look like: e.g., electronic, or perhaps should it be enough to register it at an info desk at your local hospital?

9. **Patients can also help control health data use collectively. For instance, the EHDS prescribes that the new health data access bodies such as the Belgian Health Data Agency shall cooperate with with representatives of patients. Another example is about the regular work of research institutes or companies – they could involve patients when they start assessing the privacy risks of a certain project that uses data.**

   What are your views on such collective patient control?

   Follow-ups:

   10.1 Would the collective involvement of patients help you trust more data sharing in general and the EHDS specifically? And why?
   10.2 Could such collective patient involvement in data re-use bring more patient value?
   10.3 Do you see any risks if there is collective involvement of patients in data sharing?
   10.4 What would be the best ways for patients to be involved in decisions about data re-use and data sharing?
   10.5 Would you be interested in having a collective body of patients making decisions about how your data is used and shared (e.g., you give consent once to them, and from then on they decide)?