Exploring Data Governance for Data Sharing at the Swiss University Hospitals

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Introduction

In Switzerland, anyone seeking to reuse routine health data for research purposes typically needs not only authorization from the relevant ethics committee, but also approval from the local data governance board of the data provider – such as a hospital. The same applies to those wishing to use routine data for other purposes such as quality assurance: a structured governance approval process is usually required, often even if the data is anonymized. **Local data governance within health data providing institutions (DPIs) therefore plays a central role in shaping the secondary use of routine health data.** With few exceptions, DPIs in Switzerland are under no strict legal obligation to share their data; whether they do so, depends largely on their voluntary commitment. In practice, DPIs are generally committed to share data – although data sharing with users external to the DPI faces particular regulatory and institutional hurdles. Moreover, governance bodies are embedded in a network of legal, ethical and institutional norms and, with very few exceptions, align their decision with the proceeding evaluation of the ethics committee.

Effective data governance is indispensable to unleash the potential of data-driven science and a data-informed society. On the one hand, data governance safeguards both patients and the institution from potential harm. When sharing patient health data, DPIs not only bear significant legal responsibilities to protect patients' rights but also feel ethically responsible to act in the patients' best interests. Meticulous attention to governance is therefore a cornerstone for establishing trust in health data sharing. On the other hand, effective data governance also has an equally essential role in enabling the reuse of health data. By providing central contact points, expert support and structured processes to access data, effective governance can ensure equitable data access and transparent and efficient data flows and can transform private data collections into valuable resources for a larger community. Ultimately, effective data governance must strike the right balance: preventing misuse while enabling beneficial reuse of health data.

The complexity of this undertaking can hardly be overstated. Firstly, governance bodies process a wide range of data reuse scenarios that are governed by different legal frameworks, different institutional departments and often associated with different societal expectations, risks and benefits. The Swiss legal framework alone consists in 26 different data protection regulations (including 25 different cantonal regulations and the Federal Act for Data Protection) and various special laws that govern special cases of health data, this is most importantly the Human Research Act with its Ordinances (Martani et al., 2020). Adding to this legal complexity, in practice, some adopted requirements in the general consent model are stricter than the legal requirements and the specific implementations of the general consent vary across institutions (Martani et al., 2019). Finally, data governance is accountable to diverse stakeholders with conflicting interests and the fragmented ethical frameworks are insufficient to reconcile this diversity (Blasimme et al., 2018). This *potpourri* of data, norms and interests that need to be triaged, mapped to the right kind of expertise and governed consistently makes data governance particularly challenging. Thus, data governance is more than

applying legal requirements in practice (Beaulieu & Leonelli, 2022). “No case is a standard case" seems to be the dominant view of data governance experts.

Secondly, professional data governance is internationally a relatively recent development with little prior experience or established expertise to build upon. Within the SPHN network, all data providing institutions have only set up their central data governance system in the past few years and it is only in these recent years that professional data governance roles like “data governance manager” or “chief data officer” emerged. However, accumulating best practices or common standards requires time. In the meantime, every data request might present unseen challenges and require unprecedented solutions.

Thirdly, in Switzerland, health data governance is organized on a highly fragmented basis without national coordination or a joint national data sharing framework. Each institution follows its own regulations that are influenced by local conditions regarding the maturity of the data infrastructure or available resources. This local anchoring can be advantageous for the local use of data, as the distances remain short. However, it makes national or international cooperation complex and unattractive. The fragmentation not only affects alignment among DPIs to support collaborative and consistent governance decisions in multi-centric projects but it also affects cooperation with other stakeholders and seamless integration of data governance bodies into the broader regulatory landscape to avoid double regulatory burden or regulatory gaps.

Finally, the growing interest in secondary usage of health data, the increasing complexity of settings (e.g. international collaborations or involvement of AI technologies) together with stagnating public funding for data infrastructures put considerable pressure on institutions to further streamline, professionalize and coordinate their governance with even tighter resources (Rosenbaum, 2020).

These persisting challenges seem undesirable for all stakeholders involved. The lack of common standards and shared expertise lead to uncertainty in decision making and a risk-aversive attitude, which impedes data usage and limits the benefits that are to gain from it. The situation also leads to inconsistent and fragmented decision-making across different institutions and stakeholders, which makes national and international cooperation a cumbersome undertaking. Finally, the situation also causes frustration on the side of data users, and might lead to the perception that data governance decisions are arbitrary, too time-consuming for their needs, or an unnecessary regulatory hurdle. At worst, such negative perceptions might lead to non-compliance by data users with governance requirements.

