

Project agreement for the “xx” research project

Preamble

The undersigned:

- xx (“xx” or “Lead Partner”), xx;

AND

- xx;

AND

- xx

AND

- xx

AND

- xx

wish to enter a project agreement for the “xx” research project.

The term ‘Partner’ or ‘Partners’ shall be used to refer to the parties to this Agreement both separately and jointly.

WHEREAS:

- The Lead Partner has submitted a study protocol or proposal for the Project;
- The Project will not be subject to any particular funding agency;
- Partners will jointly perform scientific research activities in accordance with the Project description and the overview of deliverables;
- The Partners have entered into consultation in order to formulate mutually acceptable conditions under which they will collaborate;
- The Partners wish to enter into an agreement under the following conditions;

AGREE AS FOLLOWS:

Definitions

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

“Affiliate” shall mean any corporation, company or other entity, which controls, or is controlled by a Partner or by another subdivision of the Partner, where control means ownership or control, direct or indirect, of more than fifty (50) percent of such corporations, company’s or other entity’s voting capital; however, any such corporation, company or other entity shall be deemed to be an Affiliate only so long as such ownership or control exists.

“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”).

"Background" means all Data, tangible and intangible items and information protected by intellectual property rights (including database rights, patents, trademarks and copyrights) and confidential information held 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.

“Agreement” means this project agreement.

“Data” means all de-identified medical data or information that has been abstracted from a patient’s chart, needed to carry out the Project. Data shall be rendered either pseudonymized or anonymized by the providing Partner prior to making them available for the Project.

“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 not capable of being over-come or which are not capable of being overcome without unreasonable investments by the Partner concerned.

“Net Proceeds” means the gross amount actually received by 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” means the research project, as described in Annex 1.

"Results" means the results, including information, whether or not they can be protected, which are generated under the Project. Such results include software and rights related to copyright, design rights, patent rights, or similar forms of protection. Results include improvement to the Background.

“Infrastructure User Agreement” means the agreement between the Partner and Medical Data Works B.V. that defines the terms of use of using the infrastructure Medical Data Works B.V. supplies for the Project.

1 Project scope

1.1

The Partners agree that they shall work together at least for the duration of the Project, until completion in accordance with the Project description (Annex 1) unless in case of premature termination as specified in Clause 12 of this Agreement.

1.2

The Project Description (**Annex 1**), the accession document (**Annex 2**) and, subject to clause 7.5, the data processing agreement (**Annex 3**) and the role of each Partner within this Project to be a data controller, a data processor or a joint data controller with the Lead Partner based on their interpretation of Applicable Law (**Annex 4**), shall form an integral part of this Agreement.

The Project Description informs the goals and objectives of the project, and signing the Agreement will be taken to mean agreement with the scientific ambitions and deliverables of the Project.

The Project requires the use of telecommunications infrastructure, specifically the Personal Health Train method for federated learning, and such infrastructure will be supplied for the purpose of this Project by Medical Data Works. Each Partner will provide a copy of a signed Infrastructure User Agreement between the Partner and Medical Data Works.

Each Partner shall diligently perform the work as requested of them to fulfil the objectives of the Project.

2 Partners

2.1

The Partners shall participate in the Project and shall actively work together. The Partners shall put all measures necessary in place with regard to Project implementation and progress and shall do so in accordance with the objective of the Project. The Partners shall implement their role(s) in the Project properly, on time and in line with the conditions of this Agreement.

2.2

Each Partner shall use reasonable efforts:

- a. to immediately and promptly (within 30 days of request by the Lead Partner) make available to the Lead Partner information necessary for completion of official reports;
- b. to notify the Lead Partner of information that a Partner receives about the Project from third parties and that may have an effect on the outcome of the Project;
- c. to ensure accuracy of information that it supplies to the Lead Partner and to the other Partners, and, where any inaccuracies or mistakes are discovered in the said information, to rectify them immediately; and,
- d. to participate in, and contribute to, meetings and gatherings in the framework of the Project in a collegiate and mutually collaborative manner.

2.3

Each Partner will be liable for its own costs and expenses arising due to participation in the Project.

2.4

The Partners may perform their obligations across one or more of their departments or their Affiliates’.

3 Lead Partner

3.1

The Lead Partner shall be responsible for ensuring the correct implementation of the Project.

3.2

The Lead Partner shall be obliged to support the Partners with information (for example, how many data subject to collect, and similar relevant information) and documents required necessary to the successful execution of the Project.

