

Swiss Learning
Health System

About the FAIRness of Computable Biomedical Knowledge in Switzerland

Written by: Abdessalam Ouazki

Supervised by: Dr. Paul Cotofrei

Policy Brief **#1**

Keywords

Computable Biomedical Knowledge

Biomedical Data

FAIR principles

Authors

Abdessalam Ouazki, PhD Assistant – Institute of Information Management, University of Neuchâtel, Switzerland

Paul Cotofrei, Senior Lecturer – Institute of Information Management, University of Neuchâtel, Switzerland

Address for correspondence

Abdessalam Ouazki

Institute of Information Management

University of Neuchâtel

A. L. Breguet 2, 2000 Neuchâtel

E-Mail: abdessalam.ouazki@unine.ch

Paul Cotofrei

Institute of Information Management

University of Neuchâtel

A. L. Breguet 2, 2000 Neuchâtel

E-Mail: paul.cotofrei@unine.ch

Suggested citation

The text of this policy brief may be freely quoted and printed, provided proper acknowledgment is given.

Ouazki A, Cotofrei P. (2024). About the FAIRness of Computable Biomedical Knowledge in Switzerland. Swiss Learning Health System.

Table of Contents

Policy Briefs and Stakeholder Dialogues of the Swiss Learning Health System.....	4
Key Messages.....	5
Background and Context.....	6
The Issue	8
A hypercompetitive research environment.....	8
Complexity and fragmentation of the stakeholder landscape	9
Technical Challenges	9
Legal uncertainty.....	10
Ethical issues and considerations	10
Conclusion.....	10
Recommendations to address CBK FAIRness in Switzerland.....	11
Recommendation 1: Systemic attribution mechanisms.....	11
Recommendation 2: Collaboration between biomedical researchers and legal experts.....	11
Recommendation 3: Standards and Technical FAIRifications.....	12
Recommendation 4: Ethical Framework for Biomedical Data and CBK.....	12
Conclusion.....	13
Implementation Considerations	14
References	18

Policy Briefs and Stakeholder Dialogues of the Swiss Learning Health System

The Swiss Learning Health System (SLHS) was established as a nationwide project in 2017, involving academic partners across Switzerland. One of its overarching objectives is to bridge research, policy, and practice by providing an infrastructure that supports learning cycles.

Learning cycles enable the continuous integration of evidence into policy and practice by:

- continuously identifying issues relevant to the health system,
- systemizing relevant evidence,
- presenting potential courses of action, and
- if necessary, revising and reshaping responses.

Key features of learning cycles in the SLHS include the development of **Policy Briefs** that serve as a basis for **Stakeholder Dialogues**.

A **Policy Brief** describes the issue at stake by explaining the relevant contextual factors. It formulates a number of recommendations to address the issue (evidence-informed recommendations, when available), and for each possible recommendation, it explains relevant aspects and potential barriers and facilitators to their implementation.

Policy Briefs serve as standalone products to inform interested audiences on potential courses of actions to address the issue, as well as input for Stakeholder Dialogues.

A **Stakeholder Dialogue** is a structured interaction where a variety of key stakeholders are brought together for the purpose of defining a common ground and to identify areas of agreement and disagreement on how to solve issues in the Swiss health system. Based on a Policy Brief, stakeholders discuss the issue, recommendations, and barriers and facilitators, and work collaboratively towards a common understanding of the issue and the best course of action. The dialogue takes the form of a deliberation to ensure that stakeholders work together to develop an understanding and solutions that are acceptable to all parties.

Key Messages

Background and Context

Computable Biomedical Knowledge (CBK) is a form of knowledge that is machine-understandable and executable, enabling quick decision-making advice related to human health on a global scale. To maximize the potential of computable knowledge, it should adhere to the FAIR principles (Findable, Accessible, Interoperable, and Reusable), which ensure scientific data's effective discovery, access, and reuse. While there's a growing global trend in adopting FAIR principles, variations in their application exist due to technical and regulatory challenges. Switzerland stands out in global biomedical research with robust healthcare and institutions like the Swiss Institute of Bioinformatics contributing significantly to the field.

The Issue

Switzerland is navigating the alignment of its CBK and biomedical data to the FAIR principles, facing challenges in data management due to regulatory, cultural, and technical barriers. The primary concerns include:

- A hypercompetitive research environment.
- A fragmented stakeholder landscape.
- Technical challenges.
- Legal uncertainty.
- Ethical consideration.

