

## Federated Learning Agreement Template for [CONSORTIUM] projects

The undersigned:

- .... [LEAD PARTNER]
- ...
- 

wish to enter into this Federated Learning Agreement (“Agreement”) for one or more projects, jointly referred to as [CONSORTIUM NAME].

The term “**Partner**” or “**Partners**” shall be used to refer to the parties to this Agreement both separately and jointly.

WHEREAS:

- Partners wish to collaborate in scientific research projects in accordance with the principles of Federated Learning;
- These Federated Learning projects are jointly referred to as the [CONSORTIUM] initiative
- The Partners have entered into consultation in order to formulate mutually acceptable conditions under which they will collaborate in [CONSORTIUM] ;
- The Partners wish to enter into an agreement under the following conditions;

AGREE AS FOLLOWS:

## 1 Definitions

“Access Rights” means licenses and user rights to Results or Background.

“Affiliate” shall mean any corporation, partnership or other entity, which directly or indirectly controls, or is controlled by, or is under common control of a Partner, where “control” means (i) the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract or otherwise, or (ii) the ownership, directly or indirectly, of more than fifty percent of the voting securities or other ownership interest of an entity. However, any such corporation, partnership or other entity shall be deemed to be an Affiliate only for so long as such ownership or control exists.

“Agreement” means this agreement and all appendices.

“Applicable Data Privacy Laws” means all applicable legislations and regulations in relation to data protection and the processing of personal data.

“Applicable Laws” means all applicable laws and regulations including Applicable Data Privacy Laws.

"Background" means all data (including Clinical Data), tangible and intangible items and information protected by intellectual property rights including inventions, database rights, patent applications, patents, copyrights, trademarks, mask works, trade secrets and any information embodying proprietary data such as technical data, computer software and confidential information and all improvements thereof owned or licensed by Partners prior to their accession to the Project or developed outside of it, which is needed for carrying out the project or using Results.

“Clinical Data” means clinical data and/or information made available for a Project by a Partner which relates to an individual patient. Clinical Data is Background. For avoidance of doubt, Clinical Data can be anonymized data, pseudonymized or identifiable data in accordance with a Partner applicable data processing rule.

“Federated Learning” means a process and associated technology whereby learning from Clinical Data takes place without Clinical Data leaving the Station and only anonymous statistical data is communicated on the Track. This approach preserves data privacy and addresses regulatory concerns while still allowing organizations to benefit from larger, more diverse training datasets.

“Force majeure” means any one or more events beyond the control of the relevant Partner, which occur after the date of signing this Agreement, were not reasonably foreseeable at the time of signing this Agreement, and the effects of which are unavoidable. The following are force majeure events (“**Force Majeure Event(s)**”) that frustrates the purpose of this Agreement: (a) acts of God; (b) flood, fire, earthquake or explosion; (c) war, invasion, hostilities (whether war is declared or not), terrorist threats or acts, riot or other civil unrest; (d) government order or law; (e) actions, embargoes or blockades in effect on or after the date of this Agreement; (f) action by any governmental authority; (g) national or regional emergency; (h) strikes, labor stoppages or slowdowns or other industrial disturbances; (i) epidemic, pandemic or similar influenza or bacterial infection; (j) emergency state; (k) shortage of adequate medical supplies and equipment; (l) shortage of power or transportation facilities; and (m) other similar events beyond the reasonable control of the impacted Partner.

“GDPR” means the European Union General Data Protection Regulation n°2016/679 dated April 27, 2016.

“Infrastructure User Agreement” means the agreement between the Partner and the Track Provider that establishes the terms and conditions governing the use of the Track.

“Net Proceeds” means the gross amount actually received by the Lead Partner (or its Affiliates), for the performance of services based on the Results or making available Results to a third party under any legal title, less out-of-pocket costs (insofar as directly attributable to the protection and/or commercialization of the Results) and less VAT (if applicable).

“Project(s)” means one or multiple research study projects governed by this Agreement and the applicable Project Agreement. A Partner may or may not participate in its absolute discretion to a specific Project.

“Project Description” means the details of the research project as set forth in Annex 1.

“Project Partner” mean a Partner that participates in a specific Project as a Train Provider and/or a Station Provider.

“Project Lead Partner” means the Partner leading a specific Project as defined in the Project Description. The Project Lead Partner may vary between Projects.

“Project Agreement” means a separate agreement that describes the specific terms and conditions for a Project. A Project Agreement will be governed by the terms of this overarching Agreement.

“Partner Data”: means any business information, end-user data, user-generated content, or other data of any type which is provided or made available by a Partner in a Project with the explicit exception of Clinical Data. An example of Partner Data is the contact information of a Partner’s employees.

"Results" means the results, including information, whether they can be protected under Applicable Laws, which are generated under the Project. Such results include but are not limited to software programs and rights related to copyright, design rights, patent rights, or similar forms of intellectual property protection.

“Station”: An information system which contains Clinical Data.

“Station Provider”: A Partner that participates in a given Project by giving permission to the Train Provider(s) in such Project to use a Partner’s Station through the Track.

“Track”: Software and infrastructure which allow Trains in a given Project to perform Federated Learning on the Clinical Data of the Station(s).

“Track Provider” means a legal entity that supplies the Track. The Track Provider may vary between Projects.

“Train”: A software application that encodes a question to Clinical Data in a mathematical/statistical algorithm. The specific question(s) to be asked is described in the Project Description.

“Train Provider”: A Partner who participates in a given Project and provides the Train that uses the Clinical Data of the Station(s) to answer the question(s) as stated in the Project Description.

## 2 Collaboration scope and Project Description

### 2.1

The Partners agree that they may decide to work together in one or more Federated Learning Projects for the duration of these Projects, until completion in accordance with the applicable mutually agreed Project Agreement which will mandatorily contain a Project Description (**Annex 1**), unless in case of premature termination as specified in Clause 12 of this Agreement.

### 2.2

For avoidance of doubt the Partners acknowledge that participation in Projects is subject to prior legal, financial and ethical assessment and hence cannot be guaranteed. Hence, a Partner shall not be held liable if it is prevented from entering into a Project or if entering into a Project would involve disproportionate effort; or otherwise decides reasonably and in good faith not to enter into a Project.

### 2.3

For each Project, a Project Agreement signed by all Project Partners participating in that Project shall be signed and executed. This Project Agreement will contain the goals and objectives of the Project, the Project Partners and the Track Provider(s). It also includes a description of each Party (as a Station Provider, Track Provider or both), the privacy roles of each Party according to Applicable Law, the terms and conditions relating to Background and Results, and other specific requirements (e.g. reports, economic conditions...). Each Project shall have a Project Lead Partner as described in the Project Description.

### 2.4

If mandated under Applicable Law then each Project Partner shall designate itself in the Project Description as a data controller, a data processor or a joint data controller.

### 2.5

The Project Description(s), the Accession Document(s) (**Annex 2**) and, the Data Processing Agreement(s) (**Annex 3**) and the Joint Controller Agreement(s) (**Annex 4**) shall form an integral part of the Project Agreement. The terms and conditions of this Agreement shall be deemed incorporated in all Project Agreement unless specifically excluded by the relevant Project Agreement. In the event of any conflict between the various provisions set out in this Agreement or otherwise contained in any Project Agreement they shall be construed as having priority in the following order (highest first):

1. This Agreement
2. The Project Agreement
3. The Data Processing Agreement (Annex 3)
4. The other appendices to the Project Agreement attached hereto as Annex 1, Annex 2 and Annex 4.

### 2.6

For avoidance of doubt the Partners may derogate to the above order of priority if the conflicting terms are expressly addressed by the Partners and resolved according to their mutual agreement in the prevailing document.

## 2.7

A Project requires the use of infrastructure (Track) which enables Federated Learning. Such infrastructure will be supplied by a Track Provider. Subject to entering a Project Agreement first each Project Partner will negotiate and conclude an Infrastructure User Agreement with a Track Provider.