To date, little is known about how data governance bodies function at the Swiss university hospitals, on what grounds they regulate data flows and how they operate (Ormond et al., 2024). Many stakeholders have emphasized the need to increase transparency about data governance practices, to share some basic knowledge with all stakeholders involved in the secondary usage of health data to facilitate data sharing and to start a national dialogue for future developments (Daniore, 2025). Our

report contributes to this discussion. It describes, on a general level, the governance processes and bodies of routinely collected health data for secondary usage at the five university hospitals in Switzerland that partake in the Swiss Personalized Health Network since 2017. It sheds light on who decides about access to routinely collected health data at the different institutions, how such access requests are being processed and on what grounds decisions are taken. It also discovers common challenges and proposes future avenues in the alignment and professionalization of health data governance for data sharing in Switzerland.

Methods

This publication is based on two rounds of interviews between May 2024 and November 2024 and a joint workshop in May 2025 with data governance experts from the five university hospitals in Switzerland that partake in the Swiss Personalized Health Network since 2017. The experts have been recruited through the members of the SPHN Data Governance Working Group (DGWG) bringing together legal and governance experts from Swiss university hospitals and higher education institutions.

The information was collected through a first round of semi-structured online interviews. The questions were shared with the interviewees in advance, while the interviews allowed for follow-up questions or additional topics to be raised by the interview partners. The interviews were recorded and thereafter transcribed in a paraphrasing way. The paraphrased answers were re-sent to the interview partners to verify the information and respond to some follow-up questions that emerged during the paraphrasing process. One institution provided the answers in a written way and responded to the follow-up questions in the second round of online interviews. From the materials, a first detailed comparison across the five institutions was composed as a basis for internal distribution and to generate preliminary results for this publication. In a second round of interviews, the preliminary results of the summary analysis were presented to the interview partners disclosing which statements in the analysis referred to their institution to initiate further discussion, verify the analysis and raise follow-up questions that emerged during the analysis process. The draft publication was then discussed in a joint workshop, where a consolidated understanding of the results and the outlook was developed. The final draft has been reviewed and approved by all participating institutions.

Data governance for data sharing at the Swiss university hospitals

Data governance encompasses the legal frameworks, institutional guidelines, technical systems, and organizational processes that regulate the flow of data and control access (Beaulieu & Leonelli, 2022). It can be structured into three interrelated components:

1. **Governance policies** – defining the purpose, scope, and rules for data management and sharing.
2. **Governance processes** – providing structured workflows and procedures for implementing policies.
3. **Governance bodies** – responsible for overseeing the policies, managing processes and in charge of decision-making.

From an institutional internal perspective, control of data access represents just one pillar of a broader data governance framework. Other key elements include defining internal responsibilities for data stewardship ('ownership'), establishing data processing standards, and setting data quality requirements (also called the intra-institutional dimension of data governance. see Andrea Martani, 2021). While these activities are indispensable for effective data governance and data sharing, the focus of this report is on data governance practices that directly control the sharing of health data for secondary use (supra-institutional dimension). Thus, the report follows the processes from submitting a data access request by an interested data user, through the evaluation process by the governance professionals to the data delivery to the user.

Roles

Enabler and gatekeepers of health data

Across all institutions a recurring theme was the role of data governance as enabler of data reuse. This is most visible in the fact that data access requests – although restricted to a selected community – they are rarely rejected; instead, governance, legal, and technical experts work closely with data users to meet ethical and legal requirements for compliant and responsible reuse. Moreover, all institutions provide supporting resources that enable the secondary use of data throughout the process and they have invested in the continuous dissemination of their services and stakeholder engagement. For example, they provide counselling services or they have set up training courses or information pages to explain how data access requests can be submitted and how they are being processed.

The enabling role of governance was also highlighted in several specific topics. For example, one institution emphasized how important it is for them that data users get in touch with governance

experts early on in order to provide data users with the best support and make data usage possible. Another institution has explained that they do not charge their data delivery services mostly because they aim to enable the reuse of data while trying to avoid any additional hurdles. Ideally, data governance provides accessible processes, fair evaluation of data usage and increases transparency of data flows and is therefore a key pillar in the FAIRification and democratization of health data referring to the idea of making scientific data Findable, Accessible, Interoperable, and Reusable (Wilkinson et al., 2016).

At the same time, all institutions evoked the idea that data governance also serves as a crucial gatekeeper, overseeing and regulating the flow of data. This role is reflected in several ways: governance boards frequently intervene with corrective requirements for data users (for example, by restricting which data variables may be delivered), they restrict the community who is authorized to submit data requests, for example through authentication procedures. On rare occasions, they also deny requests that irresolvably conflict with legal, ethical, or institutional standards. Data providing institutions carry significant legal responsibilities and are accountable if they fail to uphold these obligations. In this sense, the gatekeeping role of data governance is also a key foundation for maintaining trust in data sharing.

Intermediaries between ethics committees and data delivery

Data governance boards are just one regulatory body for health data flows. Anyone seeking to reuse routine health data for research purposes under the Human Research Act (Federal Act on Research involving Human Beings of 30 September 2011, SR 810.30) typically also needs an authorization from the relevant ethics committee proceeding the governance approval. Thus, an important clarification of roles concerns the relation between ethics committees and data governance boards of data providing institutions.