Recommendations for Action

Swiss medical research is already striving to harmonize innovative information-sharing methods with appropriate legal and ethical practices. To further strengthen this, we recommend actions in the following four spheres:

- Systemic attribution mechanisms.
- Collaboration between biomedical researchers and legal experts.
- Standards and Technical FAIRifications.
- Ethical Framework for Biomedical Data

Implementation Considerations

Barriers to implementation include:

- Dominance of a hypercompetitive research mindset.
- Prevailing legal ambiguities & regional regulatory disparities.
- Technical fragmentation & lack of unified infrastructure.

Facilitators to implementation include:

- Emphasis on collaboration & open science.
- Comprehensive education & accessible resources.
- Existing initiatives and guidelines promoting standardization & ethics.

Background and Context

Computable Biomedical Knowledge (CBK) designates a type of knowledge that is understandable and executable by machines. It arises as a result of an explicit process that can be represented and reasoned upon using logic, formal standards, and mathematical formulae (1). This process is analytic and/or deliberative by nature and brings to play the power of information technology in creating decision-specific advice related to human health. One of the main advantages of developing and using CBK is that it can generate and deliver useful information at an individual or organizational level on a worldwide scale at a great speed, which exceeds human capacity in generating, distributing, and using medical knowledge. CBK fills the gap between knowledge change and performance change that is aligned with the new knowledge (2). As learning health systems continue to learn over repeated cycles of operation, the generated knowledge grows rapidly, in such a way that only the representations of knowledge that are encoded in computable forms can reduce the lag between the learning speed and the potential to implement performance change.

The cardiovascular risk assessment calculator as an example of CBK

The atherosclerotic cardiovascular disease (ASCVD) risk estimator, developed by the American College of Cardiology, is a comprehensive tool designed to estimate a patient's 10-year risk of developing ASCVD (3). This digital tool takes into consideration a variety of patient parameters, such as age, gender, race, cholesterol levels, blood pressure, and lifestyle factors like smoking status. Based on these inputs, it calculates the initial risk of ASCVD. The calculator aims at guiding clinicians and patients in making informed decisions about cardiovascular health. It can be tested using the hyperlink in (4).

In order to take full advantage of the potential of computable knowledge, it has to be FAIR: Findable, Accessible, Interoperable, and Reusable. Developed by Wilkinson et al. (5), the FAIR principles provide a framework to improve the utility of data. They ensure that scientific data can be effectively discovered, accessed, integrated with other data, and reused for future studies, thus accelerating the pace of research and discovery.

The adoption of the FAIR Principles has reignited global discussions on improving data stewardship, particularly in the realm of open and data-driven science (6). The FAIR ethos encourages participation from both professional scientists and engaged citizens globally, without differentiation between developed and developing nations (6). The implementation of the FAIR principles for scientific data management can substantially boost both efficiency and efficacy in many sectors such as the biopharmaceutical sector, along with other life sciences fields like biomedical, environmental, agricultural, and food production fields (7). By adhering to these principles, a wealth of advanced analytical methods, such as artificial intelligence and machine learning, can automatically and on a large scale access the data they require for learning and growth. Therefore, FAIR is a key catalyst for the digital transformation (7).

Despite this positive trend, considerable variation exists in the degree of FAIRness across different domains and datasets. Multiple factors, including technical challenges, lack of awareness, and regulatory issues, can contribute to this variation (8,9). Therefore, it is essential to assess FAIRness and develop strategies to improve it in specific contexts.

Success Story of the Swiss Bioinformatics Institute

In January 2019, the Swiss Bioinformatics Institute (SIB) joined the European FAIRplus project, signifying a major step towards enhancing data sharing and reuse in life sciences (10). This ambitious project involves 22 partners from both academia and industry and is coordinated by the European intergovernmental organisation ELIXIR. By organizing training for data scientists in academia, small and medium-sized enterprises (SMEs), and pharmaceutical companies, FAIRplus aims to foster widespread adoption of best practices in data management. SIB's role in this project underscores the practical implications of implementing FAIR principles in real-world research scenarios. It also illustrates the potential impact of collaborative and interdisciplinary efforts in making biomedical knowledge more FAIR, thereby contributing significantly to the advancement of medical research and healthcare.

For computable biomedical knowledge to become widely spread and operationalized, healthcare delivery organizations should have the necessary foundations for supporting it. In their study about preparing healthcare organizations to manage computable knowledge, Adler-Milstein et al. (11) note that knowledge management in these organizations relies on an outdated biomedical library model, and that only a small number of them have developed enterprise-scale knowledge management that supports pushing computable knowledge to the forefront of their decision-making processes. Although learning health systems do not require knowledge to be represented in computable forms, the scalability of these systems is enhanced by guiding decision-makers based on processes that are routinely computed rather than generated by human review and inspection (11).

