The SPHN Legal Agreement Templates

A Unified Contractual Framework for Data Sharing in Swiss Health Research

A project of

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Executive Summary

The use of comprehensive legal agreements has become standard practice in national and international collaborations in data-driven health research. Yet, navigating the regulatory landscape and negotiating such agreements can create friction and lead to financial risks. In Switzerland, the situation is further complicated by insufficient national coordination of governance practices and a heterogeneous understanding of legal requirements – which in the past has significantly delayed the negotiation of legal agreements for large multi-party projects.

To streamline negotiations of legal agreements, the Swiss Personalized Health Network (SPHN), in collaboration with legal experts from thirteen institutions across Switzerland, have consolidated their collective experience into a unified contractual framework. This framework includes a suite of legal agreement templates, the SPHN Legal Agreement Templates, specifically designed for the Swiss health research community. The initiative supports compliance, promotes transparency, and ensures accountability in collaborative research efforts.

This paper accompanies the SPHN Legal Agreement Templates and is intended for a broad audience of professionals interested in health data sharing among multiple parties for data driven projects and provides insights into the development of the SPHN contractual framework with its Legal Agreement Templates. Its purpose is to help interested professionals with varying levels of legal expertise navigate the SPHN contractual framework, and to support all parties in making well-informed, project-specific adaptations of the templates in compliance with the legislation.

After an introduction on the purpose and development of the templates, section 2 introduces the components, content, and structure of the SPHN Legal Agreement Templates. This section is particularly relevant for those seeking to familiarize themselves with the key elements and architecture of the SPHN contractual framework.

Section 3 addresses some of the most complex and commonly debated themes in legal negotiations. It provides better understanding of major areas of negotiations and includes explanations why and how those major themes were included in the templates in a certain way. The main themes covered include:

- **Governance:** Establishing governance bodies, such as boards with clearly defined responsibilities and decision-making rules to balance control with efficiency.
- **Data Definitions:** Introducing a classification of data types to complement legal definitions and avoid misunderstandings during negotiations.
- **Data Reuse:** Encouraging the further use of project data while ensuring alignment with institutional governance policies and creating interfaces between project decision-making bodies and the governance of data-providing institutions.
- **Intellectual Property (IP):** Offering multiple options to structure IP rights and revenue sharing while acknowledging the contributions of data-providing institutions.

1 Introduction

Box 1: About the Swiss Personalized Health Network (SPHN)

SPHN is a Swiss data infrastructure coordinated by the Swiss Academy of Medical Sciences (SAMS) in collaboration with the SIB Swiss Institute of Bioinformatics.

SPHN makes health data interoperable and shareable for research in Switzerland.

During the last decade, the sharing and reuse of health data has experienced a boost of professionalization. In addition to the development of FAIR data standards ensuring reusability and the building of trusted research environments ensuring data security, the use of comprehensive legal agreements has become international standard practice[1,2,3]. It is widely acknowledged that responsible sharing of personal data and managing the risk of data re-identification not only require protection by technical measures but also legal contracts that clarify the responsibilities of all parties involved and create accountability for their actions. Setting up such an agreement before the beginning of a project provides a transparent basis to conduct the project and substantially minimizes the risk of misalignment, project delays, or even discontinuation later on. Thus, granting access to sensitive health data requires specified terms of access in binding agreements, such as Data Transfer and Use Agreements. These agreements should follow whenever possible standardized terminology and format to ensure clarity.

However, navigating the regulatory landscape and negotiating legal agreements for projects using health data remains time consuming and can cause deep friction and delays of projects that might lead to additional costs. The fragmented legal regulations and health care landscape in Switzerland accentuate these issues. Switzerland still lacks a common understanding of the requirements and a close coordination and harmonization of processes, practices, and interpretation of the law at the national level[4]. To facilitate and simplify the legal negotiations of data-driven research projects, SPHN together with legal experts from institutions across the country have developed a unified contractual framework and published several Legal Agreement Templates for the Swiss research community.

The SPHN Legal Agreement Templates[5] and this accompanying paper are tailored to the Swiss context, but they may also be helpful to set up legal frameworks in other national contexts. Terms in capital letters are further explained in the SPHN Glossary[6].

[1] Wilkinson, M. D. et al. *The FAIR Guiding Principles for scientific data management and stewardship*. Sci. Data 3. 2016:160018 doi: 10.1038/sdata.2016.18.
[2] S. Kalkman, M. Mostert, C. Gerlinger, J. J. M. Van Delden, and G. J. M. W. Van Thiel, *Responsible data sharing in international health research: A systematic review of principles and norms*. BMC Medical Ethics. 2019, doi: 10.1186/s12910-019-0359-9.
[3] Organisation for Economic Co-operation and Development (OECD). *Recommendation of the Council on Health Data Governance*. 2017.
[4] K. E. Ormond et al., *What are the bottlenecks to health data sharing in Switzerland? An interview study*. Swiss Med. Wkly., vol. 154, no. 1. 2024, doi: 10.57187/s.3538.
[5] SPHN Legal Agreement Templates. Available online: https://sphn.ch/services/dtua/
[6] SPHN Glossary, Version 2, 07 October 2025. Available online: https://sphn.ch/document/sphn-glossary/

1.1. Who is behind the unified contractual framework?

During the SPHN initiative 2017-2024, the network partners successfully established health data infrastructures across the country and facilitated data-driven projects. In terms of ethical, legal and social issues, SPHN has built a unified contractual framework and accumulated expertise on governance related implications for complex multi-center data-driven projects.

The templates have benefited from the learnings of multiple rounds of inter-institutional negotiations related to SPHN funded projects, in particular the *National Data Streams* (NDS) (see Box 2). The NDS are four multi-disciplinary projects that develop sustainable and reusable health data infrastructure in conjunction with high-end research. To further align on data sharing strategies and develop the contractual framework, SPHN mandated the *Data Governance Working Group* (see Box 3). The group held in-depth discussions to achieve national harmonization of several key issues related to this framework. The result of these efforts has been made available to the research community in Switzerland and abroad in the form of the SPHN Legal Agreement Templates that have recently been published in a new version.

Box 2: The National Data Streams

National Data Stream (NDS) projects comprise of Switzerland-wide consortia that invest in the development of a sustainable data infrastructure for high-end data-driven and personalized health research in a specific area.