Most institutions describe their role as complementary to that of the ethics committee. This is particularly evident in the evaluation of projects that undergo both a governance review and ethics review that is required under Chapter 3 of the Human Research Act (Federal Act on Research involving Human Beings of 30 September 2011, SR 810.30, Chapter 3). In such cases, the governance assessment primarily ensures that the protocol approved by the ethics committee aligns with the data delivery carried out by the technical team. In practice, governance decisions generally follow the ethics committee's positive assessment, approving data access requests to the extent that they have already been cleared by the committee. As a result, governance boards act largely as intermediaries between the ethics committee and the data delivery processes for this type of projects, relying heavily on the committee's evaluation of the data request. Furthermore, nearly all governance boards emphasize that they do not assess the scientific merit of a request, considering this the exclusive responsibility of the ethics committee. Instead, their evaluation focuses primarily on institutional aspects, such as compliance with professional secrecy obligations. There are, however, exceptions to this approach.

The role of data governance differs significantly for projects that fall outside the scope of the Human Research Act. In these cases, institutional data governance typically serves as the sole gatekeeping body responsible for ensuring the legally compliant and ethically sound use of health data. Data governance experts take this responsibility seriously and many reported to be confronted with considerable uncertainty how to uphold these responsibilities. More specifically, one institution noted the uncertainty they face when and how to involve other authorities, such as the cantonal data protection commissioner or the ethics committee to provide a voluntary advisory opinion or a statement of non-responsibility, e.g. in cases using anonymized data only. It is in the responsibility of the data governance bodies to identify the cases where involving additional bodies is beneficial. Others emphasized the need for institutions to develop robust policies and value frameworks to guide the evaluation of projects beyond the Human Research Act. One institution reported considering the creation of an independent committee dedicated to evaluating non-research projects to increase the trustworthiness of governance.

Bodies and professional roles

All university hospitals have established new professional roles to manage data governance processes and coordinate respective activities. These professional roles include, for example, Data Governance Manager, Data Governance Coordinator, or Chief Data Officer. They are generally responsible for managing data access requests, for communicating with interested data users or directing them towards other support options. In some institutions, data governance specialists can also evaluate and approve clearly defined data requests directly without the involvement of a transdisciplinary governance board, in other institutions they are also involved in the development of data governance strategies and policies.

Additionally, most institutions have formed a data governance body, commonly a “data governance board” or a “data governance commission” to process or support the evaluation of data access requests or to develop the overall data governance strategy. Within these bodies, data governance is carried out as teamwork between different subject experts and often between different departments. They require collaborative expertise within the institution and commonly involve the expertise from the legal field, data protection officers, data scientists, medical experts or information security specialists. Roles within these boards might also be filled by higher managerial positions such as the medical direction or the head of a Clinical Trial Unit.

Depending on the institution, there can be relevant differences in what kind of expertise is mobilized within these boards to evaluate data use requests for different cases. One institution selects the subject experts quite specifically depending on the type of data request submitted. Another institution involves only the relevant medical experts depending on the medical field whose data is being requested. If these differences in the involved experts affects consistency of decision making within or across institutions is an open question.

The involvement of the data governance body in evaluating data access requests also varies between institutions. In some institutions, the body decides about all requests in a joint meeting, in other institutions it serves as a body of escalation that only discusses controversial or uncertain cases, while data governance professionals evaluate most requests directly. Moreover, some boards are mainly charged with the evaluation of data use requests (and are thus similar in their function to a Data Access Committee) while others perform also more strategic roles, like the development of data governance policies or data strategies.

Processes

Data governance processes for data access typically follow a series of structured steps to ensure that requests for data are properly reviewed, assessed, and delivered. These steps often include: submission of a request, formal checks, decision-making based on ethical, legal and institutional requirements, and final data delivery. Figure 1 illustrates this process on an abstract and simplified level, highlighting the roles of different actors and the flow from initial request to secure data access. In reality, the processes vary and there are often various interactions between the expert teams (legal, technical, governance) throughout the process.