Turning to Switzerland, the country has a strong position in global biomedical research due to its robust healthcare system, advanced research and development infrastructure, and a long tradition of scientific excellence (12). Switzerland is home to several prestigious biomedical research institutions and plays a key role in several international research initiatives. The Swiss Institute of Bioinformatics (SIB), for instance, is internationally recognized for its work in bioinformatics and computational biology (13).

The Issue

It is essential to scrutinize the alignment of Swiss CKB and biomedical data and knowledge with FAIR principles. Switzerland, like many other countries, faces challenges in data management and stewardship, ranging from regulatory issues to cultural and technical barriers. These challenges can impact the FAIRness of Swiss CBK and biomedical data and, ultimately, its potential to contribute to scientific discovery and innovation.

Answering the question of how best to address the FAIRness of CBK and biomedical data is complicated by the following contributing factors:

1. A hypercompetitive research environment.
2. Complexity and fragmentation of the stakeholder landscape.
3. Technical challenges.
4. Legal uncertainty.
5. Ethical issues and considerations.

These contributing factors are explained in more detail in the following section.

A hypercompetitive research environment

Geneviève et al. (9) explain that one of the main challenges of fair and equitable data sharing in Switzerland is the hypercompetitiveness of the research landscape. This stems from a "publish or perish" paradigm, discouraging the transparent exchange of data among researchers. This fear-induced secrecy arises from concerns over losing professional standing, the potential theft of unique research concepts, or missed publication opportunities if data is shared openly (7). These fears are amplified by the lack of mechanisms for fair attribution, which can make researchers cautious about releasing datasets right after publication, especially if they haven't fully exploited their research potential. As a consequence, data sharing is often seen not as an asset but a risk that might pave the way for others to achieve more publications based on the shared data.

Data are not accessible, at least not in public repositories, because scientists want to publish their research work first.

A survey by the Swiss National Science Foundation (SNSF) and Swissuniversities reveals a nuanced picture of data sharing among researchers. While 75% of researchers provide some access to their data, only 44% use public repositories or data archives (14). The primary reasons for this limited use of open platforms are the researchers' desire to publish first and concerns over data confidentiality and usage rights. This trend indicates a broader challenge within the Swiss research community, where publication pressure and competitiveness significantly influence data sharing practices, potentially impacting the broader goal of collaborative and transparent scientific advancement.

Complexity and fragmentation of the stakeholder landscape

Touré et al. (15) explain that a vast amount of data is generated by both healthcare providers and individuals, creating a rich resource for personalized health research, public health surveillance, and enhancements in healthcare quality. This spectrum of data, spanning from conventional clinical details to imaging data, sensor readings, and multiomics, is typically highly diverse and stored across separate databases or silos. Furthermore, the true insights within this data often stay hidden due to localized or proprietary standards adopted by electronic health record (EHR) vendors (15). This fragmentation complicates the access, combination and use of data from multiple sources, such as hospitals and labs. Furthermore, the different stakeholders operating biomedical data sources often have different interests (16). A participant from the study conducted by Knobel et al. (16) indicated: “[...] the biggest challenge is that we think in a far too compartmentalised way. [...] Switzerland is already much too small, but in addition, within Switzerland, every single party thinks [again] for themselves.” Some opinions credited this to a lack of political willingness to collaborate, while others highlighted the inherent features of the Swiss political framework, like its federalist structure (16).

Technical Challenges

Understanding the intended significance of a data resource and merging data from different sources becomes a daunting task, mainly due to the lack of standardized data dictionaries and the multitude of ways metadata is represented (15). Knobel et al. (16) points out three main obstacles related to data in healthcare environments. Firstly, the absence of uniform data formats and standards across healthcare units was pinpointed as a significant technical hurdle, with disparities even within the same hospital blocking free information exchange. This problem escalates in well-established health systems where initiating changes is both complicated and costly. Secondly, the rapidly expanding volume of data constitutes a major challenge, especially for smaller organizations lacking the resources to handle it. This overflow often surpasses the capacity to process and effectively use the data, affecting its quality and calling for enhanced data annotation. Thirdly, the security aspect of health data and digital technologies introduces technical risks, such as data breaches and algorithmic manipulations.