NDS include clinical, molecular and other data that will be enriched and made further available to the research community under defined conditions. In addition, each NDS includes a lighthouse research project and several nested projects. NDS constitute central pillars of the SPHN health data ecosystem. In the long term, they shall serve as models and crystallization points for future research projects and programs making health data available for third parties and clinical applications of personalized health.

Currently, four NDS are conducted in the fields of infectious diseases in intensive care, oncology, pediatrics and quality of care. NDS are jointly funded by SPHN and Personalized Health and Related Technologies (PHRT) of the ETH domain.

Box 3: The SPHN Data Governance Working Group

SPHN mandated the Data Governance Working Group (DGWG) to promote harmonized governance frameworks for data access, enabling equitable and trustworthy further use of routine health data throughout its entire lifecycle.

The DGWG consists of representatives from data providing and receiving institutions. The group includes members from legal departments as well as data governance boards and provides expertise linked to the set-up of multi-center data-driven projects. Overarching organizations are invited as observing members to give advice and build bridges to other stakeholders. The following institutions are members of the group:

University hospitals
- University Hospital Geneva (HUG)
- University Hospital Basel (USB)
- University Hospital Lausanne (CHUV)
- University Hospital Bern (Insel)
- University Hospital Zurich (USZ)

Others
- SIB Swiss Institute of Bioinformatics

Universities
- University of Basel (Unibas)
- University of Zurich (UZH)
- University of Bern (UniBe)
- University of Lausanne (UNIL)
- University of Geneva (UNIGE)
- Eidgenössische Technische Hochschule Zürich (ETH)
- École Polytechnique Fédérale de Lausanne (EPFL)

2 The SPHN contractual framework

2.1. Components of the contractual framework

The contractual framework comprehensively describes and regulates the cooperation and conditions of data transfer and use. The contractual framework developed by SPHN is tailored to multi-center research projects aiming to form a research consortium in which the parties jointly govern the research project. The entire contractual framework therefore regulates both, project specific aspects – like the responsibilities of each party or the financing of the project – and data protection aspects

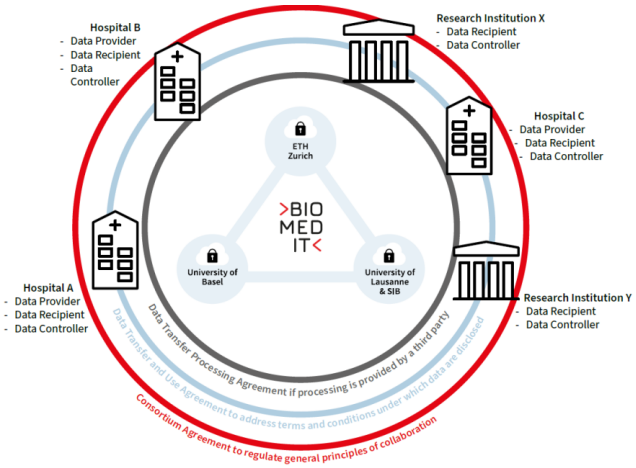

Figure 1: The three main components of the full-fledged contractual framework: Consortium Agreement as the main body (red circle) with an included Data Use and Transfer Agreement (light blue circle) plus the incorporated Data Transfer and Processing Agreement covering BioMedIT usage as trusted research environment (dark blue circle).

– like roles and linked responsibilities of participating parties according to the applicable legislation. It includes three components: the Collaboration Agreement (CA), the Data Transfer and Use Agreement (DTUA) and the Data Transfer and Processing Agreement (DTPA) (for details see Box 4 and Figure 1).

Box 4: The components of the Legal Agreement Templates

Consortium Agreement (CA)

What it is: A CA is the main legal agreement for a research project involving multiple collaborating institutions. It sets the rules for how the institutions work together, including how tasks are divided, how publications and intellectual property (IP) are handled, regulating financial arrangements, and project governance.

Who needs it: The institutions of the Principal Investigators who are sharing health data to conduct a multi-center research project.

Data Transfer and Use Agreement (DTUA)

What it is: A DTUA governs the transfer and use of health data between institutions. For example, if a hospital (the "Provider") shares data with a university (the "Recipient"), this agreement specifies the terms and conditions under which this data can be used. The Provider and the Recipient determine together the purpose of the data processing within the framework of the research project. Therefore, they both assume the role of "Data Controller" (as opposed to the role of "Data Processor" described below). The Recipients are responsible for ensuring the data's confidentiality, integrity, and security.

Who needs it: Institutions that exchange data as part of the project.

Data Transfer and Processing Agreement (DTPA)

What it is: Sometimes, the institutions (the "Controllers") may need to subcontract the secure transfer and hosting of data to a third party, such as BioMedIT, a secure IT network. The DTPA outlines the terms for this relationship, ensuring the subcontractor (the "Processor") follows the Controllers' instructions and maintains the required data access rules and data security standards. The Processors are responsible for ensuring the data's confidentiality, integrity, and security of the systems with regard to the data processing.

Who needs it: The institutions involved in the DTUA and any third-party processing data on behalf of the Controllers, like e.g., host institutions of BioMedIT nodes.

2.2. Content of the contractual framework

The Consortium Agreement (CA) regulates the project specific aspects covering all potential issues that need to be addressed in a multi-center data driven research project with health data.

The project specific aspects include the following main subjects:

– **Governance:** Defining the roles and responsibilities, like Sponsor or Investigator, in line with the Human Research Act and its ordinance. Further roles may include establishing an

Executive Board and, if needed, a Scientific Board for scientific expertise (specifying their constitution, voting rules and meeting requirements).

- **Finances:** Allocating financial resources to each party, including a project-specific description on how grant money is distributed among the Parties, the eligible costs and deliverables associated with it.
- **Reuse (open data):** Planning the conditions for reuse of the data for purposes outside the scope of the project. This includes defining the governance and authority for data reuse or deciding on a repository to make data available in the long run.
- **Intellectual Property (IP):** Defining how intellectual property rights are handled, brought into the project and developed during the project, including the licensing conditions for other parties and the distribution of revenues from IP exploitation.
- **Confidentiality:** Ensuring the confidentiality of proprietary or non-public information and the return of such information after the project termination.
- **Publications:** Rights and obligations to publish results

Setting up such an agreement before the beginning of a project provides a transparent basis to conduct the project and substantially minimizes the risk of misalignment, project delays, or even discontinuation later on. Particularly, an early agreement between the contract partners for regulating issues concerning IP and the reuse of data and publications can be essential as these aspects frequently lead to vivid discussions and disagreements. The topics of governance, data reuse (together with the distinctions between different types of data) and IP have prompted controversial discussions during negotiations of the NDS which in some cases contributed to delays of project start dates. Their relevance is explained and discussed more deeply in the third section of this paper (3.1-3.4) together with a short explanation of how they were implemented in the revised version of the Legal Agreement Template.