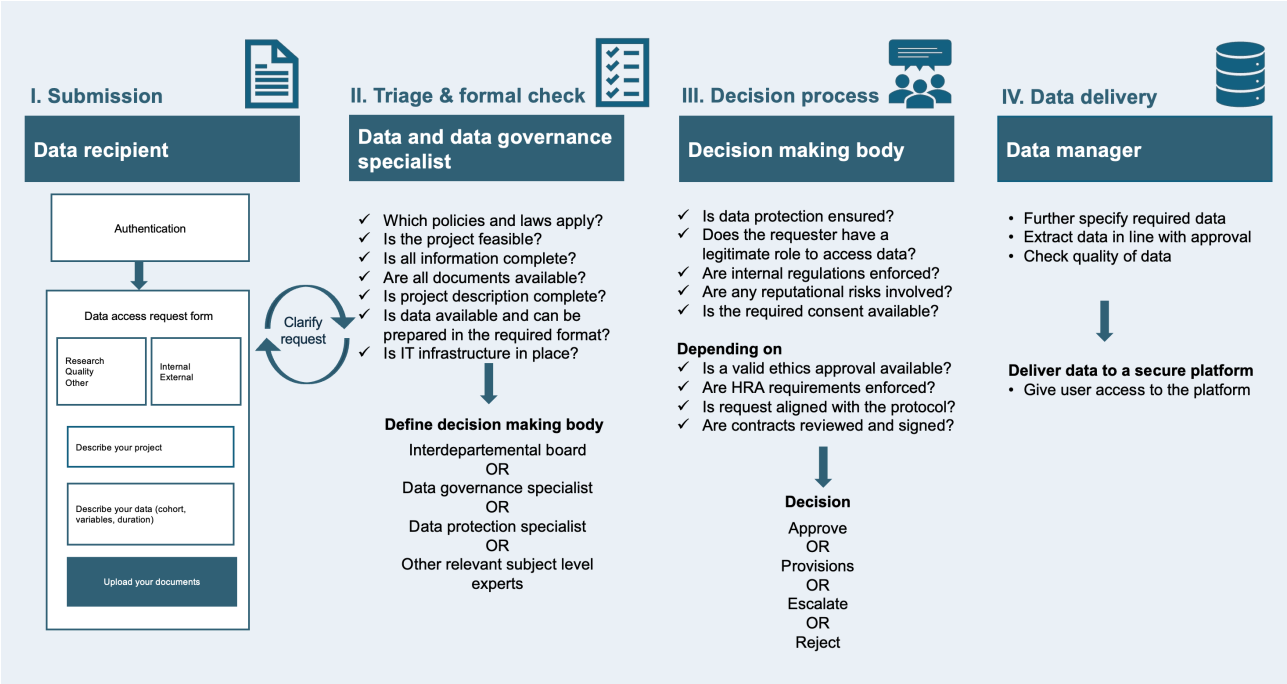

Figure 1: Model process to illustrate the stages of a data governance process for data access.

I. Submission

Most institutions provide a structured form as a single point of contact for requests covering all types of data. With one exception, this form is exclusively set up on the intranet of the institution and consequently only accessible upon authentication as an employee of the institution. For third parties the common way to access another institution's data is through establishing a collaboration with an employee of the institution, who will subsequently submit the data access request. Another institution has discussed the option of opening the access request entry point to third parties but is reluctant to further invest in this process. These data request forms are a good example to illustrate how the technical systems are also part of data governance practices: the authentication procedure enables access to data to a selected segment of users, while excluding others from directly submitting such requests. Within these forms, data requesters first need to provide structured information about the data use, for example the purpose of use, the type of data, or if data is being shared with third parties or across clinics.

II. Triage and formal check

The structured information from the submission process is used by data governance professionals to triage the request and identify the assessment process and experts for the approval. In Switzerland, as in many other countries, using health data for research purposes is subject to higher regulatory oversight and is governed by a different legal framework than using such data for other purposes like quality assurance (McLennan et al., 2018). It is therefore unsurprising that all institutions highlight that the research vs. quality distinction is one of the most crucial distinctions for the entire governance process: it defines the legal framework that applies and subsequently, whether data subjects need to consent to the secondary use of their data and whether an ethics approval is required. In some institutions the two types of requests are even processed in entirely different departments, therefore the data requester must triage between these two categories before a data access request can be made at the right contact point.

In addition to this structured information about the project, data users need to provide certain documents depending on the type of project. To use data for research purposes, a study protocol and an ethics approval are required. To conduct a simple and internal quality project, a brief project description can be sufficient. In cases where data is being shared outside the institution that generated the data, a signed contract regulating the disclosure to other parties, like a Data Transfer and Use Agreement (DTUA) needs to be submitted. To set up these documents, data users have generally already invested considerable amount of time and resources before submitting a request to the data governance bodies. Particularly the setup and review of DTUAs might require additional time before the request can be submitted.

Most data request forms allow to directly request a feasibility study to inquire about available data in the form of summary statistics without providing personal data. In these cases, governance bodies

only verify whether the request is in fact a feasibility request which is then directly transferred to the data specialists to be carried out. Generally, feasibility studies do not require an extended governance or ethics approval. Some institutions also provide self-service tools that are available upon institutional login and training or provide the option to directly contact the data specialists. However, this applies only to basic feasibility studies that have an aggregated number of events or patients as output. More complex feasibility studies – such as verifying if the quality is fit-for-purpose or studies on a federated level – require different solutions.

The formal check commonly assesses whether all the information required for the approval process has been provided and whether data is specified and available as requested at the institution and is commonly performed by a dedicated data governance professional. The formal check is often the first hurdle, as relevant documents are sometimes missing, the wrong versions of protocols are submitted, or data users struggle with identifying the correct data sources. Most governance bodies offer some sort of support for data users to meet these requirements, e.g. by providing them with feedback about what information is missing or getting them in touch with the relevant services. One institution even estimated that about 90% of the efforts for governance are spent on this part of the process. This is also the step that is most decisive to determine how fast requests can be processed, as the acquisition of the right information, e.g. signed contracts, sometimes requires several iterations between different experts and the data users.