“ Switzerland is not doing too badly in regulatory terms regarding digitalisation in the healthcare sector. However, problems arise in the effective implementation of specific projects. On the one hand, this is due to the federal structure of Switzerland with its 26 health systems. Moreover, a lack of technical standards in electronic patient records also plays a role. The large number of actors in the healthcare system from the cantons to hospitals, doctors, pharmacies, and health insurers does not make the project any easier. In addition, an obligation to introduce such a dossier was approached too late and there is still a lot of persuading the patients to be done. All these factors pose a challenge in terms of data collection and data compatibility and means that there is a lot of work still to be done. ”

Stephan Mumenthaler, director general of Scienceindustries (17)

Legal uncertainty

Geneviève et al. (9) argue that the complexity and fragmentation of the legal landscape in Switzerland form significant impediments to data sharing. Disparate legal interpretations and data protection requirements often create uncertainty, hindering research. Researchers struggle with navigating these laws and meeting varied data protection norms. Differing understandings of the same laws lead to inconsistent evaluations of similar research projects, often resulting in conservative approaches. Furthermore, ensuring legal compliance, especially in international collaborations, is challenging, often prompting the withholding of personally identifiable information (9). Additionally, legal uncertainties also envelop the tools employed for data sharing, like email, as well as the varying data security protocols among collaborating institutions, leading to additional legal ambiguity. The legislator is responsible about protecting individuals from the misuse of their data, along with any potential discrimination that can arise from it, like in the labour market for instance (9). However, the data protection laws that exist today remain insufficient to deal with sensitive personal health data (16).

Ethical issues and considerations

The protection of sensitive personal health data raises key questions about the ethical practices of its stakeholders. The Policy Kitchen discussions largely centered on the commercial use of data by tech firms, insurers, and pharmaceutical companies (16). Participants in the study conducted by Knobel et al. (16) highlighted the ethical concerns surrounding the use of medical data by certain entities outside the traditional healthcare field (e.g., Google, Apple), while some private actors in the Swiss healthcare system face stringent regulations. State collection and use of health data also garnered critical attention regarding its ethics, with concerns about potential discrimination and freedom restrictions. Additionally, the practice of general consent for research in Switzerland also raises ethical questions, with its perceived benefits for data science being weighed against the impracticality of patients retracting their consent, described by some as a “blank check” and an affront to personal autonomy (16).

Conclusion

Throughout the discussions in the preceding sections, a primary focus has been on the influences and challenges surrounding “biomedical data”. It’s crucial to underscore that while many of the cited articles predominantly reference “data”, the arguments and challenges presented are equally applicable to “biomedical knowledge”, which remains the primary subject of this policy. The intricacies of managing, sharing, and safeguarding biomedical data inherently intertwine with the stewardship of biomedical knowledge. In understanding the complexities of data management, we also gain insights into the broader spectrum of biomedical knowledge dissemination, its accessibility, and its potential for spurring innovation. As we navigate the multifaceted landscape of biomedical data, our strategies should also aim to preserve and amplify the value of the rich biomedical knowledge that it encapsulates.

Recommendations to address CBK FAIRness in Switzerland

Swiss medical research is working to balance new ways of sharing computational biomedical knowledge with the right legal and ethical practices. This means changing how researchers are credited for their work, understanding complex data rules, and making sure data use is both smart and safe. All these efforts aim to make research in Switzerland open, fair, and respectful of involved stakeholders. In the following, we outline 4 recommendations for improving CBK FAIRness in Switzerland, and highlight initiatives that have been taken in this regard. While some of the recommendations are inspired from biomedical data FAIRness, they can be readily adopted or extended to CBK.

Recommendation 1: Systemic attribution mechanisms

To overcome the challenges incurred by the hypercompetitiveness of the research landscape in Switzerland, Geneviève et al. (9) call for a recalibration of the academic culture, particularly highlighting the necessity of fairly crediting the effort involved in data sharing. The authors call for a significant shift towards cooperative research, openness in science, and justly distributed biomedical data. As the current academic reward system overlooks the time and effort involved in data and CBK collection, curation, and secondary use preparation, a potential solution lies in systemic transformations that introduce unique identifiers for datasets and comprehensive metadata—measures akin to those already employed for academic publications—ensuring original data collectors are appropriately acknowledged. Facilitating these necessary changes requires the involvement of multiple stakeholders—policy makers, funding agencies, and academic institutions. For instance, funding agencies could create recognition and reward schemes to incentivize researchers to engage with data sharing activities, on top of the traditionally recognized research publications (9). By fostering fair attribution mechanisms, the different stakeholders can help transition academic culture towards a more open and collaborative research environment that underlines the potential of data sharing rather than its perceived liabilities.

Recommendation 2: Collaboration between biomedical researchers and legal experts

Martani et al. (18) explain that it is crucial to foster communication between the research and legal domains to ensure that data-rich research projects can strike a balance between their potential and the need for privacy protection for those involved. In Switzerland, there are 26 distinct data protection regulations (18). This includes the Federal Act on Data Protection (FADP) and regulations from 25 cantons, with Jura and Neuchâtel sharing a common law. Additionally, there are laws related to biomedical research, other sector-specific norms about personal data processing, and even more guidelines in the criminal code related to data processing. Given this intricate legal landscape, it's not surprising that even those in the biomedical research arena might find it overwhelming. Hence, Martani et al. (18) underline the importance of fostering communication between the research and legal domains to ensure

that data-rich research projects can strike a balance between their potential and the need for privacy protection for those involved.