## 3 Project Partners

### 3.1

The Project Partners shall use their reasonable efforts to achieve the Project implementation and progress and shall do so in accordance with the objectives of the Project. The Project Partners shall fulfill their respective obligations and implement their role(s) in the Project in accordance with the terms hereof and the applicable Project Agreement and in order to meet the agreed timelines. The methods used to perform the obligations set forth hereunder shall be consistent with the terms of this Agreement including any applicable the service level requirements, sound business practices, and all legal and ethical obligations. A Project Partner shall be excused from delays in performing, or from its failure to perform, to the extent that such delays or failures result from other Project Partner's failure to perform or delay in performing its obligations under this Agreement or the applicable Project Agreement, or otherwise in case of a Force Majeure Event.

### 3.2

Unless otherwise agreed in the applicable Project Agreement, each Project Partner shall use reasonable efforts:

1. to promptly (within 30 days of request) upon request make available to another Project Partner information necessary for completion of official reports;
2. to notify the Project Lead Partner of information that a Project Partner receives about the Project from third parties and that may have an effect on the outcome of the Project;
3. to prevent inaccuracies of information that it supplies to the Project Lead Partner and other Partners, and, where inaccuracies are identified then rectify them promptly ; and,
4. participate in, and contribute to, meetings and gatherings in the framework of the Project in a collegiate and mutually collaborative manner.

### 3.3

Each Project Lead Partner will be liable for its own costs and expenses arising due to participation in the Project unless otherwise agreed in the Project Agreement.

### 3.4

The Partners may delegate their duties or assign their obligations to any of their Affiliates, being understood that Partners will remain responsible for their Affiliates.

## 4 Project Lead Partner

### 4.1

The Project Lead Partner shall be responsible for ensuring the correct implementation of the Project. Unless otherwise agreed in a Project Agreement the Project Lead Partner coordinates and intermediates in communication between the other Project Partners. Unless otherwise agreed in a Project Agreement any information obtained by the Project Lead Partner which can be useful for Project Partners' actions, shall be made available by the Project Lead Partner to all the Project Partners. Unless otherwise agreed in a Project Agreement Project Partners may apply to the Project Lead Partner at any moment to ask for the supply of information which is necessary for proper implementation of their portions of the Project. Unless otherwise agreed in a Project Agreement the Project Lead Partner shall ensure the timely start of the Project implementation and the completion of all the actions provided under the Project Agreement. Among its responsibilities, the Project Lead Partner may : (i) ensure that actions under the Project are implemented correctly, and (ii) shall inform the Project Partners about any circumstances which might affect the deadlines and scope of activities provided for in the applicable Project Agreement; (iii) Monitor the progress in implementing the Project, and (iv) take any actions which are necessary to remedy any issue.

### 4.2

The Project Lead Partner shall support the Project Partners with information and documents required necessary to the successful execution of the Project.

## 5 Information provision to the Project Lead Partner

### 5.1

The Partners agree to make information (except for any information that qualifies as Confidential Information) available to the Project Lead Partner for the purpose of dissemination and publicity relating specifically to a Project.

## 6 Results and Background

### 6.1

This Agreement does not affect the ownership of any Background. Hence, the Project Partners shall retain all rights to their respective Background provided for the purpose of this Agreement. No Partner shall assume any rights in the other Partner's Background provided under this Agreement and any applicable Project Agreement other than the right to use said Background to achieve the objectives of the Project Agreement. Such usage rights will be set forth in the applicable Project Agreement.

### 6.2

Unless otherwise agreed in a Project Agreement and to the extent that ownership is possible, the Project Lead Partner as sponsor of the research Project shall be assigned the Results (excluding any Background that may be incorporated or embedded therein which are deemed to be and shall remain the sole and exclusive property of the Project Partner with whom the Background originates from) that are generated within the Project which it shall consequently be free to protect (patents or any other form of protection) and exploit subject to the terms herein. Co-ownership shall be governed by a separate agreement, which shall also regulate co-owned exploitation rights. Each Clinical Data contributing Partner retains ownership/custodianship of the Clinical Data it contributes to the Project.

### 6.3

Each Project Partner shall use reasonable efforts to make the Clinical Data required for the execution of the Project available for purpose of this Agreement. Each Clinical Data contributing Project Partner retains ownership/custodianship and any other rights to the Clinical Data it contributes to the Project, unless otherwise agreed in a Project Agreement. The Clinical Data shall be treated as the Confidential Information of the contributing Project Partner and as such may not be disclosed to any third party without the previous consent of the contributing Project Partner.

### 6.4

Unless otherwise agreed in a Project Agreement, each Project Partner is hereby granted a royalty free non-exclusive, non-sublicensable, non-transferable license to use the Results for the purpose of carrying out its work under the Project, and for internal academic research and teaching purposes after completion of the Project.

### 6.5

Unless otherwise agreed in a Project Agreement, in the event that a third party wishes to purchase a license to use the Results for commercial exploitation, the Project Lead Partner may grant a license for the use of Results of the Project with the prior written consent of the Project Partner(s) that provided Clinical Data (Stations Providers) for the Project and/or Project Partner(s) who provided the computational model to be trained in this Project (Train Providers). These Project Partners and their roles are described in the Project Description. Once the Project Lead Partner has obtained the consent of all involved Project Partners, then the Project Lead Partner shall notify all such Project Partners with 30 days prior notice of any such license and shall ensure that such license will not affect the rights of the Project Partners. The Project Partners shall be entitled to withhold their consent to such license.

## 6.6

Unless otherwise agreed in a Project Agreement, in the event that there is any income generated by the Project Lead Partner from commercial exploitation of Results, it shall be divided as follows:

- 50% of all Net Proceeds shall be divided between the Project Partner(s) who provided the analysis in this Project (Train Providers), pro rate the effort measured in Full Time Equivalent (FTE) spent on the Project, based on approved statements of working hours.
- 50% of all Net Proceeds shall be divided between the Project Partners providing Clinical Station for the Project (Station Providers), pro rate the number of usable individual subjects contributed per Project Partner as stipulated by inclusion and exclusion criteria of the Project.

## 7 Access Rights

### 7.1

Access Rights shall be granted upon written request only and provided specific agreements are concluded specifying amongst others the description of the Background/Results concerned, and all conditions regarding their use. Unless otherwise agreed by the owner of the Background, Access Rights shall confer no entitlement to grant access or (sub)licenses to third parties not being Partners.

### 7.2

As regards to Results developed before the accession of the new Partner, the new Partner will be granted Access Rights on the conditions applying for Results and Background.

### 7.3

Each Partner shall ensure that it has the appropriate approvals for use of the Clinical Data in a Project and has appropriate technical and organizational measures in place in compliance with Applicable Laws and regulations.

### 7.4

When entering the Agreement and fulfilling the contractual obligations, the Partners process Partner Data. This can be information about the other Partner's employees, who are part of the Agreement, the Projects and other persons who are necessary for the completion of the Agreement. Each Partner is data controller for the processing of this personal data with reference Applicable Laws and regulations.

### 7.5

Unless otherwise agreed in a Project Agreement, each Project Party agrees to grants to Project Lead Partner and other Project Parties (as the case may be) a limited, non-exclusive, non-sublicensable, non-transferable license to use the Background (but excluding Clinical Data) contained in the Results for internal research and only as necessary for the purpose of the Project, subject to the restrictions set forth herein and any geographic, site, or other limitations as may be further specified in the Project Agreement. Such license to use the Background may be specified in more details by the Project Parties in the applicable Project Agreement.

## 8 Privacy

### 8.1

To the extent that GDPR or similar Applicable Law applies:

All Project Partners are obligated to determine their role (controller, joint controller or processor) for the processing of the Clinical Data in accordance with the Applicable Law.

The Data Controllers must be properly identified before any processing of Clinical Data can take place under the applicable Project Agreement.

