**CONSORTIUM AGREEMENT**

dated [date]

To [form a multicenter clinical research consortium to conduct a project entitled] “[InsertProjectName]” (the **Project**).

among

|  |  |
| --- | --- |
| **[#Name, Address]** | (**Party01**) |
| **[#Name, Address]** | (**Party02**) |
| **[#Name, Address]** | (**Party03**) |
| **[#Name, Address]** | (**Party04**) |
| **[#Name, Address]** | (**Party05**) |
| **[#Name, Address]** | (**Party06**) |
| **[#Name, Address]** | (**Party07**) |
| **[#Name, Address]** | (**Party08**) |
| **[#Name, Address]** | (**Party09**) |
| **[#Name, Address]** | (**Partynn**) |

(together with any other entity accessing to this Consortium Agreement, the **Parties**)

**TABLE OF CONTENTS** (with page\_##)

[1. Scope 3](#_Toc47080495)

[2. General Undertakings of The Parties 3](#_Toc47080496)

[3. Governance 4](#_Toc47080497)

[4. Financial Conditions 5](#_Toc47080498)

[5. Confidentiality 6](#_Toc47080499)

[6. Data and Human Samples 6](#_Toc47080500)

[7. Intellectual Property 7](#_Toc47080501)

[8. Publications 9](#_Toc47080502)

[9. Duration, Entry and Exit of Parties 10](#_Toc47080503)

[10. Warranties and Indemnification 11](#_Toc47080504)

[11. Miscellaneous 11](#_Toc47080505)