Particularly the specification of the requested data is often a tedious task and there exist multiple solutions to organize this difficult part of the process. All institutions confirm that this requires a lot of experience and know-how, and researchers who are familiar with the local context, (e.g. what data are locally available) generally navigate better in this part of the process. However, the granularity with which data requested for the project must be specified at this point of the process also differs between the institutions. Some institutions provide a separate form to specify the cohort or the data quite comprehensively; others only require very high-level information comparable with the research protocol. To this date, only one institution provides a data catalogue with metadata about available data, while most institutions provide counselling services by the experts at the data delivery team, while other institutions barely provide any support as data are managed highly decentralized.

III. Decision process

Decision mechanisms

The different aspects of a data request are commonly assessed by expert judgment, often without explicit decision criteria or a formal evaluation process. Institutions generally document the result of the expert's evaluation, while the documentation of what was assessed and why a decision has been taken is not systematically handled. Only one institution has made the assessment questions explicit in the evaluation process and transparently documents the outcome for each question in a central data governance tool.

The approval process is often structured in a concurrent decision-making process involving all the relevant subject experts. In one institution, the approval process is structured sequentially, where subject experts later in the process are only involved if previous assessors have positively evaluated the request. In another institution, the experts discuss the cases and form their judgment in regular joint meetings of the data governance board. Finally, in some institutions the assessment of simple cases can be performed by a single expert, generally a data governance professional, without the involvement of an interdisciplinary data governance board.

In all institutions, an overall positive assessment is granted if all subject experts approve the request unanimously. In the institution that documents the evaluation criteria, an overall positive assessment is granted if all the criteria are met. A negative assessment by one subject expert has different consequences for the overall assessment in the different institutions. In most institutions a negative assessment in one domain escalates a case, e.g. into the data governance board, that usually jointly defines measures to adjust a project. In one institution a negative decision by one assessor directly prompts an overall negative decision.

In all setups, negative overall decisions seem to be rather rare. From those institutions where statistics were available, the proportion of negative decisions were in the lower single digits. More common is that the data governance experts provide the project with advice on how to adjust their data requests such that an approval can be granted – in line with their role as enablers of health data usage. However, since this process can be reiterated many times, one institution has reported that requests can come to a halt without an explicit negative decision but also without successful data delivery. This ambiguity is avoided in those types of processes where a negative decision leads to a direct rejection of the request.

Decision criteria

The common denominator for all institutions to evaluate data access requests is compliance of the data request with the legal requirements, particularly the requirements of the Human Research Act and the cantonal or federal data protection laws.

For research projects within the Human Research Act, this means to ensure that the project was approved by an ethics committee and verifying whether the data request aligns with the specifications in the research protocol, such as the required patient consent or the cohort definition. Interestingly, all institutions have reported that data governance experts have to intervene rather frequently because of a mismatch between the protocol description and the requested data. As stated above, for these projects, the role of the data governance assessment is mostly an intermediator between the approval of the ethics commission and the data delivery team, thus the role of the governance process is to align the data delivery with the conditions granted by the ethics committee.

For simple quality assurance projects outside the scope of the Human Research Act, a plausibility check of the submission is often sufficient. Such a check might evaluate whether the stated purpose, the requested data and the person requesting the data provide a consistent overall picture. For

example, the assessment might evaluate whether the data requester is employed in the medical area for which data is being requested and hence has a plausible reason to conduct quality assurance in this area.

Other evaluation criteria concern compliance with data protection and data security requirements. Here the degree and rules of de-identification, the technical means to deliver data and the systems used to store and process data might be evaluated, e.g. if the data requester is using a secure research environment and whether the requester asks for properly de-identified data or whether the requesting person has a specific role in a project that allows this person to access the data (e.g. has a Principle Investigator role within the institution). If data is being shared with external parties, the evaluators also check for the availability of signed contracts like a DTUA.

While there is broad overall agreement on the assessment of data protection and data security requirements on a very general level, the detailed assessment of these aspects might vary considerably for different cases depending on the risks or specific settings.

One crucial difference between the institutions concerns the evaluation of the ethical and scientific value of a project. Most data governance bodies do not evaluate the social or scientific value of a project but consider this the sole responsibility of the ethics committee. There are, however, exceptions and grey areas. One institution has mentioned that they explicitly evaluate the scientific dimension of projects to ensure that the evaluation of the ethics commission is in line with institutional values regarding scientific integrity and scientific benefit or to avoid duplication of research within the institution. Other institutions mentioned that considerations regarding a project's scientific value or its scientific feasibility might be brought up as a concern during discussions in the governance assessments even though this is not explicitly evaluated in the evaluation process. Others have highlighted the principle of scientific freedom to explain why they withhold from evaluating the scientific value of a data request.