The Data Transfer and Use Agreement (DTUA) and the Data Transfer and Processing Agreement (DTPA), respectively cover the data protection aspects and integrate all relevant aspects of the Swiss data protection laws. Data protection laws in Switzerland (and in the EU) are built on several core principles of data protection[7,8] and introduce key roles[9,10]. Each role is associated with certain legal responsibilities and obligations and in the legal agreements it must be defined which party assumes what kind of role.

The main roles are the data Provider, the Recipient, the Controller, and Processor. The Provider agrees to disclose data to a data Recipient. The Controller defines the purpose and means to process the data while the Processor executes the data processing as determined by the Controller. For example, the Provider might be a hospital and the Recipient a university. They both assume the role of data Controller if they either jointly determine the purpose and means of data processing within their sphere of influence, or each party for their respective areas. An external Processor comes

[7] Data Protection Act, Art. 6. URL: https://www.fedlex.admin.ch/eli/cc/2022/491/de#art_6
[8] Regulation EU 2016/679 Chapter II. URL: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679#cpt_II
[9] Data Protection Act, Art 5. URL: https://www.fedlex.admin.ch/eli/cc/2022/491/de#art_5
[10] Regulation EU 2016/679 Chapter IV. URL: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679#cpt_IV

into play if a third party is subcontracted, for example to execute the secure hosting of the data on the BioMedIT network.

The key principles outlined in data protection laws are: purpose limitation, data minimization, security (integrity and confidentiality), lawfulness, accuracy and accountability.

The principle of purpose limitation means that data collection or processing must be closely linked to a specific purpose. In turn, it is not allowed to collect, use or transfer data without specifying why the data is being collected, processed or transferred. Most importantly, the purpose of such data usage should be evident to the data subjects and must be stated in the project proposal submitted to the ethics committee and in the DTUA. Defining the purpose of a research project or processing of data commonly requires formulating a clear and specific research question. Hence, broad purposes, like generating hypotheses in a specified area of research are not specific enough to fulfill the purpose limitation requirement.

Closely related is the idea of data minimization. It means that data transfer and processing should be limited to the extent necessary for achieving the intended purpose. In a research project this would mean that only the data that are necessary for the research project are disclosed and no other data that are unrelated to the project are disclosed. For example, if a research project studies a specific treatment for multiple sclerosis, it is not necessary to disclose data about a patient's income. This requires that researchers reflect about all the data variables that they require for their research and document this in the DTUA. It would be insufficient to specify just the patient cohort (e.g. all patients with the diagnosis of multiple sclerosis from 2020-2024) without specifying and limiting to only those data variables about the patients that are necessary for the research project.

Data security is the third important core principle for data protection[11]. It requires that those involved in the processing of personal data adopt technical and organizational measures to avoid unauthorized access to the data. Trusted Research Environments (TRE), like BioMedIT, as external processor hosting project data play an ever more important role in fulfilling this requirement. While the technical aspects are usually covered by the technical team on site, contract partners still have to specify what type of data management infrastructure they are going to use for the transfer and storage of the data and who is responsible to manage it and how this infrastructure can ensure data security. Especially when using cloud solutions, the identity of the respective service provider and the security measures provided need to be reviewed carefully.

Finally, the DTUA also stipulates that personal data must be de-identified and that any attempt at re-identification of the data subjects is inadmissible. In addition to these core principles, the DTUA ensures the liability of all involved parties in case of a violation. It furthermore explicitly grants the right to data subjects to also enforce such liability in case of violation.

2.3. Structure of the contractual framework

The SPHN contractual framework is designed to allow researchers to adapt their project specific agreement depending on already existing contracts or regulations. A variety of provided legal

[11] Data Protection Act, Art. 8. URL: https://www.fedlex.admin.ch/eli/cc/2022/491/de#art_8

agreement templates can be set up and adapted according to project specific needs following the principal idea of a building kit. This way former agreements already existing can be supplemented to simplify regulatory processes.

Depending on the project, the template selected might be either combined (incorporating multiple of the agreement types described above into a single document) or simple (cover only one agreement type). Combined templates (e.g., CA + DTUA + DTPA) have the advantage that all contractual terms and conditions are summarized in one document. However, this also implies that such a document is lengthy and might be overwhelming to handle at first. For example, the CA+DTUA+DTPA template has more than fifty pages, different schedules, annexes and even exhibits with various numbering. Nevertheless, this structure follows a system which shall help each actor involved in the project to quickly find the relevant part of the agreement. The modular setup is the reason for the different naming of the attachments: A schedule is an attachment to the main body, an annex is an attachment to a schedule and an exhibit is an attachment to an annex (see Figure 2).

Choosing the correct agreement ensures that the project complies with legal and regulatory standards and supports smooth collaboration between all parties. Depending on the specifics of a project, one type of legal agreement or a combination of it is needed. As a simple guidance, Table 1 recommends the respective agreement to be selected depending on already available project related contracts and regulations. The header, the title and the table of schedules indicate which types of templates are integrated in the template to allow for an easy grasp of this information.

Status	To Do	Template to be used
No legal agreement present	Set up agreements for the general collaboration between consortium members, and for transfer, use, and (if applicable) processing of data	CA integrating DTUA and DTPA (if BioMedIT node should be added)
Written commitment (CA) present	Set up agreement for transfer, use, and (if applicable) processing of data	DTUA integrating DTPA (if BioMedIT node should be added)
Everything in place except data processing part	Set up agreement for processing of data by service provider	DTPA (if BioMedIT node should be added)

Table 1: Recommended legal agreements to create an acceptable legal architecture for a research project depending on the availability of already signed commitments

The most frequently used combined template is the combined CA+DTUA+DTPA, which is explained in its architecture below and in Figure 2. Following the idea of a building kit, the CA is the main body of the agreement. The DTUA is included as one of the CA's schedules and the DTPA is attached as an Annex to the DTUA.

