# Collaboration Agreement („Leistungsvereinbarung“)

## Annual Report - Year 2019 (Version: 20.2.2020)

**Responsible persons at the University Hospital**

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

**Attachments:**

* Detailed financial information (Excel document)

*Please note that this feedback will not only be used to evaluate the progress of your project, it will also contribute to the mapping of existing research infrastructures of the SPHN. 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 reporting period.**

*Please note that this section was expanded compared with last year. Since we are planning to visualize the process and degree of implementation and usability of different research infrastructures, we are dependent on your feedback. Our final vision is to create a map of usable infrastructures, to facilitate the research community to find data sources, research partners, biobanks or access to novel analytic platforms.*

*While we can compile this information, we need your expertise in your special field. This report may unfortunately take some of your time, it will be the basis for our infrastructure mapping efforts. We thus kindly ask you to contribute with your knowledge and expertise.*

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.*

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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 |  |  |  |  |  |  |
| UCUM |  |  |  |  |  |  |  |  |
| SNOMED |  |  |  |  |  |  |  |  |
| CHOP |  |  |  |  |  |  |  |  |
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1. *Please briefly describe the architecture and data flow of the clinical research management systems of your UH and include a schema (max. 1 page).*

*In addition, please answer the following questions:*

* *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)?*
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?*
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)?*
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 |  |  |
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### **Strategic goals for the reporting period.**

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

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| 1. **Consent Management and Legal Framework** |
| **A1. (Hard milestone): Milestone A1 to be met at the end of Y3.**   1. The UH has formally submitted a commitment to SAMW to participate in the development of a “harmonized consent” and to use it if the content is formally accepted by the UH; 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 (max. 5-8 bullet points)*** |
| ***Not applicable in Y1 and Y2.*** |
| **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\*** |
| **B1. (Soft milestone): Milestone B1(i) to be met at the end of Y1.**  **Milestone B1(ii) is to be met at the end of Y2 and Y3.**   1. During the relevant contractual year, the UH must have actively participated in defining the initial SPHN data encoding and exchange standards. 2. (During the third contract year, the UH must have actively participated to progress on standards for data model and semantics to enable interoperability and according to scientific needs; compatible with relevant national and international standards, reporting to FOPH, and additional international standards if possible, etc. |
| ***Results (max. 5 bullet points)*** |
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| **B2. (Soft milestone): Milestone B2 to be met at the end of Y1, Y2 and Y3.**  During the contract year preceding the milestone the UH must have actively participated in defining a horizontal data set (DS) to enable feasibility studies and contributed to a SPHN catalogue of available data. |
| ***Results (max. 5 bullet points)*** |
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| **B3. (Hard milestone): Milestone B3(i) to be met at the end of Y1.**  **Milestone B3(ii) to be met at the end of Y1, Y2 and Y3.**  **Milestone B3(iii) to be met at the end of the years Y2 and Y3.**   1. The UH provides a unique patient centered de-identified ID according to the Human Research Act (HRA); 2. During the contract year preceding the milestone, the UH must technically be able to provide data in an encoded shareable way according to Appendix 2 and applicable law; 3. During the contract year preceding the milestone, the UH must have participated in the development of deduplication mechanisms with SPHN. |
| ***Results (max. 5-8 bullet points)*** |
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| **B4. (Soft milestone): Milestone B4 to be met at the end of the years Y1, Y2 and Y3.**  The UH has, during the period preceding the milestone, actively participated in defining the technical requirements to ensure access to shareable unstructured data (e.g. medical images, text, genomics, electrophysiological data, longitudinal observational data, etc.). |
| ***Results (max. 5 bullet points)*** |
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| 1. **Clinical Research Data Management at Hospitals (CDW)** |
| **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 (max. 5 bullet points)*** |
| ***Not applicable in Y1 and Y2.*** |
| **C2. (Hard milestone): Milestone C2 to be met at the end of the years Y1, Y2 and Y3.**  The UH is, at the end of each relevant contract year, technically able to harvest a horizontal data set according to B2 [as set out in Appendix 2]. |
| ***Results (max. 5-8 bullet points)*** |
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| **C3. (Hard milestone): Milestone C3 to be met at the end of the year Y3.**  The UH has, after the third contract year, implemented:   1. SPHN data encoding for clinical research data and; 2. transcoding resources for clinical data. |
| ***Results (max. 5-8 bullet points)*** |
| ***Not applicable in Y1 and Y2.*** |
| **C4. (Hard milestone): staggered by contractual year (tested on a per year-basis).**  **Milestone C4 (i) to be met at the end of the year Y1.**  **Milestone C4 (ii) to be met at the end of the years Y2 and Y3.**  The UH has provided certain defined data sets (DS). Such data sets must use an i2b2/shrine-compatible mechanism, i.e. query endpoint or data export, to establish an interface to the SPHN distributed query architecture.   1. Implement an i2b2/shrine compatible mechanism - i.e. query endpoint or data export - to establish an interface to the SPHN distributed query architecture (using test or real data). 2. The UH must technically be able to use the i2b2/shrine compatible mechanism to provide defined data sets (DS) as defined in B2. |
| ***Results (max. 5-8 bullet points)*** |
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| 1. **Biobanking Interoperability** |
| **D1. (Soft milestone): Milestone D1 to be met at the end of the year Y3.**  In collaboration with the Swiss Biobanking Platform, implementation of interoperability mechanisms between the biobanking management systems and clinical research data management platforms to ensure that sample information can be exposed together with the clinical data. |
| ***Results (max. 5 bullet points)*** |
| ***Not applicable in Y1 and Y2.*** |

### **Financial report.**

*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 be performed in the following reporting period.*

### **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)