In addition to the legal requirements, all institutions underline the importance to take decisions on data access requests in line with institutional regulations. While it is difficult to uncover the implications of such internal regulations, a few examples from the interviews illustrate that these can encompass a wide range of requirements: institutions might require the registration of research studies in an internal registry or they want to avoid duplication of research within their institution, or they want to prioritize cases to direct their resources towards certain projects.

Finally, several institutions also mentioned that their governance decisions are particularly impacted by concerns about the trust that patients put in them when providing their data for secondary use or concerns about the reputation of the institution that might be affected by sharing data. Again, it is difficult to uncover the full range of implications of such considerations but a few examples from the interviews might help to illustrate what they imply: One institution has mentioned that they have particularly high standards to respect consent of patients – sometimes beyond the legally required conditions or decision by the ethics committee. Several institutions have stated that concerns about

patient trust are becoming most relevant for data sharing with commercial entities. Others have explained that they pay particular attention not to violate the norm of professional secrecy when data is shared within the institution but across clinics. Data governance bodies thus also act as guardians of institutional values, strategies and policies.

IV. Data Delivery

Data delivery was not explicitly addressed in the interviews so there is little information available about this part of the process in practice. One hospital reports about data requests that are handled through a single, integrated Data Delivery Service tool. Researchers submit their requests via this platform, which supports both the documentation of the technical review and the governance review, as well as the communication between researchers, data engineers, and governance managers, ensuring the necessary exchange throughout the process. From a legal point of view the following aspects should be considered for the data delivery process: The linkage between data governance processes and effective data delivery remains a crucial step in data sharing including the setup of secure transfer and storage mechanisms of the project dataset. The storage location must be a trusted research environment providing a dedicated security information policy that is compliant with Swiss legislation. In any event only authorized persons are allowed to get access to the project data and process data for the limited purpose of the approved project. In addition, quality checks on data before and after effective data extraction are part of the data delivery process and must be well documented. The communication between the responsible departments needs to be well structured, making sure the respective governance bodies are well aligned with the project status. This might be ensured by selected data access teams comprising of an IT department representative, a member representing analysis services, and a representative from the legal and compliance team. In the best scenario there is a digital service tool for the access team available allowing for real time updates and SOPs integration. To what degree this legal perspective intersects with governance practices remains to be investigated in the future.

Challenges: Resolving disagreement and the risk of non-compliance

There is broad agreement across institutions on the general requirements for data access. Moreover, a well-defined research project approved by the ethics commission or simple quality projects pass the governance assessment relatively easily. However, the application of the governance requirements in practice often requires difficult case-by-case judgements that might prompt the involvement of additional experts or authorities (e.g. the ethics commission) or require escalation within the institution to resolve disagreements and uncertainties.

Most institutions have internal escalation procedures for such cases defining who is to be involved in case of uncertainty of the data governance specialists or disagreement within the data governance board. As mentioned, in some institutions the governance board is an escalation body, while in other institutions they are responsible for decision-making in all cases. It is interesting to note that data governance boards sometimes are, in addition to subject level experts, filled with higher managerial positions, which might help to provide sufficient decision power to the board in non-standard or even controversial cases. However, some institutions mentioned that they are also facing uncertainties when to involve external authorities in the process, like an advisory opinion of the ethics commission or a data protection assessment from the cantonal data protection commissioner.

Some examples from the interviews shall help illustrate which data access requests pose particular challenges and frictions in the process: Several institutions have mentioned the problem that the distinction between research projects and quality assurance projects is sometimes difficult to draw. Additionally, some have voiced suspicions that data users might attempt to exploit this uncertainty in order to avoid the higher regulatory burden of projects under the Human Research Act. Another example concerns the application of data protection principles, such as data minimization and purpose limitation, that is particularly challenging for projects involving artificial intelligence or data exploration. Another complexity that was mentioned concerns consent requirements if data is provided for registries that are used for both research and quality purposes. Also requests for anonymized data might confront data governance specialists with uncertainties because anonymized data is difficult to delineate and because such projects fall outside the legal framework (particularly the Human Research Act and data protection laws). Hence there are no other authorities to rely upon for the decision-making process. Finally, collaboration with private entities have been mentioned by several institutions as an area that raises concerns about societal trust and expectations of patients and frequently escalates into the governance board or even the highest management.

Another recurring concern across institutions is the risk of non-compliance with data governance processes. Interview partners have raised concerns that overly complex processes, intransparent decision-making or hurdles such as charging for services might incentivize non-compliance with data governance. Strategies for how to deal with the threat of non-compliance differ between institutions. Some report that they are more cautious with sanctioning non-compliance as they want people to see the services as support and avoid disincentivizing compliance, while others are stricter with sanctioning non-compliance. To counteracting such risks, institutions try to emphasize the role of data governance as support and fair enabler of data usage and have invested considerable efforts into the internal dissemination of their services and relevant know-how. At the same time, some institutions also highlighted that many researchers proactively seek assurance from the governance process that they are acting within the legal framework implying that non-compliance might not be a widespread issue.