3.3

The Lead Partner nominates a Project execution team that includes the principal investigators named on the Project description and one person from each Partner institution, and may potentially include other persons affiliated directly with the Lead Partner such as engineers, research assistants and PhD students.

The Project execution team shall be responsible for overseeing the implementation of the Project, monitoring progress on work as agreed with the Supervision Committee, and regularly reporting overall progress to the Supervision Committee.

In particular, the Project execution team is tasked with:

- Monitoring progress made by the individual Partners as well as that of the research results of the Project in its entirety;
- Providing support and guidance to Partners with regards to preparation of Data to be used in the Project;

- Providing regular means of communication for the Partners, including document exchange, email and reporting infrastructure.
- Organizing and reporting on the outcomes of Project meetings, and circulating agendas and minutes.
- Preparing a final report that will be disseminated to the Partners as well as externally as a scientific publication, at the conclusion of the Project.
- Deciding on suitable actions needed to resolve technical difficulties experienced by Partners towards achieving the objectives of the Project.

3.4

Rules of procedure; the Project execution team convenes at minimum on a fortnightly basis, or more frequently if necessary, to perform the abovementioned tasks. At its first meeting, the Project execution team will establish further rules of procedure where deemed necessary.

4 Project Supervision Committee

4.1

Role: The Project Supervision Committee is the body responsible for monitoring the overall progress of the Project and further agreeing on the allocation of work among the Partners. It will: settle any dispute arising from the Project implementation; make decisions concerning division of proceeds as referred to in Clause 6.4; advise on ethical and any other issues raised. When deemed necessary, due to failure of a majority agreement on matters relating to disputes, IP or ethical issues, ad hoc committees will be formed to deal with these specific matters arising.

4.2

Composition; the Supervision Committee shall consist of the leading investigators named on the Project description (Annex 1) plus one representative named by each Partner (so called the Partner's responsible investigator). Each Partner has the right to replace its responsible investigator and/or to appoint a proxy, after having informed the other Partners of its unilateral decision in writing. All Partners shall use apply all reasonable endeavors to maintain continuity of their representation in the Supervision Committee.

4.3

Rules of procedure; The Supervision Committee will convene at least once a month. At the first meeting, the Supervision Committee establishes further rules of procedure, including, but not limited to, the following subjects:

- frequency, notices and minutes of meetings;
- disseminating the agenda and adding items to the agenda;
- voting rules and quorum;
- the possibility of veto;

- monitoring progress towards successful execution of the Project;
- decisions regarding the evolution of the Project including, but not limited, to entry of a new Partner to the Project and the conditions attached to the accession of such a new Partner.

4.4

Any decision may also be taken without a formal meeting, provided the Lead Partner circulates to all Partners a written document which is then agreed by the majority of Partners. Such a document shall include a deadline of not less than 14 calendar days for responses. Such an agreement may also take the form of a vote via email. The Lead Partner shall immediately inform all the Partners of the outcome of such a written procedure. Meetings of the Supervision Committee shall be primarily conducted via teleconference or other equivalent electronic telecommunication means.

5 Information provision to the Lead Partner

The Partners agree to make information available to the Lead Partner for the purpose of dissemination and publicity relating specifically to this Project.

6 Results and Background

6.1

This Agreement does not affect the ownership of any Background intellectual property, which includes also improvements of such Background intellectual property to the extent that such improvement is not separable of Background intellectual property.

To the extent that ownership is possible, Lead Partner shall be assigned the Results that are generated within the Project, to the extent they constitute improvements of the Lead Partner's Background, which it shall consequently be free to protect (patents or any other form of protection) and exploit subject to the terms herein. Each Partner shall use reasonable efforts to make the Data required for the execution of the Project available and accessible. Each Data contributing Partner retains ownership of the Data it contributes to the Project.

6.2

Each of the Partners is hereby granted a free license to use of the Results for the purpose of carrying out its work under the Project, and for academic research and teaching purposes after completion of the Project, including research involving projects funded by third parties, provided that those parties neither gain nor claim any rights to the Results.

6.3

In the event that a third party wishes to purchase the Results for commercial exploitation, the Lead Partner may transfer ownership of Results during the course of the Project with the prior written consent of the Partner(s) that provided Data for the Project and/or Partner(s) who provided the computational model to be trained in this Project. The Lead Partner shall notify all Partners with 30 days prior notice of any such transfer and shall ensure that such transfer will not affect the rights of the

Partners. The Partners, assembled in the Supervision Committee, shall be entitled to withhold their consent to such transfer, but not on unreasonable grounds.