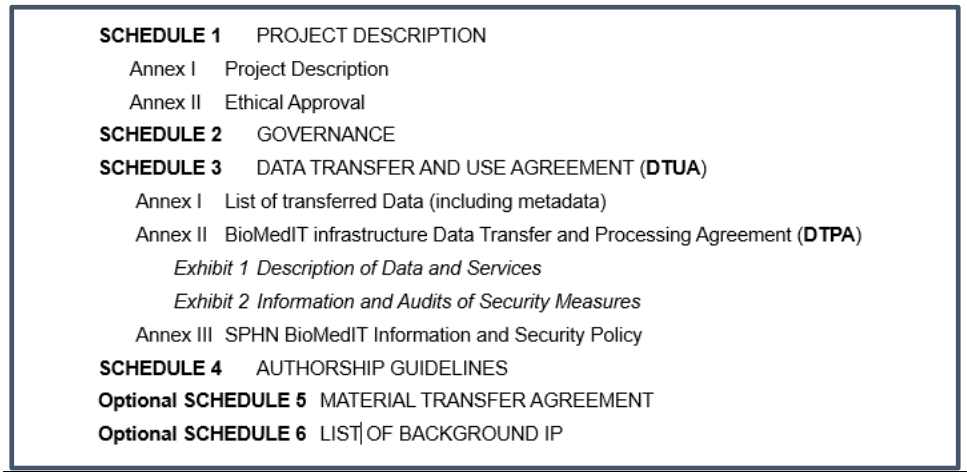

Figure 2: Structure of the legal agreement template CA+DTUA+DTPA depicted as table of content

The main body of the template consists of the clauses of the Consortium Agreement (CA). This part is the most relevant for members of the legal department and management because it sets forth the terms and conditions of the multicenter research project, general principles of collaboration, governance rules, rules on publications and intellectual property.

Schedule 1 – Project Description

All operational and technical details about the project are included here. Schedule 1 starts with a summary table listing the names of the various stakeholders of the project (e.g., sponsor, project leader, investigators etc.). It is followed by Annex I – Project Description, including detailed information about the deliverables or timelines of the project. In case there is an existing project proposal at hand, it can be copy and pasted here. Otherwise, all project-related details like a list of deliverables, milestones, timelines, gantt charts and similar type of information shall be included here. Annex II – Ethical Approval provides a space for ethical approval or statement/waiver (if it is relevant for the project). A copy of the ethical approval can be appended here to have it at hand each time when consulting the agreement. The template provides a placeholder for more annexes that can be used or simply removed if it is not necessary for a project.

Schedule 2 – Governance

It includes a list of governance bodies, such as the executive board with its responsibilities including names of persons who are representing the parties to the project.

Schedule 3 – Data Transfer and Use Agreement (DTUA)

It regulates the transfer and use of health data between institutions. At the end of the DTUA the Annexes to the DTUA are listed. Annex I contains a list of transferred data. Here all kinds of data and metadata that are transferred under the DTUA are listed. In case the project involves processing performed by the trusted research environment BioMedIT, in Annex II is an attached DTPA. It should be noted that the DTPA has a different set of signatories, because it needs to be approved by the representatives of the BioMedIT node.

The DTPA itself (being Annex II to SCHEDULE 3 to the CA) has two Exhibits. *Exhibit 1* contains the description of data to be transferred and service to be performed by the BioMedIT node, distribution of roles and responsibilities. *Exhibit 2* to the DTPA lists Information and Audits of Security Measure postulating general terms and conditions of the BioMedIT node regarding requests for information and audits. Similarly, in Annex III there is a placeholder for BioMedIT Information and Security Policy which can be accessed upon request at the email address indicated in the template.

Schedule 4 Authorship Guidelines

It proposes authorship guidelines for publications developed by the Swiss Academies of Arts and Sciences as a reference standard for the publications under the Consortium Agreement[12]. Depending on the needs of the projects, OPTIONAL SCHEDULE 5 for a Material Transfer Agreement can be included. It is based on a template provided by the Swiss Biobanking Platform[13]. Another optional schedule is SCHEDULE 6 where all background intellectual property provided by any party in the scope of the project can be listed.

3 Major discussion themes during the contractual framework development

This section delves into the main topics identified by the Data Governance Working Group as most significant – those that required in-depth discussions and led to revisions of the relevant clauses. Several clauses of the template are now presented as multiple alternatives to either choose between them or delete entirely. The background information below should enable users to understand the implications of the different options and make well-informed decisions about their preferences. The topics presented here are intended to serve both as a record of the Working Group's efforts and as guidance to gain more insights to themes relevant to the set-up of a project agreement.

Two important points should be noted. First, as stated at the beginning of the paper, these templates are intended as a starting point, providing institutions and researchers with a contractual framework for their projects. The templates were meant to be tailored and adjusted by the parties involved as needed but kept as standardized as possible to facilitate the review by legal experts in future projects.

Second, the content of the templates may not fully reflect the views of every participating institution in the Working Group. However, they are designed to support the majority of users by providing a helpful starting point and guidance for setting up agreements that outline the general principles of collaboration for their research projects.

The views that were most widely supported during the Working Group's discussions are reflected below, as well as practical feedback from the implementation of the SPHN NDS projects, addressing real-world needs.

[12] Swiss Academies of Arts and Sciences 2013. Authorship and scientific publication. Available online https://api.swiss-academies.ch/site/assets/files/4413/akademien_autorschaft_en.pdf

[13] For more information consult the Swiss Biobanking website at: https://swissbiobanking.ch/

3.1 Governance

3.1.1 Relevance of the theme

To ensure the effective execution of projects, the templates include a Governance section. This section is designed to establish specific roles and bodies responsible for the successful management of the project.

The principal roles outlined within this framework include the Project Leader, Investigator, Sponsor, as well as the Executive Board and Scientific Board. The roles of Project Leader and Sponsor are defined in Article 3 of the Human Research Ordinance (HRO)[14]. Assigning these roles is essential for the proper conduct of the project and for ensuring that liability under the Human Research Act (HRA)[15] is clearly delineated. Furthermore, ethics commissions, which grant approval for research projects, typically require the designation of both a Sponsor and a Project Leader as a condition for authorization. Note that for projects not falling under HRA, (for example if the project uses anonymized data), adapted roles might apply.

