# Collaboration Agreement („Leistungsvereinbarung“)

## Final Report - (Version: 08.03.2021)

**Responsible persons at the University Hospital**

|  |  |
| --- | --- |
| Last name, First name |  /  |
| Position |  /  |
| Institution |  |
| Address |  |
| Postcode/City |  |
| E-mail address |  |

**Attachments:**

* Detailed financial information for the year 2020 (Excel document)

*Please note that this feedback will not only be used to evaluate the completion of the Collaboration Agreement 2018-2020 but it will also contribute to the mapping of existing research infrastructures of the SPHN and reporting to the State Secretary of Education, Research, and Innovation. Infrastructure mapping will be published on the SPHN homepage and should help principle investigators of future research projects optimising their studies, finding collaborations and using existing infrastructures.*

Place, Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

CEO

Place, Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Director

### **Description of the endeavours undertaken by the UH in the frame of the Collaboration Agreement in 2020 (extended until 30.06.2021).**

1. *General comments (max. 1 page)*
2. *Implementation of standards for data*

*Please describe the implementation of clinical data standards within your hospital and add any additional standard that is not currently listed. For ease of use, you may copy your table provided in the last Annual Report 2019 and update it in a different color.*

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| --- | --- | --- | --- | --- | --- |
| **Clinical data standard** | **Standard Version** | **Degree of implementation** | **Where in the data flow is this standard implemented?** | **For which data categories is the standard implemented (e.g. for lab: chemistry, haematology, serology, etc)?** | **How is the further implementation of this standard planned?** |
| **None** | **Planned** | **Partly** | **Fully** |
| ICD | 10 |  | X |  |  |  |  |  |
| LOINC |  |  | X |  |  |  |  |  |
| ATC |  | X |  |  |  |  |  |  |
| CHOP |  |  |  |  |  |  |  |  |
| UCUM |  |  |  |  |  |  |  |  |
| SNOMED (in care) |  |  |  |  |  |  |  |  |
| NANDA |  |  |  |  |  |  |  |  |
| ICD-O |  |  |  |  |  |  |  |  |
| SPREC |  |  |  |  |  |  |  |  |
| SBP minimal data set |  |  |  |  |  |  |  |  |
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*Please briefly describe the architecture and data flow of the clinical research management systems of your UH and include a schema (max. 1 page). For ease of use, you may copy your text and schema provided in the last Annual Report 2019 and update it in a different color.*

*In addition, please answer the following questions: For ease of use, you may copy your text provided in the last Annual Report 2019 and update it in a different color.*

* *Which primary systems are already connected to your clinical data warehouse/data lake?*
	+ - * *To which degree is the data structured? What quality measures of the data are in place? How far is the implementation of the core data set?*
			* *Which purposes does your infrastructure serve (research, clinical decision support, finance, administration, etc)?*
1. *Describe how the data governance processes for the exchange of health-related data for research are organized. How are these processes related to other stakeholders (e.g. ethics committee) (max. 1 page)? For ease of use, you may copy your text provided in the last Annual Report 2019 and update it in a different color.*
	* + - *In addition, please name your hospital’s point of contact for data requests:*
2. *How do you address the exchange/alignment of structured data between your central hospital IT infrastructure, CTUs and cohorts. Are any disease specific cohorts of national importance hosted in your environment? For ease of use, you may copy your text provided in the last Annual Report 2019 and update it in a different color.*
3. *Which support structures and services do you provide to SPHN projects? Do you have a pricing structure and does it adhere to the SNSF infrastructure use cost model[[1]](#footnote-1)? For ease of use, you may copy your text provided in the last Annual Report 2019 and update it in a different color.*
4. *Data availability*

*Please describe how many patient datasets and samples are available to the SPHN research community for further use according to the FAIR principles.*

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| **Type** | **How many data with “core data sets” and “data quality information” are available?** | **Comments** |
| Clinical data | *Please indicate an order of magnitude/**unable to determine.* |  |
| Genomic data |  |  |
| Other omic data |  |  |
| Biobanking material |  |  |
|  |  |  |

### **Strategic goals for the reporting period.**

*In this section, please describe the progress made during the reporting period with respect to each milestone. Please report on the points highlighted in yellow.*

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| 1. **Consent Management and Legal Framework**
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| **A1. (Hard milestone): Milestone A1 to be met at the end of Y3.**1. *[adapted to reflect the availability of a General Consent template from Swissethics]* Is UH using the General Consent (version 2019/2 of swissethics) or, if not, in what respect does the UH General Consent differ from the harmonized template?
2. The UH has implemented a formal and documented process to continuously increase the proportion of patients who are informed about the existence of a "general consent" or a harmonized consent (if available[[2]](#footnote-2)).