It is agreed and understood that Partners may process but may not transfer any Clinical Data (even if pseudonymized) to any other Partner. Each Partner shall be responsible to ensure an appropriate legal basis pursuant to GDPR or similar Applicable Law for its processing of its Clinical Data for the purpose of the Project.

### 8.2

Each Project Partners will define its role in the Project Description (Annex 1) as follows:

#### **Station Providers**

If a Project Partner is a Station Provider in a Project then that Partner will be deemed to be either a data processor or a joint data controller.

If the Partner is a data processor in the Project than it shall be subject to the terms and conditions of the Data Processing Agreement (Annex 3) for that Project.

If the Partner is a joint data controller in the Project than it shall be subject to the terms and conditions of the Joint Controller Agreement (Annex 4) for that Project.

The Partner is also subject to the rights and obligations as a separate data controller set forth under the GDPR or other Applicable Law in relation to the processing of personal data of its patients for purposes other than conducting the Project. In particular, each Partner remains data controller of the data contained in its patients' medical records for the purposes of providing medical care to its patients and for academic research purposes.

#### **Train Providers**

If a Project Partner is a Train Provider in a Project and determines the purposes and means of processing, then that Partner is a data controller. The Train Provider is a joint data controller if other Project Partners meet the requirements of the law to qualify as data controllers.

If one of the Project Partners in the project has the role of Data Processor, then the Project Partner which has a role of Train Provider shall be subject to the terms and conditions of the Data Processing Agreement (Annex 3) for that Project.

If a Project Partner is a joint data controller, then that Partner shall be subject to the terms and conditions of the Joint Controller Agreement (Annex 4) for that Project.

In the Project Agreement the Partners may modify Annex 3 and Annex 4 as reasonably necessary to comply with applicable local, state, provincial or national laws or regulations.

For information purposes only, Annex 5 set forth some use cases designed to illustrate each role allocation among Train Providers, Station Providers, data controller and data processors.

## 9 Confidentiality

### 9.1

All information in whatever form or mode of transmission, which is disclosed by a Partner (the “Disclosing Party”) to any other Partner (the “Receiving Party”) in connection with the Project during its implementation and

which has been explicitly marked as “confidential”, or

which, when disclosed orally, has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within 15 days from oral disclosure at the latest as confidential information by the Disclosing Party, or

of which the confidential nature is reasonably apparent under the circumstances, such as, but not limited to, either anonymized or pseudonymized patient information, and/or Clinical Data and/or Results and Background (hereinafter: “Confidential Information”) shall be treated by all Partners as strictly confidential and shall only be used for the purpose of this Agreement.

### 9.2

It is expressly stated between the Partners that ownership of Confidential Information shall remain with the Disclosing Party. Partners hereby agree:

- not to disclose to any third party, directly or indirectly, all or part of the Confidential Information communicated, unless:
  - such information is generally available to the public at the time of disclosure by the Disclosing Party
  - such information can be shown to have been in Receiving Party's possession prior the time of disclosure by the Disclosing Party, and not to have been obtained directly or indirectly from the Disclosing Party;
  - information becomes generally available to the public after its communication by the Disclosing Party, without violation of this Agreement;
  - information is communicated to the Receiving Party by a third party under no obligation of confidentiality towards the Disclosing Party;
  - information must be disclosed according to an applicable law or regulation, a court decision or administrative order, being understood that the Party required to communicate Information shall prior to such disclosure notify the Disclosing Party in order to agree about the content of the divulgation.
  - the information was developed by the Receiving Party, completely independently of any disclosure by the Disclosing Party.
- that the Receiving Party shall apply the same degree of care with regard to the Confidential Information disclosed within the scope of the project as with its own confidential and/or proprietary information, but in no case less than reasonable care;
- to use such Confidential Information for the sole purpose of the Project and not to use Confidential Information for any other purpose without prior written consent of Disclosing Party or until further agreement, if any, is concluded between the Partners concerned regarding the use of Confidential Information;

- to restrict disclosure of the Confidential Information solely to those employees of Receiving Party to whom it shall be essential to disclose it in order to accomplish the above purpose and provided that such employees shall have agreed to be bound by the terms of this cooperation agreement or are bound by confidentiality and non-use obligations no less stringent than the ones contained herein ;
- to return promptly to the Disclosing Party all Confidential Information which has been supplied to or acquired by the Receiving Party including all copies thereof and to delete all Confidential Information stored in a machine-readable form provided, however, (i) each Partner shall be permitted to retain copies of the other Partner's Confidential Information solely for archival, audit, disaster recovery, legal and/or regulatory purposes, and (ii) neither Partner will be required to search archived electronic back-up files of its computer systems for the other Partner's Confidential Information in order to purge the other Partner's Confidential Information from its archived files; provided further, that any Confidential Information so retained will (x) remain subject to the obligations and restrictions contained in this Agreement, (y) will be maintained in accordance with the retaining Partner's document retention policies and procedures, and (z) the retaining Partner will not use the retained Confidential Information for any other purpose..

### 9.3

Each Partner shall promptly advise the other Partner in writing about any unauthorized disclosure, misappropriation or misuse of Confidential Information after it becomes aware of such unauthorized disclosure, misappropriation or misuse.

### 9.4

This obligation of confidentiality shall remain in force for the entire duration of this Agreement and for five (5) years after expiration thereof except for Clinical Data which will remain confidential indefinitely.

### 9.5

Notwithstanding the confidentiality regime of this article, Partners may decide to adopt specific secrecy agreements more stringent than presently stated.

## 10 Dissemination

### 10.1

Unless otherwise agreed in a Project Agreement or mandated by applicable law, Partners are allowed to make presentations and or publications of the Results of their own work carried out within the scope of a Project.

### 10.2

Unless otherwise agreed in a Project Agreement, notice of any planned publication shall be made 30 days prior to all Project Partners before the publication. An objection to the planned publication shall be made in writing to the Project Lead Partner and to any Project Partner concerned within 30 days after receipt of the notice. If no objection is made within the time limit stated above, the publication is deemed permitted.

### 10.3

An objection is justified if based on the following but not limited grounds:

- a) Confidentiality and Trade Secrets: Partner may object on the basis of protecting proprietary information, including formulations, manufacturing processes, regulatory strategies, or competitive intelligence that could harm the objecting Partner's commercial interests if disclosed.
- b) Patent and Intellectual Property Protection: Partners may object if publication compromises pending patent applications, reveal patentable innovations prematurely, or otherwise jeopardize intellectual property rights that require confidentiality for protection.
- c) Regulatory Strategy Concerns: Partners may object on the basis that publication will interfere with planned regulatory submissions, approval timelines, or communication strategies with regulatory authorities. Early or uncontrolled disclosure could complicate the approval process.
- d) Scientific Quality and Accuracy: Objections based on concerns about data interpretation, statistical analysis, study methodology, or conclusions that the objecting Partner believes are scientifically unsound or could mislead the medical community.
- e) Competitive Disadvantage: A Partner may object that publication can provide competitors with strategic insights into development programs, market positioning, or clinical approaches that would harm the objecting Partner's competitive position.
- f) Legal and Liability Risks: Concerns that publication will create legal exposure, particularly if adverse events or negative results might trigger litigation or regulatory scrutiny.
- g) Timing and Market Considerations : Publication might interfere with product launches, marketing strategies, or financial reporting timelines that could affect stock prices or business operations.

### 10.4

The objection has to include for each part of the publication objected to, the grounds of the objection for each objection, indicating which part of the publication the objection is aimed at (individual paragraphs or sentences) and a precise request for necessary modifications (including deletions).

#### 10.5

In the event that an objection is raised in accordance with the above, the Project Partner proposing the publication and the Project Partner objecting shall seek in good faith to agree to a solution whereby the objecting Project Partner(s) give permission to publish the proposed publication.