The primary authority for strategic oversight and decision-making is the Executive Board. This board is typically composed of representatives from each participating party, who convene regularly to make strategic decisions regarding the project. Decisions are generally reached through a voting process, with the rules governing this process specified in the CA. All parties are typically bound by the decisions made by the Executive Board. In addition to the Executive Board, the templates also provide the option of establishing a Scientific Board. The role of this board is to offer advisory opinions on the scientific aspects of the project. It is possible for external members, such as researchers with relevant expertise or patient representatives, to be included in this board.

The Executive Board, its power and voting rules were a focal point in many discussions during the SPHN Projects negotiations. A major concern was that representatives could make decisions that might impact other parties, even if those parties had not explicitly agreed to those decisions if the voting rule did not require unanimity. For instance, some parties emphasized during negotiations that any amendment to the project description must be approved unanimously by all parties. While this legal concern is understandable, there are occasions when the decision-making process requires a balance between the collaborative spirit that guides the research community in Switzerland on these types of projects and ensuring that the specific requirements of certain parties on more sensitive issues are respected.

Another complex problem concerns the relations between the governance of the project and the data governance of the data providers. Over the past several years, the SPHN Legal Agreement Templates have been used for several research projects in Switzerland, and in particular for the SPHN funded National Data Streams (see Box 2). These projects were designed to facilitate the further sharing of data for research purposes, specifically focusing on the further reuse of gathered project data. However, further sharing and reuse of project data depends on institutional governance

[14] Ordinance on Human Research with Exception of Clinical Trials. Chapter I, Art. 3. URL: https://www.fedlex.admin.ch/eli/cc/2013/642/en#art_3

[15] Federal Act on Research involving Human Beings. Chapter 2, Section 3. URL: https://www.fedlex.admin.ch/eli/cc/2013/617/en#chap_2/sec_3

that needs to be set out in the initial agreements at the time point of gathering project specific data. In Switzerland, researchers seeking to reuse health data for scientific purposes typically face a dual approval process: not only must they obtain authorization from the competent ethics committee, but they must also secure data access permissions from the institution that originally collected the data – often a hospital or healthcare provider.

Effective data governance plays a pivotal role in ensuring that the reuse of health data complies with legal requirements, particularly data protection laws, and aligns with the specific conditions of ethics committee approvals. It also facilitates fair and secure access to data, supports transparency in data processing, and promotes efficient data-sharing workflows. In this way, robust data governance is a cornerstone of responsible health data reuse and a key enabler of research and innovation. However, Switzerland's data governance landscape is highly decentralized without having a legislation in place that aims towards a national coordination. Governance responsibilities lie with the individual data-providing institutions, which operate under either cantonal data protection laws or the Swiss Federal Data Protection Act. Each institution may implement its own governance procedures, approval processes, and interpretation of regulatory requirements. The legal, ethical, social and institutional norms that impact data governance are already manyfold. In collaborative multi-party projects, this complexity is even more accentuated. In the absence of a national governance framework, the only way to assure effective data governance of the project's data is to create legal relations between the decisions of the Executive Board to the decision procedures of the data providing institutions. That is, for each data access request for project data, the governance bodies of all data providing institutions must be considered in the decision process. Balancing the decentralized governance with the practicality of data sharing for third parties is a major concern that impacts the setup of the templates.

3.1.2 Implementation of the theme in the template

The governance section was structured in two parts. The first (section 3.1) lists the project's key people and governance bodies together with a definition. The second (sections 3.2 and 3.3, or more if applicable) contains the rules governing the operation of the bodies listed in the first section. This includes, for example, the rules of the Executive Board, rules on membership, quorum, voting rules and meetings.

Executive Board

As elaborated above, the main challenge is to balance between control over decisions without stalling the projects. To that end, there is an extended and refined list of topics on which the Executive Board is authorized to make decisions which allows to tailor different type of decision rules to the different topics. This approach consolidates all decisions and voting rules in one section of the contract, making it easier to consult. More importantly, it allows for the selection of specific voting rules for each type of decision, depending on the nature of the project and the parties involved. To accommodate the need for great flexibility in meeting formalities and voting procedures, provisions that allow for decision-making via email and the holding of meetings through video conferencing are incorporated.

Moreover, there is a provision allowing the Executive Board to update the list of board members in Schedule 2 by a vote. This allows to make changes to board membership in a swift and easy way without the need for a formal contract amendment, which proofed highly valuable in practice.

Agency and Executive Board Authority

Another topic related to the powers of the Executive Board pertains to the concept of agency. Again, to balance the need for decision power of the individual Parties with practical concerns, the latest version of the template includes a non-agency clause with one relevant exception.

The non-agency clause states that "the Consortium Agreement does not establish any principal agent or similar relationship between the Parties, and nothing in this Consortium Agreement shall be interpreted as allowing either Party to represent or act in the name or on behalf of the other Party." The exception to the non-agency clause concerns the reuse of data during the project's duration for research purposes unrelated to the original scope of the project. To allow reuse of data the execution of a Data Transfer and Use Agreement (DTUA) is required. As it can be a huge practical hurdle to collect the signatures for such an agreement of all parties involved, the exception to the non-agency clause allows the chairperson of the Executive Board to sign the data-sharing agreement on behalf of all consortium parties, whether the data is being shared with another party to the contract or with a third party. The chairperson is thus granted the authority to represent all consortium parties solely for the purpose of signing this agreement, thereby making the process more efficient and smoother.

It is important to note that this exception merely simplifies the practical aspects of signature collection while the decision power about the reuse remains with the individual institutions through two separate clauses. First, the contract clearly specifies that any decision leading to the execution of such an agreement must first be approved by vote by the Executive Board, which generally includes a representative from each party. This decision can be subject to a unanimous vote if the parties deem it necessary. Furthermore, it is explicitly stated that any data-sharing arrangement is contingent upon the prior approval of the data provider. Thereby, the governance of the project data is clearly linked and subordinated to the data governance of individual institutions. For additional details regarding data reuse, please refer to Section 3.3 of this paper.

Scientific Board

Since the Scientific Board does not issue binding decisions and works primarily as an advisory body, the rules governing its operation can be simplified. It appears unnecessary to have clauses setting up a quorum or voting procedures, agenda and minutes, given that no binding decisions are made.

Therefore, the rules are streamlined, which also helps to clarify the distinction between this body and the Executive Board. This way the Executive Board remains the only entity empowered to make binding decisions.