**TABLE OF Schedules**

**Schedule 1** Project Description

**Schedule 2** Governance

**Schedule 3** DTUA

**Schedule 3** Authorship Guidelines

**TABLE OF DEFINED TERMS** (with page\_##)

Allocated Work 3

Authorised Representative 4

Clinical Study Protocols 3

Confidential Information 6

Consortium Agreement 3

Data 6

DTUA 6

Executive Board 4

Force Majeure Event 11

Foreground IP 8

Human Samples 6

Intellectual Property Rights 7

Investigator 4

Joint Foreground IP 8

Parties 1

Project 1

Project Description 3

Project Leader 4

Results 7

Scientific Board 4

Sole Foreground IP 8

SPHN 3

Sponsor 4

Study 4

Subcontractors 3

1. Scope
	1. **Scope**. This agreement together with its Schedules (the **Consortium Agreement**) specifies the Parties’ collaboration and their rights and obligations in relation to the Project, in accordance with the project application, description and funding decision referenced in Schedule 1 (the **Project Description**).
	2. **Hierarchy**. In case of contradiction between the terms of the main body of this Consortium Agreement and the terms of any Schedule, the terms of the main body of this Consortium Agreement shall prevail, unless the relevant Schedule makes an explicit reference to the provision of this Consortium Agreement that shall be amended.
	3. **No Agency**. This 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 for the account of the other Party. The Parties shall act in all aspects as independent contractors.
2. General Undertakings of The Parties
	1. **In General**. Each Party undertakes to use reasonable endeavours to perform and fulfil, promptly, actively and on time, all of its obligations under this Consortium Agreement – including the tasks specifically allotted to it in the Project Description (the **Allocated Work**) – in accordance with:
		* 1. its institutions’ policies;
			2. the Project Description;
			3. [the rules of the Swiss Personalized Health Network (**SPHN**) and in particular the “Funding Regulations” including “General implementation regulations for the Funding Regulation“ referenced in the Project Description];
			4. the clinical study protocols specified in the Project Description and other clinical study protocols as may be approved by the Scientific Board (the **Clinical Study Protocols**); and
			5. all applicable laws and regulations, including data protection and human research laws, and ethical guidelines.
	2. **Resources**. Each Party shall maintain and allocate sufficient resources required to carry out such tasks in a timely manner.
	3. **Collaboration**. The Parties shall promptly provide each other with all documents, objects, technical aids, and resources required to carry out the Project. The Parties will coordinate the performance of the Project and will support each other to the best of their abilities.
	4. **Subcontracting**. If necessary to implement the Project, the Parties may engage subcontractors to carry out limited parts of their Allocated Works (**Subcontractors**). The subcontracting Party shall enter with the Subcontractor into a written agreement containing terms which, at a minimum, are consistent with the terms of this Consortium Agreement and shall not conflict with the terms of this Consortium Agreement. The subcontracting Party shall be liable for the acts and omissions of its Subcontractors as if those acts and omissions had been performed by such Party and, as such, shall remain responsible for the implementation of this Consortium Agreement. Access by Subcontractors to Data and Human Samples shall be governed by Section 6.4.
3. Governance
	1. **Governance Structure**
		1. In General. The Parties shall implement a governance structure for the Project as specified in Schedule 2, composed of:
			1. the project leader (**Project Leader**) and the legal sponsor (**Sponsor**) of any clinical study or human research project study in relation to the Project (each a **Study**), as specified in Schedule 1 for the initial Study or in the relevant Clinical Study Protocol of any subsequent Study;
			2. the investigators of the Project referenced in Schedule 1 (the **Investigators**);
			3. the executive board of the Consortium (the **Executive Board**);
			4. the scientific board of the Consortium (the **Scientific Board**);
			5. the other bodies as specified in Schedule 2 or as set up by the Executive Board; and
			6. the authorized representative of each Party listed in Schedule 2 (**Authorized Representative**).
		2. Project Leader.The Project Leader is responsible for the overall management of the Study and has the responsibilities specified in this Consortium Agreement and in the Project Description.
		3. Sponsor(s). The Sponsor(s) of each Study shall take the overall responsibility for the organization and management of the Study, in accordance with this Consortium Agreement, clinical practice guidelines, the Human Research Act [RS: 810.30] and its related Ordinances.
		4. Investigators.The Investigators shall be responsible for the day-to-day supervision of the Project in accordance with the work packages and tasks defined by the Project Description, with assistance from associates and colleagues as required. They shall regularly meet or hold telephone conferences together with the Sponsor and Project Leader to discuss the progress of the Project. Face-to-face project meetings will take place as required.
		5. Executive Board.TheExecutive Board is the ultimate decision-making body that takes on behalf of the Parties all strategic decisions and that supervises activities carried out by the consortium formed hereunder and the finding of amicable solutions for any unresolved disputes between the Parties relating to the execution of the Project. Its composition, organization, and responsibilities are specified in Schedule 2. The Executive Board may delegate part of its responsibilities to other boards or subcommittees.
		6. Scientific Board.The Scientific Board is responsible for decision-making in relation to the scientific direction of the Project and to implement the coordination of the Study. Its composition, organization, and responsibilities are defined specified in Schedule 2.
	2. **Compliance**. Each Party shall procure that all governance bodies set up within the Project shall abide by the terms of this Consortium Agreement in any and all of their decisions and actions;
	3. **Replacement**. Each Party shall use reasonable efforts to keep an appropriate level of continuity in representation. Each Party shall nominate a replacement upon advance notice to the other Parties in the event that the original representative is unable to attend any scheduled meeting of a governance body. If a representative can permanently no longer participate, either Party may replace such representative at any time, upon written notice to the other Parties in accordance with Section 11.6.
	4. **Binding Effect**. The Parties agree to abide by all decisions of the Executive Board, which shall be binding on the Parties. The Parties shall ensure that decisions taken by the Executive Board are adequately communicated to personnel within each Party’s organization who have a need to know such Executive Board decisions in order to implement them. [Decisions taken by other governance bodies shall only be binding if they are ratified by the Executive Board or the Authorised Representatives.]
	5. **Changes and amendments to the Project**. Changes and amendments to the Project Description may be proposed to the Executive Board by any Party and require [simple majority] approval of the Executive Board and the relevant ethics committees to be implemented, provided always that a Party whose Allocated Work, time for performance, allocation of funds are impacted, may veto such decisions of the Executive Board, provided such veto is duly justified. In such a case, the concerned Party and the Executive Board shall discuss in good faith possible solutions to enable the continuation of the Project within 3 months.