6.4

In the event that there is any income generated by the Lead Partner from commercial exploitation of Results, it shall be divided as follows:

- 50% of all Net Proceeds shall be divided between the Partner(s) who provided the computational model to be trained in this Project (pro rate the effort measured in FTE spent on the project, based on approved statements of working hours).
- The other 50% shall be divided between the Partners providing Data for the Project, pro rate the number of usable individual subjects contributed per 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 among other 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 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 makes the Data accessible for this Project as a 'Station' as agreed upon in the Infrastructure Use Agreement between each Partner and MDW.

Each Partner is responsible for the Data that it makes accessible and ensures that it has the appropriate approvals for use of the Data in this 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 information about the other Party's employees, whom are part of the Agreement and other persons whom are necessary for the completion of the Agreement. Each Party is data controller for the procession of this personal data with reference Applicable Laws and regulations, including GDPR.

7.5

To the extent that GDPR or similar Applicable Law applies:

All Partners are obliged to determine their role for the processing of the subject Data in accordance with the Applicable Law, except if a Partner decides to submit fully anonymised Data.

Partners may differ in their opinion (based upon their interpretation of the Applicable Law in their country and role within the Project to be a data controller, a data processor or a joint data controller).

Parties will indicate in **Annex 4** which roles they have according to the options:

Option A

- The Lead Partner is subject to the rights and obligations as “data controller” set forth under the GDPR in relation to the processing of personal data for the purpose of conducting the Project in accordance with the Project. In that respect, the Lead Partner shall be considered as data controller of all Data processed for Project purposes.
- The data contributing Partner is subject to the rights and obligations as “data processor” set forth under the GDPR in relation to the processing of Data for the purpose of conducting the Project.
- Pursuant to Article 28.3 of GDPR, the Lead Partner and the data contributing Partners have concluded a data processing agreement attached in Annex 3.
- Each Partner is also subject to the rights and obligations as a separate “data controller” set forth under the GDPR 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.
- It is thus agreed and understood that Partners shall process but not transfer any Data (even if pseudonymised) to the Lead Partner. Each Partner shall be responsible to ensure an appropriate legal basis pursuant to GDPR for its processing of Data for the purpose of the Project.

Option B

Pursuant to Article 26 of the GDPR, Parties shall be considered as ss in relation of the processing of the Data for the purpose of the Project and the Parties will act in accordance with the applicable privacy laws and any (additional) applicable national law. Hereto each Partner shall:

- a) adopt appropriate technical, physical and organizational security measures, procedures, and other safeguards to protect the Data, amongst others, against security incidents;
- b) notify, without undue delay, the data contributing Partner if it becomes aware of a Data Breach (i.e. a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to use, processing of, or access to Data). In this case, and to the extent required, the Partners will work together to identify the cause of the Data Breach and take appropriate steps to remediate the Data Breach, limit its impact and prevent its re-occurrence. Each Partner keeps a record on Data Breaches in accordance with applicable laws;
- c) make available to the Data contributing Partner all information necessary and provide all reasonable assistance to demonstrate compliance with the obligations laid down in this Agreement or applicable law, including GDPR; and
- d) agree to consult with the data contributing Partner who will contact the supervisory authority however the Data contributing Partner will be the Partner to contact the patients concerned in accordance with the applicable privacy laws and any (additional) applicable national law.

8. Confidentiality

8.1

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,

(hereinafter: “Confidential Information”) shall be treated by all Partners as strictly confidential.

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 the present cooperation agreement;
 - information is communicated to the Receiving Party by a third party under no obligation of confidentiality towards the Disclosing Party;
 - information has to be disclosed according to an applicable law on regulation, a court order 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 have entered into an agreement of similar scope and obligations with Receiving Party to protect and limit the use of information of Receiving Party and the information of third parties in Receiving Party's possession;
- to return to the Disclosing Party within a reasonable amount of time 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 so far as reasonably practicable. If needed for the recording of ongoing obligations, the Receiving Party may however request to keep a copy for archival purposes only.

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

This obligation of confidentiality shall remain in force for the entire duration of this Agreement and for five years after expiration thereof, whatever the reason, including prior termination of the participation of any Partner for what concerns information communicated prior this withdrawal.