In parallel, the necessity of including both internal scientists employed by the parties and external experts has been reaffirmed. In such cases, it may be necessary for members of the Scientific Board, particularly those who are external to the consortium (i.e. scientific experts form other institutions than those who are party to the agreement) to sign a Non-Disclosure Agreement (NDA). A corresponding clause reflects this option.

3.2 Data definitions

3.2.1 Relevance of the theme

The legislation does not provide distinctions between the various sources, subject areas or processing stages of health data. It only defines the term “health-related personal data” and distinguishes between genetic and non-genetic data. [16] The concepts of anonymization and coded (pseudonymized) data are set out in the HRA with its ordinances whereas anonymized data do not apply to data protection regulations in general. Still, it is required to de-identify data to mitigate the risk of re-identification conducting a risk assessment, especially in cases when anonymization is not fully possible[17]. Other laws regulate the processing of specific types of data, like the Federal Act on Human Genetic Testing (HGTA)[18] that applies to genetic data in the clinical care context and the Federal Cancer Registry Act (CRA)[19] that regulates the mandatory reporting of cancer data and its subsequent use.

As data are being processed along the project life cycle, the scientific value of data, the legal requirements applicable to such data or the governance requirements and decision rules can change. For example, sharing aggregated data in the form of summary statistics with third parties, might not require a vote by the Executive Board, while sharing patient-level data with third parties might require unanimous agreement by the Executive Board. A common understanding of the specific data types along the life cycle might therefore be necessary to ensure a common understanding of other aspects of the collaboration.

To accommodate the need to further refine data types along the data life-cycle, the DGWG together with scientific experts have developed the following distinctions of data along the data life-cycle (see Figure 3):

– **Primary data** means data that is the direct output of data collection and has not undergone extensive processing.
– **Curated data** is data that was processed by data curation (including selection, structuring annotating, semantic mapping and more) and is ready for data analysis or training of algorithms or other outputs.
– **Combined data** is curated data from different data providers that underwent merging (combining the same data variables from different data subjects) or linkage (combining different data variables from the same data subject).
– **Deposited data** is typically patient-level data that is deposited in a repository to be reused by others for other projects. Deposited data should be FAIR to enable further reuse of the data and de-identified to assure data protection.

[16] Federal Act on Research involving Human Beings. Chapter 1 Art 3. URL: https://www.fedlex.admin.ch/eli/cc/2013/617/en#art_3
[17] https://sphn.ch/network/data-coordination-center/de-identification/
[18] Federal Act on Human Genetic Testing. URL: https://fedlex.data.admin.ch/eli/cc/2022/537
[19] Federal Cancer Registry Act. URL: https://fedlex.data.admin.ch/eli/cc/2018/289

– **Analyzed data** is data that results from applying scientific methods with the aim of generating scientific insights, e.g. in the form of summary statistics, measures of effectiveness, graphs or figures.

– **Published analyzed data** is analyzed data such as summary statistics or graphs that is published for the purpose of knowledge dissemination. Published analyzed data is usually distributed with an accompanying written publication or oral presentation to put the analyzed data into context.

The proposed terms of data types build on a related approach currently used in the EU.

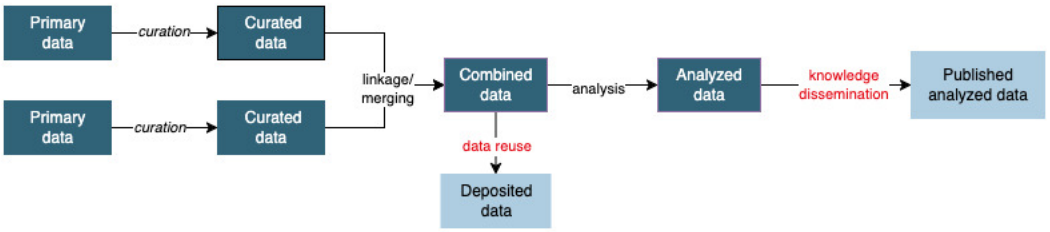

Figure 3: Data distinctions along the data life-cycle. The boxes indicate the names of the data categories; the arrows indicate the transformation process (black) or the purpose of data dissemination (red).

The distinctions between data along the life-cycle are most relevant for the topics of data reuse and intellectual property. When deciding about making data available to third parties it can be of pivotal importance to clarify at what stage of the data life cycle data should be made available for reuse. Making data available for reuse has been a controversial topic during the negotiations of the templates. The definition of data is closely linked to resolving such a controversy as collaborating institutions are typically in favor of freely sharing analyzed data, while they are more reluctant to share curated data or even combined data.

The distinctions are also relevant when discussing intellectual property. While data itself is not protectable as intellectual property, the efforts of mapping data to semantic standards or performing quality controls requires skilled intellectual work and is scientifically valuable. Therefore, data that has undergone extensive data curation (including processes like standardization or quality controls) might qualify as so-called non-inventive contribution deserving a fair share of IP exploitation revenues, whereas the contribution of non-curated primary data might not qualify as non-inventive contribution (for details see section 3.4 on intellectual property).

3.2.2 Implementation of the theme in the template

Implementing terms for data types in a template without an established legal meaning might complicate the signing of the agreement and not work for all research projects. Therefore, the scientific data definitions were not directly implemented in the templates but are provided in the SPHN Glossary accompanying the templates. In addition, an explanatory text has been added to the templates to make users aware that this option exists.

When using the templates, users are encouraged to reflect on the term “data” throughout the template to ensure that all parties are aligned on the specific categories of data referred to and to specify the data category on any occurrence if misunderstandings could emerge. This concerns particularly the section on Data and Biological Material that also regulates the further use of data outside the scope of the specific project, and the section on Intellectual Property. It is of pivotal importance that all parties agree at what stages of the data life cycle data will be made available to third parties and what type of data might meet the non-inventive contribution requirements.

To facilitate discussions and encourage the further use of data, the explanatory text also provides a general recommendation, stating that it is most useful to make combined data available in a repository or elsewhere, while primary or curated data might remain under the control of the institutions. The recommendation balances the interests of data providing institutions, who do not want to duplicate the storage of their data outside their control with the interests of researchers, who are most keen on getting access to scientifically rich data that was already extensively processed and potentially linked to other data.