Since the university hospitals are still transitioning from data management scattered throughout the institutions towards a centralized strategy, it is unsurprising that there still could be informal ways to

circumvent central data governance processes to access data. Yet, the extent of data usage non-compliant with central governance processes is mostly unknown. Only one institution has mentioned that they have made an attempt to systematically quantify the extent of non-compliance by mapping studies registered in the national study register (RAPS) with the logged requests for the data governance board.

Discussion

The results of our initial analysis and documentation of the institutional data governance processes at the Swiss university hospitals are encouraging. Overall, all five hospitals have made significant strides towards establishing professional data governance. Most have well-documented processes with clearly defined contact points, dedicated data governance professionals, mandated decision-making bodies, and policies that govern the procedures and responsibilities of the bodies as well as escalation procedures. Authorized data users (mostly employees of the institutions) can submit a data access request at an established contact point that is then processed by a structured assessment procedure, evaluated by relevant subject level experts and either granted or rejected in line with defined decision rules. Some institutions assess more than 450 data requests per year; others process around 200 or less, depending on local conditions e.g. what type of requests are submitted to the process. The importance for professional, efficient and transparent data governance surely has been recognized by all institutions.

At the same time the interviews also highlight that maturity of data governance processes varies considerably between the institutions, and some institutions are still setting up their processes and technical tools. The level of centralization also differs significantly. Some have established central data governance tools that are neatly integrated with the technical data infrastructures, others have established central data governance tools with decentralized and separated data delivery, again others have separate or decentralized governance processes and responsible entities depending on the type of data requests or data source. Moreover, data governance processes might be subject to major revisions and strategic reorientation as they are relatively new activities within these institutions. Thus, two out of five institutions have reported a substantial reorganization of their data governance activities towards the end of the documentation process. The results presented in this report therefore report a snapshot of data governance activities at the five university hospitals between May 2024 and May 2025 and cannot necessarily be extrapolated to other organizations and future developments.

The results also highlight the social and operational complexity of this undertaking. Data governance is collaborative teamwork over disciplines and departments that has to integrate various norms and interests. Navigating this *potpourri* of norms and interests makes data governance particularly

challenging. As data governance also requires cooperation across departments and existing workflows within the institutions, building data governance processes and bodies also requires efforts to build trust and encourage change within the institutions. Moreover, professional data governance is a relatively new phenomenon with little prior experience to build upon. In Switzerland there is no national coordination or barely any exchange of expertise. Resources are scarce while the interest in getting access to more data more quickly increases steadily – putting considerable pressure on the institutions to further professionalize their data governance.

Discussions of the results have identified the following overarching challenges and areas of action to further align and innovate data governance processes.

Increase alignment and transparency

While legal concerns play a central role for data governance, this documentation of the institutional governance processes clearly highlights that governance is more than the practical implementation of the law. Instead, data governance bodies also cover important gaps beyond the legal requirements to ensure the responsible use of health data. This is for example evident in the different scopes between data that is governed by institutional data governance and data that is protected by the law: Although personal data – protected by the law – clearly are at the center stage of data governance most institutions extend their scope beyond personal data and also cover other types of data, for example general financial data or anonymized health data. Its role beyond implementing legal requirements is also visible in additional norms that impact data governance, such as institutional regulations or concerns about upholding trust of patients. Thus, data governance boards are, for example, concerned with the question under what circumstances anonymized data should be shared or withhold in order to honor the trust that patients put in them: While sharing anonymized data might be unproblematic from a privacy point of view it could still harm an institution's reputation or used for purposes that conflict with social norms (in the literature sometimes referred to as "social licence" see e.g. Kalkman et al., 2019; Muller et al., 2021).

Consequently, it seems to be a common misconception that projects outside the scope of the Human Research Act or even outside the scope of the data protection law always facilitate data access. Instead, from a data governance point of view, a well-defined research project with an elaborated protocol and ethics approval is less likely to cause frictions in the governance process, whereas projects outside this scope impose a higher responsibility on the institutions and allow for greater variability in the evaluation process. For example, it is in the institution's responsibility to decide about boundary cases and ensure that projects submitted as quality projects or submitted for anonymized data have been classified correctly and responsibly, or to involve external authorities in case of uncertainty. Such boundary cases might confront governance professionals with difficult judgments that are barely risk free.

The discrepancies between what is legally required and the various norms that impact data governance risk to be an important source of friction and disagreement between stakeholders in the Swiss health data ecosystem. If data users and other stakeholders lack awareness about the relevance and benefits of data governance, the decision power of data governance bodies can be perceived as an additional burden and hindrance of data usage. Such a negative perception is also a risk of non-compliance with data governance processes. Thus, getting data users on board to avoid non-compliance requires constant communication about the added value of data governance as well as transparent policies, fair decision rules and consistent decision making about data access. Moreover, systematic assessment and quantification of non-compliance is essential to identify informal ways for data access and develop new governance strategies to cover them.