On 31 December 2020, the following information level should be reached for each of the following groups for Year 3:[[3]](#footnote-3)* ≥85% of adult DRG domain patients
* ≥50% of Tarmed domain patients
* ≥50% of pediatric DRG domain patients
1. Patients must have the possibility to choose whether to "sign" a consent.
 |
| ***Results***  |
| 1.
2.
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| **A2. (Soft milestone): Milestone A2 to be met at the end of Y1, Y2 and Y3.**The UH has, during the relevant contractual year, actively contributed to clarify and document the relationship between SPHN and the UH with respect to the legal framework and the procedures in place within the UH that relate to the sharing of consent information and the sharing of patient data (including governance, mechanisms to ensure proper implementation of consent revocation, adherence to the applicable data protection law, Human Research Act (HRA), law on public organizations and public archive laws, etc.). The documentation must cover at least (but shall not be limited to) governance aspects, procedures and other mechanisms to ensure the proper implementation of consent revocation and adherence to laws, such as: the applicable data protection act as well as the General Data Protection Regulation (GDPR) (to the extent the GDPR actually applies or has effects), the Human Research Act (HRA), the law on public organizations, public archive laws, etc.  |
| ***Results (max. 5 bullet points)*** |
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| 1. **Definition of Data Interoperability Standards\*** *[adapted according to the proposal by HIT-STAG, validated by the NSB on 18.02.2021]*
 |
| **RDF and recommended standards.**1. DCC together with the RDF taskforce develops and delivers the new schema (including recommended standards); UH are represented in the RDF taskforce and fundamentally involved in decision making as well as in the assessment of standards to be implemented. (by DCC in collaboration with RDF Task Force, by 30.04.2021-30.06.2021 for implementation)

**LOINC.**1. DCC kicks off the discussion with Laboratory Medicine departments and provides a Roadmap; UH continue the mapping based on best effort. (by DCC in collaboration with UH by 30.04.2021)
 |
| ***Results (max. 5 bullet points)*** |
| 1. ***Assessment will be initiated by the DCC. No reporting from UH required by 30.04.2021***
2. ***Please report the current status of LOINC mapping:***
 |
| **National meta-data catalogue for clinical data.** *[adapted according to the proposal by HIT-STAG, validated by the NSB on 18.02.2021]*1. Development of a short assessment approach and a corresponding questionnaire. (by DCC with validation from UH, by 28.02.2021)
2. Assessment taking place in a bilateral meeting with DCC collaborators and UH teams. (by DCC in collaboration with UH, by 15.05.2021)
3. Delivery of an assessment report and proposition how to move forward has been shared with SPHN boards. (by DCC/SPHN with validation from UH, by 30.06.2021)
 |
| ***Assessment will be initiated by the DCC. No reporting from UH required by 30.04.2021*** |
| **Access to unstructured data.** *[adapted according to the proposal by HIT-STAG, validated by the NSB on 18.02.2021]*1. Development of a short assessment approach and a corresponding questionnaire. (by DCC, with validation from UH, by 28.02.2021)
2. Assessment, taking place in a bilateral meeting with DCC collaborators and UH teams. (by DCC in collaboration with UH, by 15.05.2021)
3. Delivery of an assessment report and proposition how to move forward has been shared with SPHN boards. (by DCC/SPHN with validation from UH, by 30.06.2021)
 |
| ***Assessment will be initiated by the DCC. No reporting from UH required by 30.04.2021*** |

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| 1. **Clinical Research Data Management at Hospitals (CDW)** *[adapted according to the proposal by HIT-STAG, validated by the NSB on 18.02.2021]*
 |
| **C1. (Soft milestone): Milestone C1 to be met at the end of the year Y3.**The UH has, until the end of the third contract year, implemented and deployed internal clinical research data management systems (e.g. a data lake or Clinical Data Warehouse) at hospitals for integrating patient data in order to be able to provide data for research (including quality and security requirements).  |
| ***Results (complete table of Capabilities Level Assessment from HIT-STAG)*** |
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| --- | --- | --- |
| **Layer** | **Capability Assessment*****(1-5)*** | **Remarks** |
| App Layer |  |  |
| API Layer |  |  |
| Data Layer |  |  |
| Hard Layer |  |  |
| Governance |  |  |