Additionally, Geneviève et al. (9) argue that corrective measures should be taken if current regulations mainly hinder data exchange rather than enhance data protection. Changes necessary to strike a balance between privacy and research could be achieved without modifying legislation, by offering researchers necessary training, infrastructure, and legally-compliant data transfer mechanisms. This could be uniformly implemented through codes of conduct or an adequacy model, like data protection certification mechanisms, facilitating health data sharing and reducing risks to data subjects.

Recommendation 3: Standards and Technical FAIRifications

In modern biomedical research, ensuring data's tangibility and interoperability is paramount, which necessitates the adoption of Standards and Technical FAIRifications. By integrating recognized data protocols such as SNOMED-CT for clinical terminology (19) and HL7 FHIR for health data interchange (20), research projects can achieve greater compatibility. Investing in robust platforms like Bioconductor (21), along with the promotion of open-source tools like OpenRefine and FAIRsharing, streamlines the FAIRification process. Furthermore, the implementation of continuous training using tools like REDCap (22) ensures that researchers are equipped with current best practices, making data not just accessible but also actionable, and driving more tangible research outcomes.

The Swiss Personalized Health Network (SPHN) has undertaken a pivotal initiative to establish a cohesive and long-standing infrastructure that enables the seamless utilization and exchange of health-associated data for research, aligning with the FAIR principles (15). SPHN's concerted efforts led to the creation of a unified standard infrastructure, tailored specifically to bridge the gap between data providers and researchers. Through this initiative, the SPHN Resource Description Framework (RDF) was instituted, laying the foundation for an integrated data ecosystem. This ecosystem covers all facets, from data amalgamation, verification tools, analysis aids, to comprehensive training and documentation, ensuring uniformity in health metadata representation. Such a structured approach enables data and CBK suppliers to offer a diverse range of health data in an interoperable format, while still providing the adaptability required for specific research ventures. Consequently, Swiss researchers now benefit from access to health data that adheres to the FAIR principles and is ready for deployment in RDF databases.

Recommendation 4: Ethical Framework for Biomedical Data and CBK

As the biomedical research landscape becomes increasingly data and knowledge driven, the ethical implications of data collection, storage, analysis, and sharing warrant urgent attention. At the heart of this concern is the need to protect patient rights, especially with respect to consent, privacy, and potential harm, while also ensuring the broader research community benefits from shared insights (23). Comprehensive ethical guidelines, rooted in recognized international standards, can serve as a compass for researchers navigating this complex landscape. Such guidelines can also play a pivotal role in ensuring that data collection and analysis are conducted equitably, avoiding biases that could otherwise skew research outcomes. Institutions should look towards the establishment or strengthening of ethics review boards, which

can provide oversight for biomedical research projects and ensure their alignment with the highest ethical standards (24). Moreover, regular training sessions can equip researchers with the necessary knowledge and tools to uphold these ethical standards in all facets of their work.

Highlighted efforts in this context include the commendable endeavors of the Ethical, Legal and Social Implications advisory group (ELSlag) operating under the Swiss Personalized Health Network (SPHN). Tasked with sculpting ethical protocols for personal data processing, the ELSlag produced a well-defined ethical framework specifically targeting responsible handling of personal data within the SPHN ecosystem. This framework garnered the support and endorsement of the Swiss Biobanking Platform (SBP) and the ETH Domain Strategic Focus Area on Personalised Health and Related Technologies (PHRT). The development of this framework wasn't arbitrary; it stemmed from an intricate systematic analysis of global guidelines. Detailed insights into the methodology can be accessed through their published document (25). As a testament to its comprehensive nature, the framework not only provides directives on data collection, storage, and sharing but also explicitly encompasses health-related personal data sourced from human biological materials. This inclusive framework stands as a testament to the progressive strides being made in the realm of CBK ethics in Switzerland.

Conclusion

Ensuring that Switzerland's biomedical data and CBK adhere to FAIR principles is a multifaceted challenge. This endeavor is made intricate by with a hypercompetitive research landscape, the complexity and fragmentation of stakeholders, legal uncertainties, technical challenges, and ethical considerations. Collaborative efforts that address these contributing factors are essential for advancing the FAIRness of biomedical data in Switzerland and unlocking its potential to support scientific discovery and innovation. Policymakers, researchers, and other stakeholders must work together to create an environment that fosters transparency, collaboration, and ethical responsibility, while also navigating the unique challenges posed by the Swiss legal and political landscape. Adopting uniform data standards, improving legal definitions, and placing a strong emphasis on ethics are crucial steps towards harnessing the immense potential of the nation's biomedical data. As Switzerland refines its data governance strategies, these elements will be at the forefront, influencing not only the trajectory of local CBK research but also its global impact on healthcare innovation and delivery.