4. Financial Conditions
	1. **Allocation**. The financial conditions and grants allocated to the Parties for the completion of the Project are specified in the Project Description. Grants shall be distributed by the Project Leader specified in Schedule 1, or in the absence of a Project Leader, by the Executive Board, always in accordance with Project Description.
	2. **Costs and Expenses**. Except as expressly stated otherwise in the Project Description, each Party shall bear its own costs and expenses incurred in relation with this Consortium Agreement.
5. Confidentiality
	1. **In General**. Without prejudice to special provisions (in particular section 6 below) or laws with regard to the processing of personal data, each Party shall at any time for the duration of this Consortium Agreement, including any extension thereof, and thereafter for a period of 5 years following the termination or expiry of this Consortium Agreement, keep confidential all proprietary and/or non-public information which is marked as being confidential at the time it is disclosed hereunder or which may reasonably be regarded as confidential, including trade secrets or know-how or other related proprietary business information and data (collectively, **Confidential Information**) and shall not use such Confidential Information for any other purpose than completing the Project.
	2. **Exclusions**. Section 5.1 shall not apply to (i) any Confidential Information which one Party can reasonably demonstrate that it (a) was previously lawfully known to it, or (b) is, and/or becomes publicly available through no fault of a Party, or (c) is independently and lawfully developed by it; (ii) any disclosure required by law, provided that the receiving Party shall notify the disclosing Parties of any disclosure required by law in sufficient time so that each disclosing Party may contest such requirement, if any disclosing Party so chooses.
	3. **Return of Confidential Information.** Subject to mandatory law, upon the expiration or termination of this Consortium Agreement for whatever reason, or at the earlier request of a Party, the other Party shall, at its own costs, return or destroy all originals and copies of Confidential Information, or, in case of Confidential Information stored in electronic, magnetic or digital media, shall erase or render unreadable all materials furnished (including without limitation, working papers containing any Confidential Information or extracts therefrom) which contain Confidential Information.
6. Data and Human Samples
	1. **In General**. The Parties must process personal data and Human Samples under the Consortium Agreement in compliance with applicable data protection laws. Each Party represents and warrants that any personal data and/or Human Samples required for use in the Project that are obtained, handled or used by it will be obtained, handled or used in accordance with all relevant laws and regulations (and where applicable, ethical guidelines) regarding their collection, use, transport and subsequent disposal and that any ethics committee approvals and, as the case may be, informed patient consents required for performing the Project and for Study will be obtained prior to the commencement of the respective part of the Allocated Work as described in detail in the Project Description.
	2. **Data.** Access to, provision and exchange of data, including the metadata, between the Parties under the Project (**Data**) shall be carried out pursuant to the Data Transfer and Use Agreement (**DTUA)** substantially in the form as specified in Schedule 3, including its annexes (**DTPA and Minimal Security Requirement**).
	3. **Human Samples**. “**Human Samples”** means human biological material, including any portion of any tissue, blood, cerebrospinal fluid, cells or sub-cellular structures such as DNA, or any derivative of such human biological material such as pathogens (bacteria, viruses, fungi, parasites), serum, stem cells, cell lines and any human biological product. Access to, provision and exchange of Human Samples under the Project shall be carried out pursuant to the terms of this Consortium Agreement, any Clinical Study Protocols and the following principles:
		* 1. only Parties that are [hospitals **//or//** university/university hospital] shall be allowed to permanently store Human Samples. Collected Human Samples will be aliquoted (split) into fragments of the original sample at the microbiology institutions of each Party that is a [university/university hospital]. One aliquot will be shipped to the Party/ies performing examinations such as sequencing and metabolomics as described in the Project Description and/or the respective Clinical Study Protocol. Leftover aliquots will be stored at each microbiology institution for at least 5 years;
			2. Human Samples shall not be disposed of or acquired as such for research purposes in return for payment or other non-cash advantage. However, the foregoing shall not apply to operations such as preparation, transport, storage etc. of Human Samples;
			3. The Parties may only use the Human Samples received under this Consortium Agreement for the Project and shall either return or destroy the Human Samples after the related activities to the providing Party, or if requested by the patient.
	4. **Access**. Parties can use and may share Data and Human Samples under their custodianship with any third party providing analyses within the Project, if and to the extent required for the Project, provided that the Data and Human Samples: (i) are disposed in accordance with all necessary patient consents, regulatory approvals and the purpose of the Project, under terms at least equivalent to those of this Consortium Agreement and the DTUA and (ii) remain confidential and are published only after the publication of the Results from the Project by the Executive Board pursuant to Section 8.
7. Intellectual Property
	1. **Definitions**. “**Intellectual Property Rights”** means all present and future rights and prerogatives, registered or not, arising from Swiss or any other national or international legislation, in copyright, rights to software, databases, trademark protection, corporate names, trade and business names, domain names, designs and patents of invention, semiconductor topography rights, know-how, confidentiality and business secrets, and rights in the nature of unfair competition right, and all other intellectual property or similar proprietary rights of whatever nature (including, without limitation, applications to register or rights to apply for registration). For the sake of clarity, Intellectual Property Rights do not include Data and/or Human Samples; “**Results**”meansanyresults generated by a Party from its participation in the Project – such as invention, data, software, algorithms, knowledge, know-how or information, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including Intellectual Property Rights.
	2. **Duty to Inform.** Each Party generating Results shall promptly inform the [Sponsor/ Project Leader] and all Parties having contributed to such Results.
	3. **Background IP**. Each Party shall retain all title, right and interest in and to its respective Intellectual Property Rights existing as of the date of this Consortium Agreement or which is later developed independently from the Project (the “**Background IP**”). Unless otherwise agreed herein, nothing in this Consortium Agreement shall be construed as a transfer, license, and/or assignment by a Party to the other Party of ownership of, title, right or interest in and to its respective Background IP.
	4. **Foreground IP**