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| **Federated Query System (FQS).** *[adapted according to the proposal by HIT-STAG, validated by the NSB on 18.02.2021]*Improvements regarding data quality (by UH by 31.03.2021):* Duplicate records are identified and removed and a process is in place to detect and filter out duplicates before loading new data;
* Cases without a link to a patient are identified and removed and a process is in place to detect cases without patients and filter them out before loading new data;
* Values that represent a placeholder (e.g. failed measurements of Lab values) are removed
* Assessment of other data quality issues and their solution. (by DCC/UH in collaboration with Clinerion)

Specifications and quality guideline:* A technical format specification document and a guideline for data validation for UH is elaborated (by DCC in collaboration with UH and Clinerion)
* Data is delivered accordingly to the specifications and quality guideline (by UH by 30.04.2021)

New data loads (by 31.03.2021, by UH in collaboration with DCC and Clinerion):* All five UH have loaded consented data from the period of 1.1.2015 until at least 31.12.2020 into their local instance of the FQS (demographics [gender, age], medication [ATC], diagnosis [ICD10], procedure [CHOP], lab [LOINC codes only]);
* It is ensured that new consented data (from 1.1.2020 onwards) are fed into the system on a regular basis.
* Data quality checks are carried out according to the documents described in Goal 1 before every data load

Legal framework for access to FQS by researchers:* Documents regarding the legal framework (e.g. Access and Use Policy, Institutional Collaboration Agreement, Participation Rules, etc.) are elaborated by SIB (by DCC in collaboration with SIB Legal, by 31.01.2021)
* The legal ad hoc Working Group discusses, consults, consolidates and approves a final version of the documents (by DCC in collaboration with ad hoc Working Group and UH, by 31.03.2021)

Maintainability of the system:* A consolidated concept for a harmonized integration solution and a maintainability plan for the FQS is elaborated; (by DCC in collaboration with UH and Clinerion, by 30.04.2021)
* An equivalent solution over all five UH regarding the local integration of the FQS in the hospital system is in production and allows to meet maintainability requirements. (by UH, by 30.06.2021)
 |
| ***Results (max. 5-8 bullet points each on data quality and data loads)*** |
| ***Data Quality:******Data Loads:*** |

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| 1. **Biobanking Interoperability** *[adapted according to the proposal by HIT-STAG, validated by the NSB on 18.02.2021]*
 |
| 1. Development of a short assessment approach and a corresponding questionnaire. (by DCC with validation from UH, by 28.02.2021)
2. Assessment taking place in a bilateral meeting with DCC collaborators and UH teams. (by DCC in collaboration with UH, by 15.05.2021)
3. Delivery of an assessment report and proposition how to move forward has been shared with SPHN boards. (by DCC/SPHN with validation from UH, by 30.06.2021)
 |
| ***Results (max. 5 bullet points)*** |
| ***Assessment will be initiated by the DCC. No reporting from UH required by 30.04.2021*** |

### **Financial report 2020.**

*In this section, please provide an overview and comment i) the use of SPHN funds, ii) own contributions ‘in cash’ and ‘in kind’ provided by the involved partners (“Matching Funds“).*

*Please copy-paste the Tables of the “Overview tab” and of the “Summary tab” from the Financial Report Excel file provided by the SPHN Management Office to compile your detailed financial report.*

*A blank template of this file is available on the SPHN website (*[*www.sphn.ch/en/funding/documents-forms.html*](http://www.sphn.ch/en/funding/documents-forms.html)*).*

*Replace this table with the table of the “Summary tab” of the Financial Report Excel file*

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*Replace this table with the table of the “Summary tab” of the Financial Report Excel file*

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### **Next steps (max. 1 page).**

*In this section, please provide an overview of the work that will still be accomplished until 30.06.2021. Please highlight and specify for which objectives you foresee difficulties to complete by 30.06.2021.*

### **What additional support from SPHN would be desirable within this Collaboration Agreement?**

### **Outlook 2021-2024:**

* *What are your requirements, needs, and expectations towards SPHN for the next funding period?*
* *Which services/infrastructures should SPHN centralize in the future with regards to sustainability?*
1. <http://www.snf.ch/en/funding/infrastructures/use-of-infrastructure/Pages/default.aspx> [↑](#footnote-ref-1)
2. The “harmonized consent” is deemed to be available if the form was developed and approved by the relevant authorities (Ethics committees) and the UH. [↑](#footnote-ref-2)
3. European patients can be excluded to make sure that we are not exposing ourselves to the new European framework on data protection. [↑](#footnote-ref-3)