Implementation Considerations

In the following, we describe barriers and facilitators for each recommendation, at different levels.

Table 3: Facilitators to improve CBK fairness in Switzerland

Levels	Recommendation 1: Systemic attribution mechanisms	Recommendation 2: Collaboration between biomedical researchers and legal experts	Recommendation 3: Standards and Technical FAIR-ifications	Recommendation 4: Ethical Framework for Biomedical Data
Researchers	<p>Actively adopt and use unique identifiers for their datasets and CBK artifacts.</p> <p>Collaborate openly, share data/knowledge, and ensure proper credit is given to all contributors.</p>	<p>Initiate dialogues with legal experts to understand regulations better.</p> <p>Participate in joint seminars/workshops with legal professionals.</p>	<p>Adopt and consistently use recognized data protocols in their projects.</p> <p>Participate in continuous training to stay updated with best practices.</p>	<p>Stay informed and adhere to ethical guidelines in all research activities.</p> <p>Attend training sessions on research ethics and apply learned principles in their work.</p>
Academic institutions	<p>Establish and promote fair attribution mechanisms within the institution for CBK.</p> <p>Incentivize open collaboration and CBK/data sharing among researchers.</p>	<p>Organize collaborative workshops involving both researchers and legal experts.</p> <p>Offer resources and support for understanding complex data regulations.</p>	<p>Organize collaborative workshops involving both researchers and legal experts.</p> <p>Offer resources and support for understanding complex CBK and data regulations.</p>	<p>Develop, maintain, and promote institutional ethical guidelines for biomedical research.</p> <p>Strengthen or establish ethics review boards for oversight.</p>
Funding agencies	<p>Foster a culture of data sharing by recognizing and rewarding data sharing activities</p>	<p>Allocate funding for projects that prioritize collaborations between researchers and legal experts.</p>	<p>Incentivize the adoption of recognized CBK protocols through funding preferences</p>	<p>Dedicate funds for projects that emphasize ethical considerations in their research</p>

	<p>in addition to traditional research outputs</p> <p>Advocate for the use of unique identifiers and comprehensive metadata for datasets and CBK artifacts.</p>	<p>Facilitate workshops or seminars that bring together biomedical researchers and legal professionals to address regulatory challenges.</p>	<p>or requirements</p> <p>Support projects that utilize or integrate platforms and tools for FAIR CBK management.</p>	<p>plans. Encourage institutions to establish or reinforce ethics review boards through grant requirements.</p>
<p>Policymakers</p>	<p>Advocate for national standards in recognizing and crediting CBK sharing efforts, reducing discrepancies arising from federalism</p> <p>Foster cooperation among different regions by emphasizing the collective benefits of a unified academic culture.</p>	<p>Promote national collaboration frameworks between biomedical researchers and legal experts, bypassing regional silos.</p> <p>Address the federalist structure by streamlining data protection regulations, offering a clear national direction, while respecting regional nuances.</p>	<p>Promote centralized platforms for CBK sharing that cater to the diverse needs of the Swiss research community.</p> <p>Encourage national training initiatives that respect the diverse regional landscapes but offer a unified FAIR practice education.</p>	<p>Work closely with regional ethics boards to ensure uniform ethical standards while considering regional specificities</p> <p>Encourage national discourse on the ethical considerations of CBK, promoting a shared understanding and approach across regions.</p>
<p>Electronic Health Record (EHR) vendors</p>	<p>Incorporate features that allow easy tracking and crediting of CBK artifacts sharing within their systems.</p> <p>Advocate for and support initiatives that standardize the recording of information to ensure uniformity and ease of sharing.</p>	<p>Ensure that their platforms adhere to all regional and national data protection regulations, simplifying the process for researchers.</p> <p>Collaborate closely with legal experts to ensure that EHR systems are designed with privacy and compliance in mind.</p>	<p>Prioritize the adoption of internationally recognized CBK protocols and standards in their platforms.</p> <p>Invest in features that promote FAIR data principles.</p>	<p>Incorporate robust, standardized ethical guidelines into their platforms to guide CBK collection, storage, and sharing.</p>