**[Alternative 1:** Joint IP only for common works, otherwise IP owned solely by the party generating it.]

* + 1. Joint Foreground IP. If two or more Parties have jointly generated Intellectual Property Rights, and where it is not possible to separate from each other their individual contributions, all right, title and interest in and to Intellectual Property Rights generated within the Project shall be owned jointly by the Parties who have contributed to it (**Joint Foreground IP**). The involved Parties shall set forth, by separate mutual agreement, their respective rights, duties and responsibility relating to the Joint Foreground IP, subject to the terms of Section 7.7. Such an agreement shall not cause a delay of publication of the Results any longer than defined in Section 8.2.
		2. Sole Foreground IP. All Intellectual Property Rights in Results which are neither Background IP nor Joint Foreground IP shall be owned and vest solely in the Party generating them (**Sole Foreground IP**, and together with the Joint Foreground IP, the **Foreground IP**). Such Party shall be free to use such Sole Foreground IP in any form whatsoever, subject to Section 7.7.

**Alternative 2:** The IP is jointly owned by the Parties.

All right, Intellectual Property Rights, title and interest in and to the Results shall be owned jointly by the Parties (the **Foreground IP**). The Parties shall set forth, by separate mutual agreement, their respective rights, duties and responsibility relating to the Joint Foreground IP. Such an agreement shall not cause a delay of publication of the Results any longer than as defined in Section 8.2.