#### 10.6

Unless otherwise agreed in a Project Agreement, in the event that parts of a publication are objected to on the grounds listed in Clause 10.3b, the publication will be permitted after expiry of a period of three (3) calendar months following the first submission of the proposed publication in accordance with Clause 10.2, to allow for the filing of patent applications (regardless of whether a patent application has indeed been filed before or on the expiry date of the aforementioned period).

#### 10.7

Unless otherwise agreed in a Project Agreement, in the event parts of a publication are objected to on the grounds listed in Clause 10.3b, the publication will in any case be permitted in the event the Project Partner proposing the publication removes those parts from the intended publication .

#### 10.8

For the avoidance of doubt, a Project Partner shall not publish Results or Background of another Project Partner, even if such Result or Background is amalgamated with the Project Partner's Results, without the other Project Partner's prior written approval.

#### 10.9

The Project Partners' contributions to any publication will be acknowledged and the Project Partners' responsible representative will be designated as a publication co-author, in accordance with ICMJE guidelines or other general guidelines. Unless otherwise agreed in a Project Agreement, it is the stated intention that a group authorship will be applied for, such that all persons affiliated with any one of the Project Partners that have made a significant academic contribution to the work of the Project other than the Partners representative, shall also be included in a group authorship.

#### 10.10

Nothing in this Agreement shall be construed as conferring rights to use another Project Partner's name, mark, logo or symbol, or the name of any trustee, officer, faculty member, student or employee thereof, for publicity, advertising or endorsement purposes, without such Partner's prior written consent.

## 11 Amendment

### 11.1

No variation of this Agreement shall be effective unless the variation instrument is in writing and signed by all Partners (or their authorized representatives). No variation of this Agreement shall take effect until the date specified in the written variation instrument, and until such instrument is so signed in writing.

## 12 Term & Accession

### 12.1

This Agreement shall enter into effect as of the last date of signature thereof and shall be active for a term of five (5) years or for as long as a Project Agreement is enforceable between Partners.

Notwithstanding any termination or expiration of this Agreement, the terms and conditions of this Agreement shall continue to apply to and govern any Project that is in effect at the time of such termination or expiration until such Project expires or is terminated in accordance with its terms. For clarity, no new Project may be executed under this Agreement after its termination or expiration.

### 12.2

A new entity becomes a Partner to this Agreement upon signature of the accession document (Annex 2) by the new Partner and [LEAD PARTNER], provided all Partners thereof consent beforehand to the new entity becoming a Partner in accordance with the decision voting process set forth in section 13.1. Such accession shall have effect from the date identified in the accession document.

### 12.3

Partners are entitled to withhold their consent to a new entity to become a Partner, but not on unreasonable grounds. It shall be deemed reasonable to withhold consent for previous violation of Applicable Laws when such violation has been publicly adjudicated in a court of law, or where such violation while not adjudicated in court were publicly alleged and tarnished the reputation of the party applying to become a Partner.

### 12.4

Partners may determine and apply special conditions upon which a new Partner may enter this Agreement. Such conditions will be documented as an appendix to Annex 2.

## 13 Decision voting rule

### 13.1

Decisions requiring Partner approval under this Agreement or any applicable Project Agreement may be made by majority vote of the Partners, provided that no less than seventy-five percent (75%) of all Partners participate in the voting process. For purposes of this provision:

- a) "Majority vote" means more than fifty percent (50%) of the Partners who participate in the voting process;
- b) "Participation in the voting process" includes casting a vote in favor, casting a vote against, or formally abstaining from the vote;
- c) Partners who fail to respond to a voting notice within the time period specified in the notice shall be deemed not to have participated in the voting process;
- d) If the minimum participation threshold of seventy-five percent (75%) is not met, the proposed decision shall not be approved regardless of the vote outcome among participating Partners; and
- e) The Partners may establish additional procedures for notice, timing, and conduct of votes in accordance with this provision.

## 14 Termination

### 14.1

Where one of the Partners:

- a) goes into liquidation, applies for a moratorium on payments, is wound up, for which a debt settlement is put in place or for which a different arrangement is put in place for its creditors;
- b) is affected by a Force Majeure Event that continues without interruption for a period of more than 90 calendar days;
- c) is in breach of any of its obligation and has failed to remedy this breach within 30 days from notification thereof by [LEAD PARTNER] ;
- d) this Agreement with such Partner will be terminated.

Each Partner may terminate this Agreement at any time without cause by providing 90 days' written notice to the other Partners. Upon such termination: (i) Any Project Agreement executed hereunder and in effect at the time of termination notice shall remain in full force and effect and shall be governed by the terms of this Agreement until completion thereof, unless otherwise terminated in accordance with the specific terms of such Project Agreement; (ii) No Partner shall be obligated to enter into any new Project Agreement after the effective date of the termination notice; (iii) Partners shall cooperate in good faith to ensure orderly completion of ongoing projects, including reasonable transition assistance as may be required.

### 14.2

If one of the Partners is terminated, the terminated partner shall immediately inform the Project Lead Partner. There is no mandatory notice period, however the terminated Project Partner will assist the Project Lead Partner to manage Project transition, insofar as to minimize disruption to the Project.

If one of the Partners is thought to be in breach of this Agreement (and consequently under any applicable Project Agreement to which the breaching Partner is part of), the Partner in question shall be notified in writing by [LEAD PARTNER] regarding the specific breach(es). The remaining Partners shall only be able to decide to terminate the Agreement with the Partner in question if the issue(s) raised has not been rectified within 30 days, after notification of breach has been given by [LEAD PARTNER] . The Partners may also immediately terminate a Partner who is in breach of its contractual obligation ("Breaching Partner") when such breach is egregious enough to justify immediate termination or cannot be remedied. A breach is deemed egregious enough to justify immediate termination when it is a violation of Applicable Data Privacy Laws, a breach of confidentiality or non-use obligation, or a violation of the Breaching Party code of conduct or Anti Bribery and Corruption (ABAC) Applicable Laws.

### 14.3

Following the termination of the Agreement as stated in Clause 14.1 or 14.2, the breaching Partner will be terminated from any on-going Project, and any such Project involving the terminated Partner shall be continued by the remaining Partners. If the terminated Partner happens to be a Project Lead Partner, the remaining Project Partners shall decide which Project Partner will be appointed as new Project Lead Partner. The Partner with which the Agreement has been terminated shall be obligated to make available to all remaining Project Partners all relevant documents, drawings and information (including Confidential Information pertaining to the Project) relating to implementation of the Project, as such facilitating implementation of the Project in line with the Project Description.

#### 14.4

Where participation by a Partner has been terminated in accordance with Clause 14.1, its share in Project revenue and costs shall be calculated on the basis of the period ending one day prior to the termination date. All payments to which this leaving Partner is entitled shall be suspended until all costs and interest due from this Partner have been paid. The amount of all costs and interest due from the leaving Partner shall be offset against the payments due to the leaving Partner.

#### 14.5

Where participation by the Project Lead Partner has been terminated in accordance with Clause 14.1 and the remaining Project Partners are unable or unwilling to continue the Project with a new Project Lead Partner in accordance with clause 14.3, the remaining Project Partners shall undertake to cooperate in the proper settlement of the consequences resulting from the revocation and termination of the Project.

#### 14.6

The termination of this Agreement will not affect any rights or obligations of a Partner that have accrued or matured prior to termination. Clauses 0, 0, 0, 0, 0, 0 and 0 will survive the termination of this Agreement for any reason. This includes the obligation to provide all input, deliverables and documents for the period of its participation.

## 15 Liability

### 15.1

Each Partner undertakes to take part in the efficient implementation of a Project, and to cooperate, perform and fulfil all its obligations under this Agreement as may be reasonably required from it and in good faith.