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

9. Dissemination

9.1

Partners are allowed to make presentations and or publications of the Results of their own work carried out within the scope of the Project.

9.2

Notice of any planned publication shall be made 30 days prior to all Partners before the publication. Any objection to the planned publication shall be made in writing to the Lead Partner and to any Partner

concerned within 30 days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.

9.3

An objection is justified if based of the following grounds:

- a. if the protection by intellectual property rights of the objecting Partner's Results would be adversely affected by the proposed publication,
- b. that the proposed publication includes Confidential Information of the objecting Partner

9.4

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).

9.5

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

9.6

In the event that parts of a publication are objected to on the grounds listed in Clause 9.3.a, 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 9.2, 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).

9.7

In the event parts of a publication are objected to on the grounds listed in Clause 9.3.b, the publication will in any case be permitted in the event the Partner proposing the publication removes those parts from the intended publication and only the scientific integrity of such proposed publication is kept.

9.8

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

For the avoidance of doubt, the mere absence of an objection according to Clause 9.2 will be considered as an approval.

9.9

The Partners' contributions to any publication will be acknowledged and the Partners' responsible representative will be designated as a publication co-author, in accordance with general principles accepted among publishers and academic institutes.

It is the stated intention here that a group authorship will be applied for, such that all persons affiliated with any one of the 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.

9.10

Nothing in this Agreement shall be construed as conferring rights to use another 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.

A Partner may acknowledge another Partner's participation in the Project and any scientific contributions in academic publications.

Each Partner's use of the name, symbols and/or marks of another Partner, or the names of the other Partner's employees, shall be limited to identification of the other Partner as a research collaborator.

Each Party may include factual information about another Party in listings of sponsored research projects without such Party's prior written consent.

10. Amendment

10.1

It shall only be possible to amend this Agreement in writing, with the permission of all Partners.

11. Term

11.1

This Agreement shall enter into effect as of **15th of July 2021** and shall be active for at least the term of the Project, or until formal conclusion of the project agreed to by the Partners. Where necessary for realization of the Project and with the agreement of the Partners, the term of this Agreement may be extended.

A new entity becomes a Partner to this Agreement upon signature of the accession document (Annex 2) by the new Partner and on behalf of the Project by an appointed representative of the Project execution team. Such accession shall have effect from the date identified in the accession document. The Parties may determine special conditions upon which a new Partner may enter this Agreement. Such conditions will be documented as an appendix to Annex 2.

12. Termination

12.1

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 situation that continues without interruption for a period of more than 30 days;
- c. is in default and this default cannot be rectified within 30 days. The 30-day period shall start once a notice of default has been issued by the Lead Partner, after having obtained approval from the Steering Committee;

this Agreement with such Partner will be terminated.

If one of the Partners is no longer able to, or no longer wishes to, take part in the project, the withdrawing partner shall immediately inform the Lead Partner. There is no mandatory notice period, however the withdrawing Partner will assist the Lead Partner to manage such a transition, insofar as to minimize disruption to the rest of the Project.

If one of the Partners is thought to be in breach of this Agreement, the Partner in question shall be notified in writing by the Supervision Committee 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 the Supervision Committee.

12.2

Following the termination of the Agreement as stated in Clause 12.1, the Project shall be continued by the remaining Partners, where this lies within their capacity to do so. If the defaulting or terminating Partner happens to be the Lead Partner, the remaining Partners shall decide in close consultation with the Supervision Committee, which Partner will be appointed as new Lead Partner. The Partner with which the Agreement has been terminated shall be obliged to make available to the remaining Partners all relevant documents, drawings and information relating to implementation of the Project, as such facilitating implementation of the Project in line with the Project Description wherever possible.

While the remaining Partners may use the Data contributed by a terminating Partner for the Project and work approved prior to termination, the remaining Partners may not use contributed Data for any new Project(s) or other works. To the extent that it is not transformed and integrated into the Results rendering its separation impossible, the Data contributed shall be erased or destroyed and a certification of such destruction shall be provided to the terminating partner.

12.3

Where participation by a Partner has been terminated in accordance with Clause 12.1, its share in the 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.

12.4

Where participation by the Lead Partner has been terminated in accordance with Clause 12.1 and the remaining Partners are unable or unwilling to continue the Project with a new Lead Partner in accordance with clause 12.2, this Agreement shall be terminated. The Partners shall undertake to

cooperate in the proper settlement of the consequences resulting from the revocation and termination of the Project.

