

Infrastructure User Agreement

This agreement (the “Agreement”) is entered into as of the date stated below (“Effective Date”) between [TRACK PROVIDER] (“Track Provider”) and [INSTITUTION] (“Institution”). Track Provider and Institution are referred to collectively herein as “Parties” or individually as “Party”.

1 Definitions

1.1 “Clinical Data”

All clinical data and/or information made available by a given Member which relates to an individual patient.

1.2 “Confidential Information”

Any information, in tangible or non-tangible form, and/or physical items or materials, that is marked as confidential by the disclosing Party or that is clearly recognizable as confidential to a reasonable person with no special knowledge of the disclosing Party’s activities. If Confidential Information is disclosed orally, the Confidential Information will be identified as confidential at the time of disclosure.

1.3 “Project”

A project where one or more Members wish to share certain Clinical Data and/or use certain Clinical Data for the purpose of performing scientific research.

1.4 “Project Agreement”

An agreement between the Members with specific terms and conditions for a Project. Track Provider may or may not be a party in the Project Agreement.

1.5 “Station”

An information system which contains Clinical Data.

1.6 “Station Provider”

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

1.7 “Member”

A legal entity, which participates as a Train Provider and/or a Station Provider in one or more Projects.

1.8 “Leading Member”

A Member who leads the Project as defined in the Project Agreement.

1.9 “Institution Data”

Any business information, end-user data, user-generated content, or other data of any type which is provided or made available by a Member via the Track with the explicit exception of Clinical Data. One example of Institution Data are the names and emails of employees that need to be stored by Track Provider as registered users of the Track.

1.10 “Train”

A software application that encodes a question to Clinical Data in a mathematical/statistical algorithm. The specific question(s) to be asked are stated in the Project Agreement.

1.11 “Train Provider”

A Member 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 Agreement.

1.12 “Individual Terms of Use”

The Terms of Use for an individual, authorized by Institution to access the Track, is published by Track Provider on its website. These terms may be updated, amended and or revised by Track Provider at any time by posting a new version and informing by email each individual that has access to the Track. Each individual must accept and agree to these Individual Terms of Use before using the Track. The Individual Terms of Use describe the terms and conditions governing each such individual's access to and use of the Track.

1.13 “Track”

Software and infrastructure which allows Trains in a given Project to perform federated learning on the Clinical Data of the Station(s).

1.14 “Track Provider”

The organization that provides the Track, Medical Data Works B.V.

1.15 “Federated Learning”

Learning from Clinical Data where no Clinical Data leaves the Station and only anonymous statistical data is communicated on the Track.

1.16 “Effective Date”

The date of the last signature.

2 Preamble

Track Provider implements a privacy preserving distributed infrastructure as proposed by the Personal Health Train, please see here: <https://www.dtls.nl/fair-data/personal-health-train/>.

According to the Personal Health Train principles, a user needing to use decentralized data sends a software application called a “**Train**” which encodes a question as a mathematical algorithm. This application is received by a “**Station**” which supplies the Clinical Data that is needed to answer the question. The answer to the question is subsequently communicated to the user, but no privacy sensitive or subject level Clinical Data is being exchanged. The “**Track**” of the Personal Health Train is the IT infrastructure that delivers Trains to Stations.

This Infrastructure User Agreement is a contractual agreement between Train Provider(s), Station Provider(s) and the Track Provider.

Track Provider will support the Federated Learning Project(s). It is the operating principle of Federated Learning that Clinical Data does not leave the Station. As such, Track Provider is not a processor of Clinical Data per definition of the EU General Data Protection Regulation but solely the provider of the Track. The Track Provider enforces the legal use of Trains and Stations, and this Agreement defines the terms and conditions for the use of the Track.

Institution desires to become a Member and wishes to use the Track as a Train Provider or a Station Provider for at least one Project, where Institution is either responsible for Clinical Data in their Station(s) and/or responsible for the question(s) inside their Train(s). The role of the Institution in a specific Project is defined in the Project Agreement.

Subject to the terms of this Agreement, Track Provider is willing to provide Institution with access to the Track for purpose of conducting one or more Projects.

NOW THEREFORE, the Parties agree as follows:

3 License & Right to Use

3.1

Track Provider grants to Institution a personal, limited, non-exclusive, non-transferable, revocable license and right to use the Track solely for the limited purpose of acting as a Station Provider and/or a Train Provider in the Project.