### 15.2

In respect of any information or materials (incl. Results and Background) supplied by one Partner to another under a Project, no warranty or representation of any kind is made, given or implied as to the sufficiency or fitness for purpose nor as to the absence of any infringement of any proprietary rights of third parties. Therefore,

- the recipient Partner shall in all cases be entirely and solely liable for the use to which it puts such information and materials, and
- no Partner granting Access Rights shall be liable in case of infringement of proprietary rights of a third party resulting from any other Partner exercising its Access Rights.

### 15.3

No Partner shall be responsible or liable to any other Partner for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue or loss of contracts.

### 15.4

A Partner's total aggregate liability vis a vis each individual Partner or vis à vis all the Partners collectively shall be limited to the Partner's share of the total costs of the Projects. Hence, the total aggregate liability of a Partner for each Partner claim or for series of claims brought by different Partners under the applicable Project Agreement will not exceed the amount paid by the Partner which liability is sought. This liability cap will not apply when the damage was caused intentionally or with gross negligence. For avoidance of doubt the liability of each Partner shall be several, but not joint. The limitation of liability set forth in this paragraph shall apply only to claims between the Partners inter se and shall not apply to claims by third parties against one or more Partners. In the event that Partners are subject to joint and several liability towards third parties, the Partners shall be liable to each other in proportion to their respective share of fault for such third-party claims.

### 15.5

Each Partner shall be solely liable for any loss, damage or injury to third parties resulting from the performance of the said Partner's obligations by it or on its behalf under this Agreement or from its use of Results or Background.

### 15.6

If the performance of any part of this Agreement or any applicable Project Agreement by a Partner thereto shall be prevented, restricted, interfered with or affected for any length of time by a Force Majeure Event, such Partner shall not be responsible for delay or failure of performance of this Agreement or the applicable Project Agreement for such length of time.

## 16 Dispute Resolution

### 16.1

The Partners shall endeavor to resolve any disputes, controversies, or claims arising out of or relating to this Agreement, including but not limited to disputes concerning the interpretation, performance, breach, or termination of this Agreement, through good faith negotiations and amicable discussion. In the event that the Partners are unable to resolve any dispute amicably within sixty (60) days of written notice of such dispute being given by one party to the other, such dispute shall be submitted to the exclusive jurisdiction of the competent courts of the country and jurisdiction where the Partner against whom the claim is brought has its principal place of business or registered office.

This Agreement and any disputes arising hereunder shall be governed by the laws of the jurisdiction where the defendant Partner is established, without regard to conflict of law principles.

## 17 Signatures

The Partners have caused this Agreement to be duly signed by the undersigned authorized representatives in separate signature pages.

[LEAD PARTNER]

Signature:

Date:

Name:

Position:

Partner:

Signature:

Date:

Name:

Position:

## Annex 1 – Project Description

Objective: [Describe the project objectives, including the question that will be answered (Train)]

Data: [Describe the data being used in the project, consider describing the in- and exclusion criteria and the data elements required]

Partner Background : [briefly describe the Background that is disclosed for the project]

Methods: [Describe what you will do with the data]

Lead Project Partner: [Name]

Project Partners: [Name]

Track Provider: [Name]

Project Agreement: [Yes/No]

### **[Project Partner Name]**

Project role: [Train Provider / Station Provider / Train & Station Provider / Other, specify]

GDPR or other Applicable Law role: [Data Controller / Joint Controller / Data Processor / Other, specify]

Sub-processors: [No / Specify]

Date:

Name:

Position:

[repeat for each partner]

## Annex 2 - Accession Agreement Template

Accession agreement of a new Partner to the “Federated Learning Agreement for [CONSORTIUM] projects“

[OFFICIAL NAME OF THE NEW PARTNER]

hereby consents to become a Partner to the Agreement identified above and accepts all the rights and obligations of a Partner starting [date].

[LEAD PARTNER] hereby certifies that the existing Partners have accepted the accession of [the name of the new Partner] starting [date].

This Accession document has been duly signed by the undersigned authorized representatives.

[Date and Place]

[INSERT NAME OF THE NEW PARTNER]

Signature(s) Name(s) Title(s)

[Date and Place]

[LEAD PARTNER]

Signature(s) Name(s) Title(s)

## Annex 3 – Data Processing Agreement (“DPA”)

This Data Processing Agreement is an integrated part of the Agreement.

All defined terms within the Agreement shall have the same meaning when used in this Data Processing Agreement, unless explicitly defined otherwise in this Data Processing Agreement.

“Applicable Law” means all applicable rules and legislation in relation data protection and the processing of personal data (including the General Data Protection Regulation 2016/679 (“GDPR”).

“Personal Data” shall have the meaning ascribed to it in the Applicable Law.

### 1 Scope

A Partner acts as a data processor as defined under article 4-8 of the GDPR (“Data Processor”) for another Partner who acts as data controller as defined under article 4-7 of the GDPR (“Data Controller”), when the Data Processor processes Personal Data for the Data Controller as set out in the Project Description.

### 2 Processing of personal data

#### 2.1

Instructions: The Data Processor is instructed to process the Personal Data for the term of this Data Processing Agreement and only for the purposes of performing the data processing tasks set out in the Project Description. The Data Processor may not process or use Personal Data for any purpose other than in the Agreement or lawful and reasonable instructions, including with regard to transfers of personal data to a third country or an international organization, unless the Data Processor is required to do so according to Union or Member State law or other Applicable Law. In that case, the Data Processor shall inform the Data Controller in writing of that legal requirement before processing, unless that law prohibits such information on important grounds of public interest.

#### 2.2

Data Processor shall at all times maintain a record of processing of Personal Data in accordance with Applicable Law and if the Data Processor considers an instruction from the Data Controller to be in violation of the Applicable Law, the Data Processor shall promptly inform the Data Controller in writing about this. If the Data Controller persists in its unlawful instruction, then the Data Processor may either suspend the processing to which the unlawful instruction relates, or otherwise terminate the Agreement and this DPA.

### 3 Data processors obligation

#### 3.1

The Data Processor must ensure that persons authorized to process the Personal Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality. The Data Processor shall take full responsibility in the event there is a breach of said confidentiality obligation.

### 3.2

The Data Processor shall implement appropriate technical and organizational measures which shall be no less stringent than the ones reproduced in Schedule A attached hereto to prevent that the Personal Data processed is:

- i. accidentally or unlawfully destroyed, lost or altered,
- ii. disclosed or made available without authorization, or
- iii. otherwise processed in violation of Applicable Law.

### 3.3

The Data Processor must also comply with the special data security requirements of the Project if stipulated in the Project Description or Project Agreement.

### 3.4

The appropriate technical and organizational security measures must be determined with due regard for:

- i. the current state of the art,
- ii. the cost of their implementation, and
- iii. the nature, scope, context and purposes of processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons.

### 3.5

The Data Processor shall upon request provide the Data Controller with sufficient information to enable the Data Controller to ensure that the Data Processor's obligations under this Data Processing Agreement are complied with, including ensuring that the appropriate technical and organizational security measures have been implemented.

### 3.6

The relationship of the Partners and the nature of the Project outlined in the Agreement are such that the Data Controller has no access to the identity of the Data Processor's patients but also no access to the personal data of the Data Processor's patients. Therefore, the Data Controller relies on the Data Processor to be able, by means of appropriate technical and organizational measures, to fulfil the obligation imposed to the Data Controller under Applicable Laws. Data Processor shall therefore respond to requests from Data Processor's patients ("**Data Subjects**") pursuant to Applicable Laws (such as, the right of access, the right to rectification, the right to erasure, the right to restrict the processing, the right to data portability and the right to object).

### 3.7

The Data Controller is entitled to appoint at its own cost an independent expert, who shall have access to the Data Processor's data processing facilities and receive the necessary information for the sole purpose of auditing whether the Data Processor has complied with its obligations. The Data Processor may reasonably and in a justified manner object to the appointment of this proposed expert. The expert shall upon the Data Processor's request sign a non-disclosure agreement provided by the Data Processor, and treat all information obtained or received from the Data Processor confidentially, and may only pass on, the findings as described under clause 3.9(ii) below to the Data Controller.