* 1. **Licences to use Results.** Each Party generating Results hereby grants to all other Parties a royalty-free, worldwide, non-transferable, non-exclusive, irrevocable license, with the right to grant sublicences only to Subcontractors, to access and use such Results (including any Background IP and Foreground IP therein) solely for the purpose and to the extent necessary for undertaking and completing the Project.
	2. **Licence to Foreground IP.** Each Party generating Foreground IP by using Data, Human Samples, Confidential Information or Background IP of another Party hereby grant to that Party a royalty-free, worldwide, non-transferrable, non-exclusive, irrevocable license, with the right to grant sublicenses, to access and use that Foreground IP for purposes of internal scientific research.
	3. **IP Exploitation**
		1. Exploitations of Foreground IP. With respect to the exploitation of Foreground IP (e.g. granting of licenses to third parties), the Parties shall mutually consult each other and agree upon the conditions and sharing of revenues, if any, whereby appropriate account is taken of significant non-inventive contributions (such as providing know-how, Data, Human Sample). The owners of Foreground IP shall pay to Parties having contributed to generating the Foreground IP [a fair share of *or* [...]% on] any net revenues received by Recipient for the commercialization of the Foreground IP].
		2. Patent Protection. **[To adapt to Section 7.4:** If an owner of Sole Foreground IP or the owners of Joint Foreground IP decide not to pursue or maintain a patent application based on the Results, the Executive Board may decide to protect or commercialize the Results in the name of all Parties.] If the Executive Board decides not to pursue or maintain a patent application based on a Project Invention, any Party or group of Parties may negotiate with the Parties owning the Project Invention terms and conditions for transferring the rights to protect or commercialize the respective Project Invention.
	4. **Open Source**. Notwithstanding anything to the contrary in this Section 7, the Parties agree to make software implementations necessary for making the Results available to the public upon publication by means of open source software release. In order to do so, the Parties shall consult with each other and agree on the strategy and use of any open source software and its respective licensing terms and possible effects (such as but not limited to viral effects also known as copy left effects), before the first publication of the Results. The use of open source software in the Project shall be in accordance with its respective licenses and all relevant notices retained.
1. Publications
	1. **In General**. The Parties agree that the Results shall be made public as soon as possible by the Party having generated it, unless publication goes against its legitimate interests (for instance, because the Results have not yet been protected, the Results concern trade secrets, or disclosing the Results would infringe on applicable personal data protection, security related, or other applicable obligations). Published information shall be deposited in an open access data repository to the extent reasonably possible.
	2. **Right to object**. Prior to the publication of its Results, the publishing Party shall submit to the other Parties for review a draft of the publication. Each other Party shall have [60] days to request the disclosing Party to:
		* 1. withdraw any Confidential Information provided by it, in which the affected Party shall use their best efforts to provide scientifically meaningful equivalent information for such deleted Confidential Information.
			2. postpone, for no more than [6] months, the publication of the Results for which the affected Party wishes to file a patent application (as the case may be, pursuant to Section 7.7.2).
	3. **Authorship Guidelines and Acknowledgment**. All publications of the Results must be compliant with the authorship guidelines specified in Schedule 4 (Authorship Guidelines)and shall acknowledge the role and contribution of the consortium formed hereunder and of the Parties that provided the Data and Human Sample, in accordance with best scientific practice.
2. Duration, Entry and Exit of Parties
	1. **Duration**. This Consortium Agreement will enter into force once signed by all Parties and will continue in force until [date **// or //** completion of the Project], subject to early termination decided by the Executive Board with a [two third] majority of the votes cast.
	2. **Accession**. The Executive Board shall be entitled to accept submissions of entities to become party of the consortium formed hereunder. The new entity shall execute this Consortium Agreement or an adapted version of it, or a deed of adherence in a form acceptable to the Execution Board, upon which it shall become a new Party and be subject to all the terms and conditions of this Consortium Agreement. The Parties unconditionally accept any such entity as a Party.
	3. **Exit.** Each Party may exit from the Consortium Agreement by giving [60] days advance written notice to the other Parties. The withdrawal of a Party from the Consortium Agreement shall not affect the rights and responsibilities of the other Parties.
	4. **Eviction**. In the event of a material breach of the Consortium Agreement or of other agreements for the implementation of the Project, such as the DTUA, by a Party, [the Executive Board] shall give written notice to the breaching Party to allow the latter to remedy the breach within thirty [30] days. If the breach has not been rectified within said period, the other Parties may terminate the breaching Party’s participation [through a decision of the Executive Board requiring at least two third of the votes cast in which the representative of the breaching Party shall not participate], in which case the breaching Party’s participation and all rights granted to the breaching Party according to this Consortium Agreement will cease immediately.
	5. **Effects of termination of expiry**. Upon termination or expiry of this Consortium Agreement (respectively in case of an exit or eviction of a Party, for that Party only), all Confidential Information, Data and Human Samples, if any, shall immediately be returned or destroyed, as per request of the providing or disclosing Party. Expiration or termination of this Consortium Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Provisions which by their nature are intended to survive expiration or termination of the Consortium Agreement, shall survive.
3. Warranties and Indemnification
	1. **In General**. The Parties shall perform the Project and their respective Allocated Work to the best of their scientific knowledge, exercising due care, taking into account recognized scientific standards and shall endeavour to achieve the goals of the Project aimed for in the Project Description. By its nature, research involves the risk of unforeseen consequences. The Parties therefore do not make any representation that the intended goals and results of the Project will be reached, nor that their Allocated Work will lead to any particular result. [The Parties make no warranties, neither express nor implied, regarding the Results, including but not limited to warranties of originality, accuracy, non-infringement of third party rights, merchantability, completeness or fitness for a particular purpose. There is no duty to conduct searches with regard to registered intellectual property rights.]
	2. **No liability**. Subject to Sections 10.3 and 10.4 and the DTUA, the Parties assume no liability for any damages, including but not limited to any indirect or consequential loss or similar damage (e.g. loss of profit, loss of revenue or loss of contracts inter alia due to a shutdown; other costs and expenses) suffered in connection with this Consortium Agreement, provided such damage was not caused by a wilful intent or act of gross negligence. This limitation of liability shall also apply to the Parties' auxiliary persons (including but not limited to consultants and students), agents and subcontractors.
	3. **Use of Results**. The Parties use the Results at their own risk. A Party using any of the Results shall, to the fullest extent permitted by the applicable law, defend, indemnify and hold the other Parties harmless against third party claims which are based on the Party’s use of the Results.