Table 4: Barriers to improve CBK fairness in Switzerland

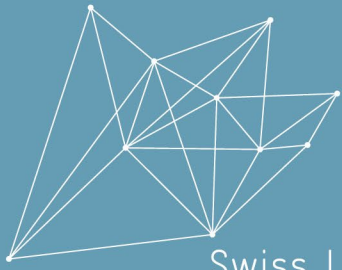
Levels	Recommendation 1: Systemic attribution mechanisms	Recommendation 2: Collaboration between biomedical researchers and legal experts	Recommendation 3: Standards and Technical FAIR-ifications	Recommendation 4: Ethical Framework for Biomedical Data
Research Culture	<p>Hypercompetitiveness may lead researchers to withhold data and CBK artifacts, fearing it may compromise their competitive edge.</p> <p>Reluctance to change existing practices and norms, especially in an environment where individual success is highly prized.</p>	<p>Researchers might prioritize individual or institutional gains over collaborative efforts due to competitive pressures.</p> <p>Misalignment of goals between legal experts and researchers in a hypercompetitive environment.</p>	<p>A focus on individual or proprietary solutions over standardized ones due to the race to be first or unique.</p> <p>Reluctance to invest time in learning or applying new technical standards if it doesn't directly contribute to competitive advantage.</p>	<p>Ethical considerations might be overlooked in the rush to publish or achieve results.</p> <p>Reluctance to invest time in understanding or adhering to ethical guidelines if they are perceived as additional hurdles.</p>
Current Legal System	<p>Ambiguity in data and CBK ownership and rights due to varying legal interpretations could hinder proper attribution.</p> <p>Legal complexities might discourage researchers from sharing CBK and data, fearing they might inadvertently breach some regulations.</p>	<p>Discrepancies between cantonal and federal laws may lead to confusion and impede effective collaboration.</p> <p>Legal concerns surrounding communication tools like email might discourage open communication between stakeholders.</p>	<p>Inconsistent data protection requirements could deter institutions and researchers from adopting standard practices.</p> <p>The legal ambiguity might slow down the adoption of international data protocols and standards.</p>	<p>Ethical guidelines may conflict with existing legal interpretations, creating confusion for researchers.</p> <p>Variability in legal requirements across regions might make it challenging to establish a uniform ethical framework.</p>

<p>Technical infrascture</p>	<p>Lack of standardized platforms may for validating, storing and sharing CBK make it difficult to attribute data correctly or consistently.</p> <p>If CBK artifacts don't have a consistent structure or platform, it could lead to issues in recognizing and crediting original data collectors.</p>	<p>Disparate tools and technologies might lead to ineffective communication and misunderstandings, especially when discussing complex legal nuances.</p>	<p>Absence of standards can result in incompatibility issues, where CBK artifacts from different sources don't align.</p> <p>The lack of infrastructure for sharing CBK artifacts means data may not be accessible or interpretable by all researchers.</p>	<p>Without standardized infrastructure, ensuring that ethical guidelines are adhered to consistently can be a challenge.</p> <p>The absence of robust and standardized infrastructure might increase the risk of data breaches or misuse, which would be an ethical concern.</p>
------------------------------	--	--	---	--