### 3.8

The Data Processor must give authorities who by Union or Member State law have a right to enter the Data Controller's or the Data Controller's processors' facilities, or representatives of the authorities, access to the Data Processor's physical facilities against proper proof of identity and mandate, during normal business hours and upon reasonable prior written notice.

### 3.9

The Data Processor must without undue delay, and where feasible within 48 hours, notify the Data Controller in writing about:

- i. any request for disclosure of Personal Data processed under the Agreement by authorities, unless expressly prohibited under Union or Member State law,
- ii. any finding of
  - a. breach of security that results in accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, Personal Data transmitted, stored or otherwise processed by the Data Processor under the Agreement ("Data Breach"), or
  - b. other failure to comply with the Data Processor's obligations under Clause 3, or
- iii. any request for access to the Personal Data (with the exception of medical records of the Data Processor's patients for which the Data Processor is considered Data Controller) received directly from the Data Subjects or from third parties.

### 3.10

Such a notification from the Data Processor to the Data Controller with regard to a breach of security as meant in Clause 3.9(ii)(a) will contain at least the following information:

- i. The nature of the Personal Data Breach, stating the categories and (by approximation) the number of Data Subjects concerned, and stating the categories and (by approximation) the number of the personal data registers affected (datasets);
- ii. The likely consequences of the Personal Data Breach;
- iii. A proposal for measures to be taken to address the Personal Data Breach, including (where appropriate) measures to mitigate any possible adverse effects of such breach.

The Data Processor shall document (and shall keep such documentation available for the Data Controller) any Personal Data Breaches, including the facts related to the Personal Data Breach, its effects and the corrective measures taken. After consulting with the Data Controller, the Data Processor shall take any measures needed to limit the (possible) adverse effects of Personal Data Breaches (unless such consultation cannot be awaited due to the nature of the Personal Data Breach).

### 3.11

The Data Processor must promptly and reasonably execute all actions required to handle :

- i. responses to any breach of security as described in 3.9(ii) above and
- ii. any requests from Data Subjects under Chapter III of the GDPR, including requests for access, rectification, restriction of processing or erasure. The Data Processor must also reasonably implement the appropriate technical and organizational measures to enable the Data Controller to fulfil the Data Controller's obligation to respond to such requests. Any reasonable documented costs and expenses pre-approved in writing by the Data Controller related to the

above will be reimbursed by the Data Controller to the extent such costs and expenses are not related to any requirements according to Applicable Law imposed on the Data Processor or due to any breach of this Data Processing Agreement or the Agreement by Data Processor.

### 3.12

The Data Processor must reasonably assist the Data Controller with meeting the other obligations that may be incumbent on the Data Controller according to Union or Member State law or other Applicable Law where the assistance of the Data Processor is implied, and where the assistance of the Data Processor is necessary for the Data Controller to comply with its obligations. This includes, but is not limited to, at the request to provide the Data Controller with all necessary information about an incident under Clause 3.9(ii), and all necessary information for an impact assessment in accordance with Article 35 and Article 36 of the GDPR. Any reasonable documented costs and expenses pre-approved in writing by the Data Controller related to the above will be reimbursed by the Data Controller to the extent such expenses are not related to any requirements according to Applicable Law imposed on the Data Processor or due to breach of this Data Processing Agreement or the Agreement by Data Processor.

## 4 Subprocessors

### 4.1

The Data Processor may only engage a subprocessor, with prior specific or general written consent from the Data Controller, such consent not to be unreasonably withheld, conditioned or delayed. At the time of this Data Processing Agreement, the Data Processor uses the subprocessor listed in the Project Description, all of which are hereby authorized. The Data Processor undertakes to inform the Data Controller of any intended changes concerning the addition or replacement of a subprocessor by providing a reasonable prior written notice to the Data Controller. The Data Controller may reasonably and in a justified manner object to the use of a subprocessor. The Data Processor must inform the Data Controller in writing of the discontinued use of a subprocessor.

### 4.2

Prior to the engagement of a subprocessor, the Data Processor shall conclude a written agreement with the subprocessor, in which at least similar data protection obligations as set out in this Data Processing Agreement shall be imposed on the subprocessor, including obligations to implement appropriate technical and organizational measures and to ensure that the transfer of Personal Data is done in such a manner that the processing will meet the requirements of the Applicable Law.

### 4.3

The Data Processor shall remain fully liable to the Data Controller for the performance of the subprocessor obligations under this Data Processing Agreement. The fact that the Data Controller has given consent to the Data Processor's use of a subprocessor is without prejudice for the Data Processor's duty to comply with this Data Processing Agreement.

### 4.4

The parties shall endeavor to resolve any disputes, controversies, or claims arising out of or relating to this Data Processing Agreement, including but not limited to disputes concerning the interpretation, performance, breach, or termination of this agreement, through good faith negotiations and amicable discussion. In the event that the parties are unable to resolve any dispute amicably within sixty (60) days

of written notice of such dispute being given by one party to the other, such dispute shall be submitted to the exclusive jurisdiction of the competent courts of the country and jurisdiction where the party against whom the claim is brought has its principal place of business or registered office.

This Data Processing Agreement and any disputes arising hereunder shall be governed by the laws of the jurisdiction where the defendant party is established, without regard to conflict of law principles.

## Schedule A

### Technical and Organizational Measures

The following Technical and Organizational Measures are implemented by the Partners to ensure the security of the personal data, including protection against a breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorized disclosure or access.

**Admission Control.** All sites where the data is stored including data centers, offices and off-site storage facilities will have physical security controls (procedures, systems and logs) designed to prevent unauthorized access.

**Insight Control.** Central identity management system to prevent unauthorized use of data processing equipment using (i) unique account identifiers with clear ownership and no indication of privileges, (ii) strong password policy covering password strength and aging requirements and (iii) automatic locking of accounts after unsuccessful login attempts.

**Access Control.** Access to all systems governed by 'least privilege' principles based on job role and need for access with elevated access rights provided via secondary account. Person accessing system is always clearly identifiable (shared accounts are not permitted). Enhanced user authentication process (i.e. two factor authentication) required for remote access to internal network. Information security is monitored, and security event information is sent to a centralized logging system for analysis and reporting. Automatic log-off after 15 minutes or less of inactivity requiring password to log back in or alternatively duty to log off when leaving the workplace. Access to back up data and media is restricted to authorized personnel only.

**Transfer Control.** Only secure communication channels are used to transfer personal data. Procedures and technical controls are used ensure secure transfer including use of industry accepted strong encryption. Only authorized users permitted to use removable devices (e.g. USB drives) and only approved removable devices. All data written to portable storage media must be encrypted using strong encryption. Strong encryption used for all data exchanges over unsecured networks.

**Input Control.** All changes (entry, modification, and deletion) to data are recorded to create an audit trail of the changes made and to attribute them to a specific user account. Log files are sent to centralized collection server for analysis and storage. Access to centralized collection server is restricted to authorized personnel only.

**Order Control.** All employees and contractors are made aware of Partner's information security policies and processes and the requirement to keep personal data confidential. All employees and contractors sign appropriate confidentiality agreements before being granted access to network / data assets.

**Availability Control.** Back up strategy, tested on a regular basis, ensuring encryption and routine deletion of backup.

## Annex 4 – Joint Controller Agreement

This Joint Controller Agreement is an integrated part of the Agreement.

All defined terms within the Agreement shall have the same meaning when used in this Joint Controller Agreement, unless explicitly defined otherwise in this Joint Controller Agreement.

“Applicable Law” means all applicable rules and legislation in relation data protection and the processing of personal data (including the General Data Protection Regulation 2016/679 (“GDPR”).