3.3 Data reuse and open data

3.3.1 Relevance of the theme

The reuse of health data is increasingly recognized as a cornerstone of research conducted in Switzerland, enabling more efficient, cost-effective, and innovative scientific exploration. Supported by national initiatives and growing demand from the research community, technological and institutional capacities are evolving, but the legal and governance frameworks enabling data reuse remain under development. Health data reuse, however, is essential to maximizing the value of research outputs. Researchers and their institutions often invest considerable effort in making qualitative data available and creating enriched datasets. Without mechanisms for further use, those datasets risk becoming inaccessible or underutilized after a project ends. This loss not only wastes resources but also limits scientific progress.

Across Swiss research institutions, there is a clear and growing demand to address this gap through both technical infrastructure and supportive governance. National and international initiatives referring to the FAIR data principles (Findable, Accessible, Interoperable, Reusable) such as Open Research Data[20] and Switzerland's Open Research Data (ORD) strategy[21] as well as the European Health Data Space Regulation[22] are actively promoting open access and reuse of datasets. These frameworks support the systematic preservation, discoverability, and sharing of data, aligning with global standards and reinforcing Switzerland's commitment to responsible and innovative research practices.

[20] National Strategy Council Open Research Data. Website available online: https://openresearchdata.swiss/
[21] Swissuniversities (2021) Swiss National Open Research Data Strategy. Available online: https://www.swissuniversities.ch/fileadmin/swissuniversities/Dokumente/Hochschulpolitik/ORD/Swiss_National_ORD_Strategy_en.pdf
[22] European Health Data Space Regulation (EHDS) - European Commission. Available online: https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

Despite these advances, the Swiss legal framework for data reuse remains limited and complex. The Swiss Human Research Act governs the reuse of personal data in research with varying provisions depending on the level of de-identified data, which might be pseudonymized or anonymized data[23]. While researchers have shown adaptability in navigating this complexity, there is widespread recognition that the current legislation does not adequately support the needs of innovative, data-driven research projects. A motion submitted to the Swiss Council of States in August 2022 emphasized the urgent need for a reliable and enabling legal framework[24]. It called for a framework law on data reuse, aiming to establish governance models, support pilot projects, and provide legal clarity. This law is expected to enter consultation by the end of 2026 and will mark a pivotal step toward ensuring data reuse aligns with privacy standards while fostering innovation and public trust.

In the absence of an implemented national framework for open data and data reuse, the contractual framework of the project should provide terms on the further use of data suitable to the participating Parties. Such terms should include and balance governance aspects like the decision power of the involved bodies and parties, legal aspects like the required contracts for data reuse, practical aspects like the collection of signatures within the project consortium and strategic aspects like the choice of a repository for long-term storage for the project's data. Researchers are strongly encouraged to avoid scenarios where datasets are left in limbo at the end of a project, with no clear provisions for their continued use or preservation. However, it needs to be taken into account that some parties might be reluctant to transfer data and delegate their decision power to long-term repositories or other governance bodies.

3.3.2 Implementation of the theme in the template

To regulate the reuse of the data in the templates, it includes two dedicated clauses (6.4 and 6.5 of the CA). One addresses the reuse of the data during the terms of the CA and one addresses the reuse of data after the termination of the CA.

To enable the further use of data during the terms of the CA, the templates empower a designated chairperson to sign reuse contracts on behalf of all project consortium members after an approval of the Executive Board (see exception to the non-agency clause in section 3.1.). Therefore, the template provides a practical solution to streamline data sharing agreements, as this avoids the long-lasting process of requiring all project consortium members to sign such agreements and represents a significant step forward. At the same time, the decision power about further use is fully retained by the institutions, as the reuse of data is subject to a vote of the Executive Board and prior approval of all data providing institutions.

Concrete clauses that address further use of project datasets (Combined data and Analyzed data) after the termination of a collaboration agreement remain controversial. The solution presented in the template is a clause that encourages the parties to name a specific repository in which the data will be deposited after the termination. As repositories for sensitive health data are still rare in Switzerland, the explanatory text also invokes the possibility to agree on an institutional data platform

[23] Frédéric Erard / Mathilde Heusghem / Clément Parisato, Biomedical Research and Open Data, in: Jusletter 30. Januar 2023 Available online : https://jusletter.weblaw.ch/juslissues/2023/1140/recherche-biomedical_4b9e008242.html__ONCE&login=false).
[24] The Swiss Parliament. https://www.parlament.ch/en/ratsbetrieb/suche-curia-vista/geschaeft?AffairId=20223890

or a BioMedIT node. Moreover, the clause obliges the parties to establish a strategy for data reuse at least six months before the termination of the contract. Analyzed data that is supposed to be disseminated, needs to be transferred to a medium that meets the requirements of the project and the consortium.

Addressing the question of further use beyond project termination remains a critical challenge for the future. This issue is particularly pressing given the strong demand from researchers for clear solutions that preserve the scientific value of data. Continued collaboration and dialogue will be essential to meet these needs and advance the responsible and effective use of data.

3.4 Intellectual property

3.4.1 Relevance of the theme

Intellectual Property (IP) is very often one of the hot topics discussed between the contract parties. Understandably, the institutions would like to see a return on their investment in new developments, which is mostly by securing, and, more importantly, by exploiting their IP.

IP constitutes factually a monopoly, because its owner decides whether and under which circumstances third parties are allowed to use the IP, therefore it is crucial to find a balance between these legitimate interests and the principles of open research, as outlined in the Swiss National Open Research Data Strategy[25]. How these aspects are weighed, depends also on the contract partners: Industry will have another, possibly more adamant position regarding IP than academia and researchers. In any event, it is advisable to clarify the goals and intended outcomes of each project: Will the results be openly accessible? Will data be shared and/or reused? Will software be developed within the project? Is it based on open-source software and therefore also to be handled as such?

The results of a project can include for example an invention, data, software, algorithms, knowledge, know-how or information. Results can be protectable as IP (Foreground IP) or in form of data, algorithms, knowledge, know-how or information of any kind, that cannot be filed as i.e. patent, design or in some jurisdictions even as copy right.