References

- [1] Wyatt J, Scott P. Computable knowledge is the enemy of disease. *BMJ Health & Care Informatics*. 2020;27(2).
- [2] Friedman CP, Flynn AJ. Computable knowledge: an imperative for learning health systems. *Learn Health Syst*. 2019; 3 (4): e10203. LRH2-2019-08-0027.
- [3] Goff DC Jr, Lloyd-Jones DM, Bennett G, et al. 2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2014 Jun 24;129(25 Suppl 2):S49-73. doi: 10.1161/01.cir.0000437741.48606.98. Epub 2013 Nov 12. PMID: 24222018.
- [4] Calculator: Cardiovascular risk assessment in adults (10-year, ACC/AHA 2013) (Patient education)." UpToDate. Available from: <https://www.uptodate.com/contents/calculator-cardiovascular-risk-assessment-in-adults-10-year-acc-aha-2013-patient-education>.
- [5] Wilkinson MD, Dumontier M, Aalbersberg IJ, Appleton G, Axton M, Baak A, Blomberg N, Boiten JW, da Silva Santos LB, Bourne PE, Bouwman J. The FAIR Guiding Principles for scientific data management and stewardship. *Scientific data*. 2016 Mar 15;3(1):1-9.
- [6] Mons B, Neylon C, Velterop J, Dumontier M, da Silva Santos LO, Wilkinson MD. Cloudy, increasingly FAIR; revisiting the FAIR Data guiding principles for the European Open Science Cloud. *Information services & use*. 2017 Jan 1;37(1):49-56.
- [7] Wise J, de Barron AG, Splendiani A, Balali-Mood B, Vasant D, Little E, Mellino G, Harrow I, Smith I, Taubert J, van Bochove K. Implementation and relevance of FAIR data principles in biopharmaceutical R&D. *Drug discovery today*. 2019 Apr 1;24(4):933-8.
- [8] Wilkinson MD, Dumontier M, Sansone SA, Bonino da Silva Santos LO, Prieto M, Batista D, McQuilton P, Kuhn T, Rocca-Serra P, Crosas M, Schultes E. Evaluating FAIR maturity through a scalable, automated, community-governed framework. *Scientific data*. 2019 Sep 20;6(1):174.
- [9] Geneviève LD, Martani A, Perneger T, Wangmo T, Elger BS. Systemic fairness for sharing health data: perspectives from Swiss stakeholders. *Frontiers in Public Health*. 2021 May 5;9:669463.
- [10] Swiss Institute of Bioinformatics. SIB is part of a European project to improve data sharing and reuse in the life sciences [Internet]. 2019 Feb 11. Available from: <https://sib.swiss/news/sib-is-part-of-a-european-project-to-improve-data-sharing-and-reuse-in-the-life-sciences>.
- [11] Adler - Milstein J, Nong P, Friedman CP. Preparing healthcare delivery organizations for managing computable knowledge. *Learning Health Systems*. 2019 Apr;3(2):e10070.
- [12] Baillie Gerritsen V, Palagi PM, Durinx C. Bioinformatics on a national scale: an example from Switzerland. *Briefings in bioinformatics*. 2019 Mar;20(2):361-9.
- [13] Appel RD, Feytmans E, editors. *Bioinformatics: a swiss perspective*. World Scientific; 2009.
- [14] Swiss National Science Foundation. 75% of researchers make their data accessible [Internet]. 2019 May 23. Available from: <https://www.snf.ch/en/RbhzyVGnZoNKcDz8/news/news-190523-3-out-of-4-researchers-share-their-data>.

- [15] Touré V, Krauss P, Gnodtke K, Buchhorn J, Unni D, Horki P, Raisaro JL, Kalt K, Teixeira D, Cramer K, Österle S. FAIRification of health-related data using semantic web technologies in the Swiss Personalized Health Network. *Scientific Data*. 2023 Mar 10;10(1):127.
- [16] Knobel I, Fegert M, Detreköy N. Health Data Governance: What's in it for Switzerland? *Swiss Forum on Foreign Policy*; 2020 Dec. Available from: https://www.foraus.ch/wp-content/uploads/2020/12/20201216_IDH_EN_WEB.pdf
- [17] Burton P. Building a Health Data Ecosystem in Switzerland [Internet]. *PharmaBoardroom*. 2021 Feb 12. Available from: <https://pharmaboardroom.com/articles/building-a-health-data-ecosystem-in-switzerland/>.
- [18] Martani A, Egli P, Widmer M, Elger B. Data protection and biomedical research in Switzerland: setting the record straight. *Swiss Medical Weekly*. 2020 Sep 1;150(3536):w20332-.
- [19] Lee D, de Keizer N, Lau F, Cornet R. Literature review of SNOMED CT use. *Journal of the American Medical Informatics Association*. 2014 Feb 1;21(e1):e11-9.
- [20] Ayaz M, Pasha MF, Alzahrani MY, Budiarto R, Stiawan D. The Fast Health Interoperability Resources (FHIR) standard: systematic literature review of implementations, applications, challenges and opportunities. *JMIR medical informatics*. 2021 Jul 30;9(7):e21929.
- [21] Gentleman RC, Carey VJ, Bates DM, Bolstad B, Dettling M, Dudoit S, Ellis B, Gautier L, Ge Y, Gentry J, Hornik K. Bioconductor: open software development for computational biology and bioinformatics. *Genome biology*. 2004 Sep;5(10):1-6.
- [22] Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, McLeod L, Delacqua G, Delacqua F, Kirby J, Duda SN. The REDCap consortium: building an international community of software platform partners. *Journal of biomedical informatics*. 2019 Jul 1;95:103208.
- [23] Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical?. *Jama*. 2000 May 24;283(20):2701-11.
- [24] United States. National Commission for the Protection of Human Subjects of Biomedical, Behavioral Research. The Belmont report: ethical principles and guidelines for the protection of human subjects of research. Department of Health, Education, and Welfare, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; 1978.
- [25] Swiss Personalised Health Network. Ethical Framework for Responsible Data Processing in Personalized Health Research [Internet]. 2nd ed. 2018 May 7. Available from: https://swissethics.ch/assets/pos_papiere_leitfaden/ethical_framework_20180507_sphn.pdf.



Swiss Learning
Health System