Whereas:

- a) the Joint Controllers have entered into cooperation the subject of which is to conduct the Project;
- b) the Project requires that the Joint Controllers process personal data, whilst they jointly determine the purposes and means of processing of personal data;
- c) the processing of personal data by the Joint Controllers requires that a transparent manner of determining their respective responsibilities be established as regards their compliance with the obligations under the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (hereinafter referred to as “General Data Protection Regulation” and other generally Applicable Law as well as relations between the Joint Controllers and the data subjects;
- d) on concluding this Joint Controller Agreement, the Partners, seek to regulate the terms of processing of personal data in such a way that they meet the provisions of the GDPR, and
- e) with regard to the data they process, the Joint Controllers act as controllers for the purposes of Article 24 et seq. of the GDPR,

the Partners decided to enter into the following Joint Controller Agreement:

### 5 Definitions

For the purposes of this Joint Controller Agreement, the Partners agree that the following terms shall have the following meaning:

“Controller/Joint Controller” means any natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data;

“Personal Data” means any information relating to an identified or identifiable natural person (hereinafter referred to as “data subject”) including Clinical Data;

“Third Country” means any country that is not a member of the European Union or the European Economic Area or any international organization;

“Processor” means any natural or legal person, public authority, agency or other body which processes Personal Data on behalf of the Controller;

“Data Protection Law” means the GDPR and other Applicable Law as well as other provisions of EU

Member State's national law applicable to a relevant Partner, passed in relation to personal data protection, including in particular the provisions of the given Controller's national law;

"Processing" means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction;

"General Data Protection Regulation", "GDPR" means the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC; wherever this Agreement refers to specific Articles of GDPR, it shall also apply to the corresponding provisions in national legislation guaranteeing a similar level of safety;

"Information System" means a group of cooperating devices, programs, information processing procedures and program tools used for the purpose of data processing;

"Joint Controller Agreement" means this agreement on Joint Control of Personal Data;

## 6 Scope

### 6.1

This Joint Controller Agreement regulates mutual relations between the Partners as regards the joint control of Personal Data, and in particular it determines in a transparent manner the Joint Controllers' responsibilities for compliance with the obligations under the GDPR or other Applicable Law; it also defines the representation of the Joint Controllers in contacts with the data subjects and their relations with those data subjects.

### 6.2

For the purpose of proper implementation of this Joint Controller Agreement, the Joint Controllers shall:

- i. cooperate on performing the obligations of the Joint Controllers of Personal Data;
- ii. process the Personal Data with which they have been entrusted with regard to the Cooperation pursuant to this Joint Controller Agreement, the Agreement, GDPR, Project Description, Project Agreement and other generally applicable laws and
- iii. refrain from any legal or factual actions which might in any way undermine the security of Personal Data or threaten the other Joint Controller with civil, administrative or criminal liability.

Categories of data subjects and personal data, the purposes and means of processing, including the participation of Joint Controllers in those processes, as well as the categories of recipients of the Personal Data are defined in the Project Description.

## 7 Controllers' rights and obligations

### 7.1

The Joint Controllers declare that they have the means enabling them to process and protect Personal Data they are processing, including information systems meeting the requirements of the appropriate level of security, as stipulated by the GDPR. They will each fully adhere to the applicable Data Protection Law(s) with respect to obligations and responsibilities of controllers.

### 7.2

In particular, the Joint Controllers shall:

- i. exercise due diligence in processing Personal Data and process Personal Data pursuant to the Agreement, the GDPR and other provisions of Data Protection Law(s), including the appropriate provisions of each Controller's national law;
- ii. restrict access to Personal Data only to persons who need the access to Personal Data for the purposes of the Project Agreement, provide those persons with relevant authorizations, offer relevant training on personal data protection and ensure confidentiality of Personal Data processed thereby, both during and after their employment or other cooperation with a Joint Controller;
- iii. assist the other Joint Controller, where possible, in meeting its (i) obligation to respond to requests from data subjects and (ii) obligations laid down in Articles 32 through 36 of the GDPR;

The Joint Controllers shall provide each other with the necessary assistance in carrying out the obligations referred to in section 2 point 5) above, in particular in the notification of a personal data breach, by:

- i. providing, at the request of a Controller, information concerning the processing of personal data immediately upon receipt of such request as soon as possible;
- ii. notifying the other Joint Controllers of any breach as soon as possible but not later than 48 hours of its discovery. The notification should include all the information referred to in Article 33 (3) of the GDPR. If - and to the extent that - the information cannot be provided at the same time, they can be given successively without undue delay;
- iii. providing to the other Joint Controllers all information necessary for the communication of a personal data breach to the data subject;
- iv. informing the other Joint Controllers of inquiries, requests or demands from data subjects and other individuals, national or European Union public administrations, including relevant supervisory authorities and courts, as well as any controls or inspections by such authorities in connection with the joint controllership of Personal Data; information shall be provided promptly and in such a way as to enable the other Joint Controllers to comply with the obligations set out in sections 2 and 3, without undue delay but not later than 7 calendar days after receipt of an inquiry, request or demand or after the start of a control or inspection.

## 8 Data subjects' rights

### 8.1

The Joint Controllers shall inform, in any way they deem appropriate, the data subjects of the essences of this Joint Controller Agreement and shall provide them the information referred to in the Project Description in accordance with Article 26 and Article 12 of the GDPR.

### 8.2

The information referred to in section 8.1 shall be primarily provided to the data subjects by the Controller who collects the personal data.

### 8.3

Data subjects may contact any of the Joint Controllers about the rights granted to them by Articles 15 - 22 of the GDPR. The contacted Controller shall identify the responsible Controller and forward the request internally to this Controller. The originally contacted Controller shall carry out all necessary communication with the data subject.

### 8.4

The responsible Controller shall be determined as follows: If the data of the data subject is part of a set of data which can be attributed to a Controller, this Controller shall be responsible. In all other cases the Controller contacted by the data subject shall be the responsible Controller.

### 8.5

The Joint Controllers undertake to comply with the data subjects' rights and shall assist one another with the execution of data subjects' requests.

## 9 Transfers of Personal Data to third countries

Controller and/or its Processor(s) that transfer(s) personal data in the scope of the execution of the Agreement to a Controller and/or Processor and/or other entity situated in the third country that does not present adequate safeguards under the GDPR shall ensure that such transfer is possible and that it complies with the GDPR (e.g. pursuant to Article 45 of the GDPR – on the basis of an adequacy decision Article 46.2.c) of GDPR – on the basis of standard data protection clauses adopted by the Commission in accordance with the examination procedure in Article 93.2 or pursuant to Article 49 of the GDPR. A copy of standard data protection clauses referred to in the preceding sentence shall be provided when so requested by a data subject.

## 10 Entrusting Processors with processing of Personal Data

### 10.1

The Controllers jointly consent to each of them entrusting Processors with processing of Personal Data subject to this Joint Controller Agreement on terms and to the degree defined by this Agreement and Article 28 of the GDPR.

## 10.2

Each Controller may entrust Processors with processing of Personal Data under this Joint Controller Agreement only for the purposes of this Joint Controller Agreement and the Project.

## 10.3

Processors can only carry out specific Personal Data processing activities on behalf of a Controller once the Controller has entered into a contract with such a Processor laying down the obligations of the latter related to Personal Data protection in a manner ensuring sufficient guarantees of technical and organizational measures for the processing to meet the requirements of the GDPR.

## 10.4

This Paragraph shall apply in the case of any intended modifications regarding adding processors or replacing processors with other processors.

## 11 Controllers' liability

The liability of the Partners is governed by the legal regulations, in particular Article 82 of the GDPR with regard to the processing activities that they are in charge of as defined in regard of the Controller's role in the Project.

## 12 Collaboration of the Partners

### 12.1

The Partners shall cooperate in supervising the implementation of this Joint Controller Agreement.

### 12.2

The Partners agree that at the time of the implementation of the Joint Controller Agreement they shall cooperate closely, informing one another of any circumstances that have or may have effect on processing of Personal Data.

