Supplemental Methods:

Understanding bottlenecks to Swiss data sharing: Interview guide

** Review consent and any potential risks or benefits from study participation (see consent page)

** Overview of study purpose and interview process

Facilitating the sharing of health-related data for research has been identified by numerous scientific, political and economic stakeholders as a key success factor for the future of Switzerland. Several health research coordinating organizations (including SPHN, SCTO, SBP, BCPM) are active in this area, based on national or local mandates.

In our prior work, we have understood that there are many potential bottlenecks to data sharing, some based on real legal, ethical or logistical issues, and some based on unclear areas and/or misconceptions. As such, the main point of this research study is to examine your attitudes towards the bottlenecks in data sharing in Switzerland, and to find out which areas need clarification and/or specific guidance in order to make the process go more smoothly.

1. First, can you tell me a little bit about your specific responsibilities within the pathway to biomedical datasharing within Switzerland (there may be more than one that fit your roles)? How much experience do you have in this/these areas

For example, some of the responsibilities that may come up would include

- Providing data (might be at the level of a PI/project leader or institution)
- Data owner
- Data engineers in specific institutions, responsible for data processing beforehand of data sharing in terms of coding and providing only the data set necessary for the research project
- Person responsible for ensuring data integrity (quality issues)
- Recipient of data
- Hosting the data
- Project coordinators or data manager
- External processor (e.g. Provide or service the platform: BioMedIT or someone else)
- Other service providers (e.g. Genome center)
- Responsibility for data security and protection
- Legal assessment of documents/contracts governing data/sample sharing, intellectual property
- Ethics review of research application dossiers
- Data governance board member that reviews data sharing projects
- Stakeholders who are responsible for interpretation and coordination processes (e.g. us)

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2. What experiences have you had with data sharing thus far?

3. When you started in a position that played a role in data sharing, what tasks were clear to you around your role and also the role of the others around you (how you would work together)? What was not?

4. From the perspective of your role, what are the major areas where you feel you need more information or clarification about data sharing in Switzerland? What are your biggest roadblocks for sharing or receiving data?
**Depending on what they bring up, it's fine to go to some of the prompts that come up below, rather than waiting and going back.

TRANSITION
Now we'd like to get more specific and make sure that we get your thoughts about some of the areas that have previously been identified as potential challenges. So we are going to go into some details. We will address: organization/processes, legal aspects, data privacy, and data re-use.

5. Are there specific worries or uncertainties **about the process or logistics** that you have about the data sharing process? Tell me how you handle these things when they arise.

    a. Can you give us an idea about the actual process of how you exchange data (e.g. do you exchange by cloud, CD-ROM, email, which clouds / email-transfer do you use?
        i. Do you share data and samples both?
        ii. What are the requirements and processes to request a data set for sharing? (or, to process it for external sharing, if that is your role)
        iii. What are the designated points of contacts? Are there points where it is not clear who to communicate with?
        iv. Are you aware of the internal governance points to provide or receive data?

    b. If you receive data from multiple sites for a single project:
        i. how do you deal with the access requirements/technical aspects of the sharing process for samples or data when they are coming from multiple sites that may all have different processes;
        ii. who supports you during this process?
        iii. from your perspective, how does this impact interoperability (data quality impacts study feasibility)
        iv. What would make this easier/smoother for you?

6. Are there specific worries or uncertainties that you or the involved parties have where you **perceive that the law, regulation or policy makes things particularly challenging** for data sharing, or areas where you are unclear how to interpret the meaning of the law? Tell me how you handle these issues when they arise.

    i. How do data/sample ownership issues impact sharing? How do you define ownership?
    ii. How do you view/handle IP issues before sharing?
    iii. How do you handle attribution (publication and distribution of credit) in the context of data exchange?
    iv. What are the potential bottlenecks that you see in private partner/industry sharing relationships?
    v. What contracts or legal documents do you perceive are needed? How can you find the templates, are they useful etc? where are the barriers?
    vi. If you could recommend specific topics that the ELSI advisory group could clarify or have reviewed by legal experts in order for you and your institution to feel more comfortable with the process of data sharing, what topics do you feel most require guidance?
    vii. Applicable law - canton, federal, GDPR - how do you think about these three things in relationship to data sharing?

7. Let's talk about **data privacy issues** and how they impact your experience with data sharing: What issues do you have and how do you handle them?
    i. How do you define when data are considered anonymized/pseudoanonymized (coded)?
    ii. How does this categorization impact the different stages of your data sharing processes? For example, data preparation, the legal review, receiving and storing the data, considering whether recontact is necessary
    iii. What about types of data that may be shared? (genetic vs. non-genetic? Pseudonymized/(coded) vs. anonymous? Individual vs. aggregate? Data from clinical records vs. research records vs. combined sets?)
    iv. If you have done international data sharing, what issues have you faced in either direction? For example, what are the implications of EU GDPR; giving data to US because data protections are lower (easy to get/harder to give), etc.

    In our past research, some people have mentioned that the potential bottlenecks might differ on the basis of specific features of the **consent process**. Can you comment on this aspect?
    v. What are your thoughts about the way in which potential recontact of participants could impact data sharing?

vi. What concerns, if any, do you have about withdrawal or revocation of consent (Widerruf) of health data?
vii. In the past there was an opt-out process - how do you think the change to general consent has impacted the process? Would it again be a good thing (e.g. more data, etc)?
viii. What about a dynamic consent model - how might that impact things (positively or as a challenge)

8. What are your opinions about opening up the data sets and results data for **reuse** more broadly (as according to the FAIR principles).
    i. How do you make your data accessible?
    ii. What are the challenges/blockades?
    iii. What tools/sources of support do you use to facilitate research projects with further use of data and samples. How might the type of sharing relationship impact your concerns or questions? Examples might include sharing to a commercial entity vs. a public one, or sharing outside the SPHN network, or even internationally.
    iv. What thoughts do you have about incentives for data reuse?
    v. Are there uncertainties or barriers about the specific manner in which data sets are shared that you would like to discuss?

TRANSITION
As we wrap up our interview, just a few final questions to make sure we have addressed everything:

9. Do you have specific questions or worries about the related ethics applications/protocols, or about the way that an ethics review committee might review a data sharing proposal that we haven't yet discussed?

10. Are there any other organizational or technical aspects that we have not yet discussed that you want to raise for our consideration?