12.5

The termination of this Agreement will not affect any rights or obligations of a Partner that have accrued or matured prior to termination. Clauses 5, 6, 7, 8, 9, 13 and 14 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.

13. Liability

13.1

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

13.2

In respect of any information or materials (incl. Results and Background) supplied by one Partner to another under the 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.

13.3

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, provided such damage was not caused by a willful act or by a breach of confidentiality.

13.4

A Partner's aggregate liability towards the other Partners collectively shall be limited to the Partner's share of the total costs of the Project, provided such damage was not caused by a willful act or gross negligence.

13.5

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.

13.6

No Partner shall be considered to be in default if such default is caused by Force Majeure.

14. Concluding provisions

14.1

In case of any dispute over the interpretation or the execution of this Agreement, the parties undertake to make every effort to settle their dispute by amicable agreement. If the parties are unable to settle a dispute arising out of or in connection with this Agreement, the territorially competent court shall be that of the place where the defendant resides. The applicable law will be the national law of the defendant court.

15. Signatures

As Witness:

The Parties have caused this Project Agreement to be duly signed by the undersigned authorized representatives in separate signature pages the day and year first above written.

Lead Partner: xx

Signature(s):

Name(s): xx

Title(s): xx

As Witness:

The Parties have caused this Project Agreement to be duly signed by the undersigned authorized representatives in separate signature pages the day and year first above written.

Partner: {please insert you details here, and signatory's details below}

Signature(s):

Name(s):

Title(s):

Annex 1

PROJECT DESCRIPTION

Annex 2

Template of accession document for adding members to the existing Project Agreement

ACCESSION

of a new Partner to

Project Agreement for the “xx” project (Annex 1), version [..., DD-MM-YYYY]

[OFFICIAL NAME OF THE NEW PARTNER]

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

xx (“xx”) hereby certifies that the Partners has accepted in the meeting held on [date] the accession of [the name of the new Partner] to the project starting [date].

The Project Description has been updated to include the contribution of the new partner, and the Partners has given its agreement to this amendment.

This Accession document has been done in 2 originals to be 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]

[INSERT NAME OF THE SUPERVISION COMMITTEE REPRESENTATIVE]

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

Annex 3 - DATA PROCESSING AGREEMENT

This data processing agreement, including any appendices hereto, (together the "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")).

1 SCOPE OF THE DATA PROCESSING AGREEMENT

1.1 The PARTNER acts as a data processor as defined under article 4, 8) of the GDPR ("Data Processor") for the LEAD PARTNER who acts as data controller as defined under article 4, 7) of the GDPR ("Data Controller"), when the PARTNER processes Personal Data for the LEAD PARTNER as set out in Appendix 1.

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 Appendix 1. The Data Processor may not process or use Personal Data for any purpose other than in the Agreement or 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. 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.

3 THE DATA PROCESSOR'S OBLIGATIONS

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 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 Appendix 1.

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 Parties and the nature of the Project outlined in the Agreement are such that the Data Controller has not only 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 needs to rely on the Data Processor in order 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") in accordance with Article 3.1.2 of the Agreement 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 72 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 (a) responses to any breach of security as described in 3.9(ii) above and (b) 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 Annex 3 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 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 Annex 3 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. At the time of this Data Processing Agreement, the Data Processor uses the subprocessor listed in Appendix 2. 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 the same 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 Controller has the right to receive a copy of the relevant provisions of Data Processor's agreement with the subprocessor related to data protection obligations. 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.

Annex 4 – Roles in accordance with Clause 7.5:

Partners are obliged to determine their role for the processing of the subject Data in accordance with the Applicable Law, except if a Partner decides to submit fully anonymised Data. Partners may differ in their opinion (based upon their interpretation of the Applicable Law in their country and role within the Project to be a data controller, a data processor or a joint data controller.

Lead Partner – xx

Lead Partner – Controller
xx – Processor

Lead Partner - xx

Joint Controllers

Lead Partner – xx

Joint Controllers

Lead Partner – xx

Joint Controllers

Lead Partner – xx

Joint Controllers

Lead Partner – xx

Joint Controllers

Lead Partner – xx

Joint Controllers

Lead Partner – xx

Joint Controllers

Lead Partner – xx

Joint Controllers

Lead Partner – xx

Joint Controllers

Lead Partner – xx

Joint Controllers

Lead Partner – xx

Joint Controllers