*[Optional: to be discussed according to the configuration of the project and the will of the parties:]*

* 1. **Sponsor's liability**. The Sponsor shall defend and indemnify a Party, its directors, agents, employees and all Study personnel from any liability or loss resulting from judgments or claims against them arising out of the activities to be carried out pursuant to the obligations of this Consortium Agreement; provided, however, that Sponsor shall not defend and indemnify a Party from liability resulting from wilful misconduct or gross negligence of such Party, its directors, agents, or employees.
1. Miscellaneous
	1. **Force Majeure****.** A Party will not be in breach of its contractual obligations in case of delay in performing, or failure to perform, its obligations to the extent such delay or failure is caused by the occurrence of any contingency beyond the reasonable control, and without any fault, of such Party, which contingencies include natural disasters of a particular intensity, war, epidemics, riot, strike, hacking, power failure or Internet network failure (**Force Majeure Event**). In such event, the time limits for performance will be extended for a period of time equivalent to the time lost due to the Force Majeure Event. In order to avail itself of the relief provided in this Section 10.4, the affected Party shall act with due diligence to remedy the cause of, or to mitigate or overcome, such delay or failure.
	2. **Assignment**. Neither Party may transfer this Consortium Agreement, or assign in whole or in part its rights or obligations under this Consortium Agreement, without the prior written consent of the other Parties. Any transfer or assignment made without such consent shall be null.
	3. **Severability**. If any provision of this Consortium Agreement is held to be invalid or unenforceable for any reason, the Parties shall replace it by a substitute provision that achieves to the fullest extent possible the same legal and economic purposes as those of the invalid or unenforceable provision. In any event, the remainder of this Consortium Agreement shall remain in full force and effect between the Parties.
	4. **Electronic Form**. The words “execution”, “signature” and similar words in this Agreement shall be deemed to include unqualified electronic signatures (e.g. Docusign or any equivalent e-signature provider) which shall be of the same legal effect, validity or enforceability as a manually executed signature; while the term “in writing” shall include communications by email or other electronic forms.
	5. **Further Actions**. The Parties shall communicate, sign and deliver any information or document, and shall take any action or decision required to effect or implement this Agreement.
	6. **Notices**. Any notice made under this Agreement shall be in writing, in English, and shall be either personally delivered or mailed by registered mail, or emailed to the Parties Authorized Representative's addresses listed in Schedule 2. Such addresses may be changed, from time to time, by means of a notice given to the other Parties in the manner provided in this Section 11.6. In the event that notification has to be made within a certain period of time, the relevant Party should have complied with such requirement if it has at the last day of such period (i) mailed, transmitted or initiated delivery procedure per registered mail, or (ii) received delivery confirmation of the electronic communication, as the case may be.
	7. **No Waiver and Enforceability**. No delay or failure by a Party to exercise any of its powers, rights or remedies under the Consortium Agreement will operate as a waiver of them nor will any single or partial exercise of any such powers, rights or remedies preclude any other or further exercise of them. Any waiver to be effective must be in writing.
	8. **Amendment**. The Consortium Agreement (including this Clause) may be amended only by (i) a written instrument duly signed by the Parties or (ii) a resolution of the Executive Board in accordance with Section 3.4.
	9. **Governing Law**. This Consortium Agreement and the respective rights and obligations of the Parties shall be governed exclusively by Swiss law, without regard to its conflict of laws provisions. The provisions of the United Nations Convention on Contracts for the International Sale of Goods dated 11 April 1980 are excluded.
	10. **Jurisdiction**. Dispute in relation to this Consortium Agreement shall be submitted to the exclusive jurisdiction of the competent courts [at the defendant's registered office in Switzerland], subject to the right to appeal to the Swiss Federal Tribunal.