An important distinction is made between IP, non-inventive contributions and data: all are intangible assets, and are usually owned by an entity or a person respectively, disclosed to a closed circle of individuals, or sometimes declared as open. IP has always an inventive or creative component as the legal descriptions of patents[26,27] designs[28,] trademarks[29] and copyrights[30] show. Know-how and trade secrets on the other hand, are non-published or trivial information that might entail an economic

[25] Swissuniversities (2021) Swiss National Open Research Data Strategy. Available online: https://www.swissuniversities.ch/fileadmin/swissuniversities/Dokumente/Hochschulpolitik/ORD/Swiss_National_ORD_Strategy_en.pdf
[26] Federal Act on Patents for Inventions, Art 1. URL: https://www.fedlex.admin.ch/eli/cc/1955/871_893_899/de#art_1
[27] Federal Act on Patents for Inventions, Art 7. URL: https://www.fedlex.admin.ch/eli/cc/1955/871_893_899/de#art_7
[28] Federal Act on the Protection of Designs, Art 2. URL: https://www.fedlex.admin.ch/eli/cc/2002/226/de#art_2
[29] Federal Act on the Protection of Trade Marks and Indication of Source, Art 1. URL: https://www.fedlex.admin.ch/eli/cc/1993/274_274_274/de#art_1
[30] Federal Act on Copyright and Related Rights, Art 2. URL: https://www.fedlex.admin.ch/eli/cc/1993/1798_1798_1798/de#art_2

advantage for its owner. Whereas data are according to the Cambridge Dictionary “information, especially facts or numbers, collected to be examined and considered and used to help decision-making, or information in an electronic form that can be stored and used by a computer”[31].

Intellectual property rights do not include data. However, data and know-how can be acknowledged as a non-inventive contribution that contributed to the generation of IP rights and consequently subject to receiving a share of IP revenues generated by the IP owners. The exploitation of Foreground IP was the most discussed section during the revision process of the template, especially in connection with the interpretation of “significant non-inventive contributions”: It has been broadly argued in favor and against this wording. Some have stated that the request by data providers for a percentage of the revenue generated goes against the objective of Open Science[32], particularly Open Research Data[33], as it constitutes an economic barrier to the reuse of health data. On the other hand, it has been stated that for the work that has to be invested by the data providers for the curation of the data, it would be only fair to receive a share on any revenue.

Another distinction is made between background and foreground IP. Background IP includes all IP that the parties own independent of the project in the contract, whereas foreground IP refers to all IP generated within the scope of the project. If two or more parties partner-up in a project, they declare that each party remains the owner of its background IP. However, they might grant a non-exclusive, free license of the background IP to their contract partners within the strict contractual boundaries of the project. Usually, the protection of background IP is undisputed. Especially, if for the sake of clarity, a list of the background IP is included in the agreement. It is understood that the disclosure of background IP is bound to strict confidentiality provisions that must be reflected in the agreement.

Regarding foreground IP and other results, the contract partners must decide if and how they want to protect the results (i.e. analyzed data, IP and or know-how) and how they want to share them: They may agree on joint ownership for all results and IP resulting from the project or on sole ownership.

In a second step the parties must decide how they want to regulate the exploitation of potential foreground IP[34]. There are basically three options:

1. Any revenue coming from foreground IP will be shared equally.

2. The share of the revenue depends on the contribution of each party to the IP. For this option, the parties can agree on a percentage, which they set out in the agreement.

[31] Cambridge Englisch Wörterbuch: https://dictionary.cambridge.org/de/worterbuch/englisch/data
[32] Swissuniversities (2021) Swiss National Open Research Data Strategy. Available online: https://www.swissuniversities.ch/fileadmin/swissuniversities/Dokumente/Hochschulpolitik/ORD/Swiss_National_ORD_Strategy_en.pdf
[33] National Strategy Council Open Research Data. Website available online: https://openresearchdata.swiss/
[34] The World Medical Association, Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks, Art. 18: https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/

3. The parties can postpone the decision about the share and set out in the agreement, that any exploitation of joint foreground IP will be agreed in a separate contract between the parties.

The third option might be more attractive if no commercializable IP is to be expected from the project, in order to facilitate the negotiations. Which alternatives are chosen depends very much on who the partners are: There might be a difference between a private public partnership and a purely academic collaboration.

Regarding the patent protection of foreground IP, the template foresees the possibility to give the Executive Board the power to decide on the protection or commercialization of results. Even though for this option there were remaining discussions in the Group, the present document remains a template, its provisions are optional and adaptable and must be agreed by the consortium members.

Another complex question is whether the Executive Board is granting the power to decide how to deal with foreground IP, in the event that the owner res. not all of the owners want to file for patent protection. Again, this point is only worth negotiating, if foreground IP is expected at all. On the other hand, if the case occurs that the opinions about the patentability of foreground IP diverge, giving the Executive Board the last say could represent a good solution.

In the following, guidance is provided to define project regulations regarding IP in its broadest sense.

3.4.2 Implementation of the theme in the template

Background IP

If background IP is needed in the project, it is advisable to attach a list of background IP as an annex to the agreement. Experience has shown that the compilation of an IP list needs a certain expertise. Therefore, it is advisable to involve knowledgeable colleagues e.g. from the legal department. Also, the form and extend of the disclosure of the background IP between the parties has to be established. In the event that the partner needs to use background IP, a license can be agreed. This can be limited to the project or also beyond it, depending on what is agreed.

Foreground IP

Depending on the expected results of the project, which could be data, software, algorithms inventions, new know-how etc. the parties have to agree, how they want to handle the ownership of these assets, which at the time point of contract negotiations do usually not exist.

The template provides two alternatives:

– **Alternative 1** applies when future IP shall be jointly owned *only if* the contributions of each party cannot be clearly separated.

– **Alternative 2** applies when the parties agree to joint ownership of the future IP under all circumstances.

In both cases, the scope of a potential license to the partner who does not own the results must be defined. Additionally, foreground IP should be considered in the same way as background IP, as previously described.

IP Exploitation

Regarding the exploitation of potential foreground IP it has to be decided if already in the agreement a fair share (possibly also with an exact percentage) of the revenues generated from the commercialization of the IP needs to be set out or if the decision needs to be postponed to a later time-point.

Which position regarding the “significant non-inventive contribution” carries more weight depends heavily on the consortium's composition and the nature of the project. To ensure a fair balance between each party's contributions and the exploitation of the results, several factors should be taken into account: the amount of work required to curate, prepare, and otherwise process the data to make it suitable for the project; the resources each party has available to carry out this work; and whether the intended outcome of the project is a marketable product, such as an algorithm. The template encourages to take significant non-inventive contributions into account when negotiating IP exploitation while allowing the parties to choose, entirely delete, respectively to find a wording that fits the project and interests the best.