### 12.3

Each Project Partner designates a contact point to coordinate the collaboration of the Project Partners in connection with the implementation of the Joint Controller Agreement and the Project, disclosing their personal data in the Project Description.

### 12.4

Amendments to the Project shall not require an amendment of the Joint Controller Agreement, however all Project Partners shall have to be notified thereof either in writing or electronically by the Project Lead Partner.

## 13 Term and termination of the Joint Controller Agreement

### 13.1

The Joint Controller Agreement will take effect as of the start of the Project.

## 13.2

The Joint Controller Agreement shall be concluded for the period of implementation of the Project and as long as and until, after the termination of the Project, obligations still have to be fulfilled.

## 14 Final provisions

### 14.1

The Partners hereby agree that, unless otherwise agreed, the Controllers shall process Personal Data pursuant to this Joint Controller Agreement free of charge, and neither the conclusion of this Joint Controller Agreement nor the processing of data pursuant thereto shall entitle any Controller to seek, on whatever legal basis,

- a) remuneration,
- b) reimbursement of any costs or expenses incurred for the purpose of due performance of the Agreement,
- c) exemption from any obligations contracted to that end or advances on such costs or expenses,

even if at the time of entering into the Project or concluding this Agreement, despite exercising due care, the Controller was unable to foresee the circumstances justifying such rises, costs, expenses or obligations.

### 14.2

Should any provision hereof become invalid or ineffective, the Partners shall adopt all measures possible to replace it with a valid and effective provision reflecting the goal and meaning of the invalid or ineffective provision to the extent of applicable law. Should any provision hereof be or become invalid or ineffective at any time, it shall not restrict the validity or effectiveness of the remaining provisions of the Agreement.

### 14.3

In the event of any discrepancies between the provisions of the Joint Controller Agreement and the Project Agreement agreed by the Partners, the provisions of this Joint Controller Agreement shall prevail.

### 14.4

Any amendments hereto must be in writing on sanction of invalidity.

### 14.5

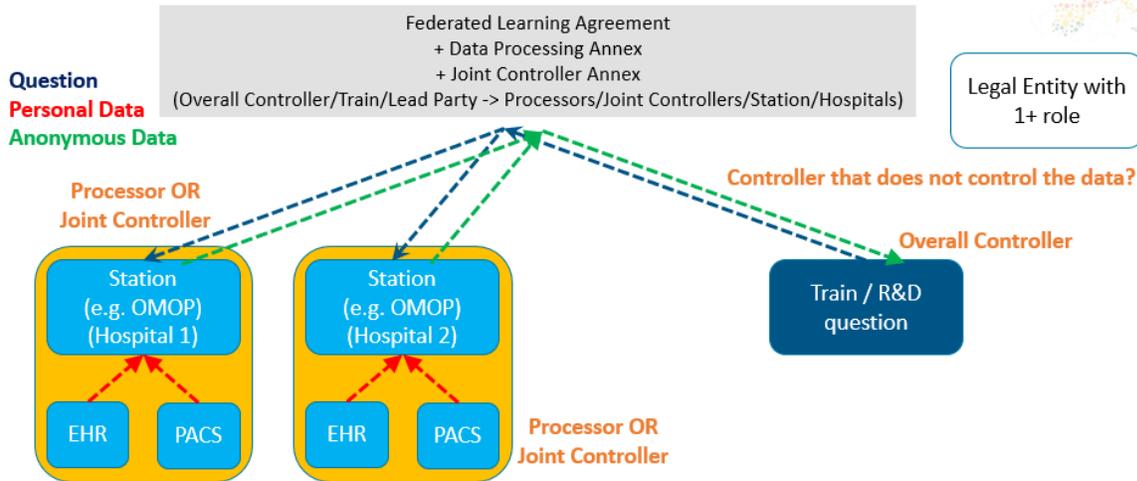
The parties shall endeavor to resolve any disputes, controversies, or claims arising out of or relating to this Joint Controller Agreement, including but not limited to disputes concerning the interpretation, performance, breach, or termination of this agreement, through good faith negotiations and amicable discussion. In the event that the parties are unable to resolve any dispute amicably within sixty (60) days of written notice of such dispute being given by one party to the other, such dispute shall be submitted to the exclusive jurisdiction of the competent courts of the country and jurisdiction where the Controller against whom the claim is brought has its principal place of business or registered office.

This Joint Controller Agreement and any disputes arising hereunder shall be governed by the laws of the jurisdiction where the defendant Controller is established, without regard to conflict of law principles.

In cases where claims are brought against multiple Joint Controllers established in different jurisdictions, the claimant may choose the jurisdiction of any one of the defendant Controllers for the resolution of the entire dispute.

# Annex 5 – Federated Learning Agreement Use Cases Examples

## Federated Learning Agreement

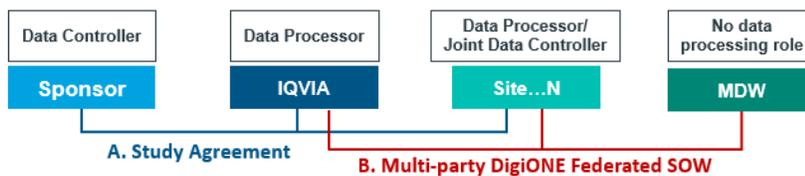


Under GDPR, a controller is the legal entity that "determines the purposes for which and the means by which personal data is processed. So, if your company/organisation decides 'why' and 'how' the personal data should be processed it is the data controller.". ([source](#))



## Study contracting example - Commercial study lead by IQVIA

Upfront legal agreements need to be in place between relevant parties i.e. Infrastructure User Agreements with Medical Data Works and the multi-party DigiONE Federated Learning Agreement

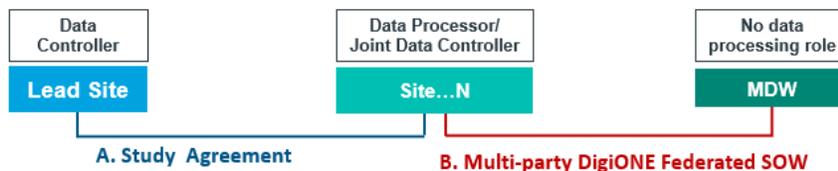


Agreement	Contracting Parties	Comments
A. Study Agreement	Sponsor, IQVIA, with all study sites	Bipartite or Tripartite Study Templates tailored to each country to align with their national standard templates for retrospective studies, and implement the objectives of the DigiONE Federated SOW
B. DigiONE Federated SOW	All relevant parties involved in the study, e.g., MDW, IQVIA, and a subset of DigiONE	Multi-party Statement of Work which describes the project, data, methods, and the (data processing) roles of each party. IQVIA will act on behalf of the Sponsor

Each participating site can choose to be either a Data Processor or Joint Data Controller based on their preference. Both scenarios are covered in the Federated Learning Agreement, Annex 3 (Data Processing Agreement), and Annex 4 (Joint Controller Agreement)

## Study contracting example – Academic study lead by a site

Upfront legal agreements need to be in place between relevant parties i.e. Infrastructure User Agreements with Medical Data Works and the multi-party DigiONE Federated Learning Agreement



Agreement	Contracting Parties	Comments
<b>A. Study Agreement</b>	Between study sites, led by the Lead Site	Formal or informal agreement between parties to collaborate on a Study
<b>B. DigiONE Federated SOW</b>	All relevant parties involved in the study, e.g., MDW, and a subset of DigiONE hospitals	Multi-party Statement of Work which describes the project, data, methods, and the (data processing) roles of each party. The site that is initiating the study is the Lead Site.

Each participating site can choose to be either a Data Processor or Joint Data Controller based on their preference. Both scenarios are covered in the Federated Learning Agreement, Annex 3 (Data Processing Agreement), and Annex 4 (Joint Controller Agreement)