[signatures on the following page]

|  |  |
| --- | --- |
| **[#Entity1Name]****[#RepresentativeName]** |  |
| **[#Entity2Name]****[#RepresentativeName]** |  |
| **[#Entity3Name]****[#RepresentativeName]** |  |
| **[#RepresentativeName]****[#Entity4Name]** |  |
| **[#Entity5Name]****[#RepresentativeName]** |  |
| **[#Entity6Name]****[#RepresentativeName]** |  |

Schedule 1 – Project Description

This Schedule 1 (Project Description) is composed of the summary table below and of the following exhibits:

**Exhibit A** Project Application ref. [#InsertReference] dated [#InsertDate].

**Exhibit B** Ethical proposal application [#InsertSponsorName] dated [#InsertDate].

**Exhibit C** Clinical study protocol [#InsertName] dated [#InsertDate].

[**Exhibit D**] [#InsertDescription]

|  |
| --- |
| **Summary Table** |
| **Sponsor** | [#InsertSponsorName] |
| **Project Leader** | [#InsertProjectLeaderName] |
| **Investigators** | [#InsertInvestigatorsName] |
| **Title** | [#InsertProjectName] |
| **Short Title** | [#InsertShortProjectName] |
| **Description**  | See Exhibit A and Exhibit B. |
| **Clinical Study Protocols** | See Exhibit C |
| **Allocated Works and deliverables** | See Exhibit A. |
| **Timeline** | See Exhibit A. |
| **Financing** | See Exhibit A. |
| **[other]** | [#Insertdescription] |
| **Applicable guidelines**  | SPHN “Funding Regulations” including “General implementation regulations for the Funding Regulation“  |

Schedule 2 – Governance

This Schedule 2 (Govervance) lists the governance bodies for the Project.

1. Authorized Representative

For all matters which do not fall under the remit of a specific body, each Party shall act through its Authorized Representative listed below, which shall have the power to represent and bind the Parties, and which shall act as is the contact point within their organization.

|  |  |  |
| --- | --- | --- |
| **Name of Party** | **Authorized Representative** | **Postal Address and email address** |
| [#Entity1Name] | [#RepresentativeName] | [#PostalAdress][#EmailAdress] |
| [#Entity2Name] | [#RepresentativeName] | [#PostalAdress][#EmailAdress] |
| [#Entity3Name] | [#RepresentativeName] | [#PostalAdress][#EmailAdress] |
| [#Entity4Name] | [#RepresentativeName] | [#PostalAdress][#EmailAdress] |
| [#Entity5Name] | [#RepresentativeName] | [#PostalAdress][#EmailAdress] |
| [#Entity6Name] | [#RepresentativeName] | [#PostalAdress][#EmailAdress] |
| [#Entity7Name] | [#RepresentativeName] | [#PostalAdress][#EmailAdress] |
| [#Entity8Name] | [#RepresentativeName] | [#PostalAdress][#EmailAdress] |
| [#Entity9Name] | [#RepresentativeName] | [#PostalAdress][#EmailAdress] |