The controversial discussions outside the simple standard cases also highlight that the norms that govern data governance decisions are not always made explicit and transparent in the decision criteria that are applied in the approval process. Instead, some implicit norms and concerns might be raised in informal discussions in the data governance boards (like concerns about sharing data with industry partners) or they can be embedded into the socio-technical systems (like the restricted access to the data request forms for employees of the institution). As data governance boards are not independent bodies of the data providing institutions but also guard institutional interests and values, implicit norms or institutional interests clearly play a role in the informal decision processes.

This is problematic as institutions make barely explicit what such obligations imply for the regulation of data flows and how this affects data sharing to promote future research for the common good. Consequently, vested interests of data providing institutions have been criticized as a major hurdle for data sharing undertakings (ALLEA, 2021; Martani et al., 2021; Ormond et al., 2024; Raposo, 2025). To promote collaboration and trust within and between institutions, it is indispensable to make such norms and interests transparent and form a common understanding of their implications on data flows. Ideally, these norms should be consolidated into a common value framework for the health data ecosystem with a clearly defined social value for everyone involved.

Finally, proper data governance requires close interaction with a range of other responsible agents. Most importantly, this concerns ethics committees, but also data protection commissioners and data recipient institutions such as universities, registries, or data repositories. The relationship with ethics committees should be cooperative and seamless to avoid duplicative regulatory burdens and mitigate unnecessary frustrations. At the same time, interactions with other agents should be grounded in a shared understanding of the respective roles and responsibilities in governing and enabling secondary data use. Since data governance boards are not legally mandated in their role (unlike ethics committees), it is particularly important to clarify their role within the broader regulatory landscape, align on a common mission, and engage in dialogue with other stakeholders. This will foster cooperation and build trust between all agents involved throughout the entire lifecycle of data.

Innovation of data governance and democratization of data access

It is encouraging to see that data governance professionals see themselves mostly as enablers of data usage and all institutions significantly contribute to this role by providing supporting resources and well-functioning governance instruments. Ideally, data governance enables the secondary use of data by providing accessible data request contact points, training options for data users or even data catalogues to find the data that is available for national and international use. Thereby, mature data governance processes will shift the access requirements from the traditional paradigm of "knowing the right person" towards a democratic approach with transparent and rule-governed processes that are open for everyone who is willing to comply with the rules. There is, however, a tension with the fact that current governance practices seem to be inwards oriented and follow the traditional paradigm of (multi-center) clinical trials. This is most visible in the poorly developed data access request processes for external data users. While restricting data access requests to a trusted segment of data users (e.g. admitting academic researchers but excluding private entities) is a common model for data governance, the restriction to within institutional data usage clearly stands in the way of FAIR (most importantly Findable and Accessible (Wilkinson et al., 2016) or democratic access to health data. On what norms this practice is grounded is currently unclear.

The traditional mindset is also visible in the fact that data governance processes end with the data delivery. However, in a health data ecosystem, the data delivery from primary data to data users is only the very beginning of the data lifecycle, where data get enriched, linked and prepared for analysis by multiple actors from multiple perspectives later on. The increasing gaps in time, space and social bonds between data collection and data usage is precisely what characterizes the secondary use of health data in a mature health data ecosystem. To enable and ensure the trustworthy use of health data across time, space and social bonds, data governance has to evolve, cooperate and extend its functions over the entire life cycle of data. In these models, traditional roles like physician-researchers as simultaneously data producers and data users; local principal investigators as scientific leads; or even traditional sponsors as the main accountable legal entity might need to be adapted and redefined. Moreover, there is potential to further strengthen the role of data governance as enablers by starting the collaboration between governance and data users before the final data access request (with all elaborated documents) is being submitted. Thereby, questions like feasibility or legal boundaries could be incorporated earlier to provide the best possible support and advice. Such developments would already provide an important contribution towards the enabling role of data governance.

Finally, the traditional mindset is also visible in the yet unresolved question how to finance data management and processing and whether data delivery or other data services should be charged. In other words, who pays for the vision of the Swiss health data ecosystem is yet an unresolved question and most institutions have not yet established data services that could be provided to external parties on a scalable level. Moreover, in Switzerland the collaboration with private entities for

health research or health data infrastructure is a socially sensitive topic, spurring reluctance of academic and public institutions to explore large scale private-public collaborations.

Apart from a few exceptions, data providing institutions have no legal obligation to make their data available for secondary use and due to the lack of resources they may focus their efforts on optimizing internal usage of data for other purposes first. Particularly data sharing on a national level thus largely depends on the commitment of the institutions and sustainable financing strategies for the implementation of the future FAIR Swiss health data ecosystem.

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