1. Executive Board

|  |  |
| --- | --- |
| **Members** | The Executive Board shall consist of one representative of each Party. The Composition of the Executive Board as of the time of signature of the Consortium Agreement is as follows:[#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party] |
| **Chairperson** | Members of Executive Board shall appoint a person who will chair the meetings (as defined below) on a rotating basis (**EB** **Chairperson**).The initial EB Chairperson is [#Name(First Name Last Name), #Party] |
| **Responsibilities** | The Executive Board shall decide on, including but not limited to, the following matters:* + - 1. manage, oversee and coordinate the Parties’ relationship under the Consortium Agreement;
			2. evaluate the progress and activities towards achievement of the targets and results of the Project;
			3. amending the Project Description;
			4. review and determine extension of time or re-formulation of the Project;
			5. define the organization, composition and the *modus operandi* of the Project;
			6. identify and seek to resolve any issues that arise between the Parties, which cannot otherwise be resolved between the Parties;
			7. decide on the admission of new Parties;
			8. discuss other subject matters related to this Consortium Agreement;
			9. terminating this Consortium Agreement.
 |
| **Board Meetings** | The Executive Board shall meet at least [quarterly], at venues to be agreed, or at any other time [as agreed by the Parties]. Meetings may be held in person, by telephone, or by video conference. Meetings will be convened with at least [one] month written notice in advance by the EB Chairperson. Agenda items may be addressed by any member to the EB Chairperson no later than [15] days prior to the meeting date. An agenda will be provided by the EB Chairperson [10] days in advance of the meeting. |
| **Voting Rules** | Each member shall have one vote. The members shall act in good faith to cooperate with one another and seek agreement with respect to issues to be decided. The members shall first try to reach consensus. However, if consensus cannot be reached, decisions of the Board will require simple majority, unless another majority is specified in the Consortium Agreement. |
| **Minutes** | The Parties shall agree upon which member acts as secretary and prepare the minutes of a particular meeting at such meeting. The assigned Party shall send the minutes to each of the Executive Board members within [15] days after the meeting. Any member that was present to that meeting may object to the minutes, within [2] weeks of receipt, if they are incorrect by notice to the EB Chairperson. In case of objection, the EB Chairperson shall try to resolve the objection in a telephone conference, in which case the adapted minutes shall be sent a new [2]-week objection period shall start. |

1. Scientific Board

|  |  |
| --- | --- |
| **Members** | The Scientific Board shall consist of [●]. The composition of the Scientific Board as of the time of signature of the Consortium Agreement is as follows:[#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party] |
| **Chairperson** | The Executive Board shall appoint the chairperson of the Scientific Board (**SB** **Chairperson**).The initial SB Chairperson is [#Name(First Name Last Name), #Party]. |
| **Responsibilities** | Matters pertaining to the scientific direction of the Project and to implement the coordination of the Study, such as:* + - 1. Approval of further Clinical Study Protocols;
			2. Secondary data analysis;
			3. Follow-up studies;
			4. Studies analysing new data.
 |
| **Board Meetings** | [*Same as the Executive Board.*] |
| **Voting Rules** | [*Same as the Executive Board.*] |
| **Minutes** | [*Same as the Executive Board.*] |

1. [Other]

|  |  |
| --- | --- |
| **Members** | The [name] shall consist of [●]. The composition of the [name] as of the time of signature of the Consortium Agreement is as follows:[#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party] |
| **Chairperson** | The Executive Board shall appoint the chairperson of the [name] (**[xx]** **Chairperson**).The initial [xx] Chairperson is [#Name(First Name Last Name), #Party] |
| **Responsibilities** | [#Insertdescription]. |
| **Board Meetings** | [*Same as the Executive Board.*] |
| **Voting Rules** | [*Same as the Executive Board.*] |
| **Minutes** | [*Same as the Executive Board.*] |

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Schedule 3 – DTUA

[*see separate document*]

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Schedule 4 – Authorship Guidelines

[All publications of the Results must be compliant with the authorship guidelines of the Swiss Academies of Arts and Sciences, as updated from time to time, accessible at:

<http://www.akademien-schweiz.ch/en/dms/E/Publications/Guidelines-and-Recommendations/integrity/Academies_Authorship.pdf>.

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