3.2

In order to use the Track as a Station, Institution might need to install Track software on Institution's own computing equipment, and must extract appropriate Clinical Data and store it in a semantic interoperable endpoint (i.e. the Station) according to the standards supported by the Track. The foregoing activities are the sole responsibility of Institution. Institution is solely responsible and liable for all Clinical Data that is placed in the Station.

4 Terms of Use

4.1

The Track is intended for research or statistical purposes only and is not cleared by any regulatory body or agency. The Track is forbidden to be used for any clinical care application.

4.2

Institution agrees, on behalf of itself and its authorized representatives accessing the Track, not to:

- (a) knowingly infringe on Track Provider's or other third-party intellectual property rights;
- (b) collect data from other Members, or otherwise access the Track, using automated means (e.g. "bots") without Track Provider's prior written permission;
- (c) upload viruses or other malicious code;
- (d) solicit login information or access an account belonging to anyone else;
- (e) disable, overburden or impair the proper working or appearance of the Track, such as a denial of service attack or interference with page rendering or other functionality or otherwise impose an unreasonable or disproportionately large load on the network or infrastructure;
- (f) access parts of the Track to which Institution is not authorized to access or attempt to circumvent any restrictions imposed on Institution's use or access of the Track;
- (g) attempt to decipher, decompile, disassemble or reverse-engineer any of the software comprising or in any way making up a part of the Track;
- (h) take any action that violates or threatens the system or network security;
- (i) engage in any other conduct that restricts or inhibits any other person or Member from using or enjoying the Track.

4.3

Track Provider agrees to not

- (a) knowingly infringe on Institution's or other third-party intellectual property rights;
- (b) provide Track software that contains viruses or other malicious code;
- (c) access information systems of Institution to which it is not authorized;
- (d) attempt to circumvent any restrictions imposed by Institution on its information systems;
- (e) attempt to decipher, decompile, disassemble or reverse-engineer any of the software comprising or in any way making up a part of the Station, Train or any other software of Institution;

(f) take any action that violates or threatens Institution's systems or network security;

4.4

Access to and use of the Track is at Institution's own risk and liability and is subject to this Agreement and all applicable laws, statutes, and/or regulations. Track Provider reserves the right to disable Institution's access to the Track in accordance with this Agreement.

4.5

Institution must ensure that all Institution Data shared via the Track does not contain or constitute any Clinical Data. Track Provider shall notify Institution if Track Provider becomes aware that Track Provider has incidentally or inadvertently come into possession of Clinical Data. In that case Track Provider will immediately and permanently destroy these data. Institution shall notify Track Provider if Institution becomes aware that Institution has incidentally or inadvertently come into possession of Clinical Data of a Member other than the Institution. In that case Institution will immediately and permanently destroy these data. Track Provider will investigate from which Member this Clinical Data originated and will notify that Member.

4.6

Institution acknowledges that Track Provider will process Institution Data including but not limited to names and contact details of Institution's representatives for the sole purpose of operation of the Track and the enforcement of this Agreement.

4.7

In its use of the Track, Institution must not, whether by act or omission, violate the EU General Data Protection Regulation and/or any other laws similar to the GDPR and applicable in the Project.

Track Provider as provider of the Track must not, whether by act or omission, violate the EU General Data Protection Regulation and/or any other laws similar to the GDPR and applicable in the Project.

4.8

Institution will be entirely responsible for all Institution Data that Institution uploads, downloads, posts, transmits or otherwise makes available or uses through the Track. Institution acknowledges that Track Provider does not create, pre-approve, endorse, support or generally monitor Institution Data or Institution's use of the Track.

4.9

Institution acknowledges that Track Provider may establish general practices and limits concerning use of the Track, including but not limited to the

- Maximum number of days that Institution Data will be retained by the Track;
- Maximum size of any or all Institution Data;

- Maximum disk space that will be allotted on the Track;
- Computing power of the Track;
- Maximum number of times and duration Institution may use the Track in a given period of time.

4.10

To the extent admissible by law, Institution agrees that Track Provider has no responsibility or liability for the deletion or failure of the Track to store any Institution Data, messages and other communications or other materials maintained or transmitted by the Track.

4.11

Institution acknowledges that Track Provider reserves the right to reasonably log off, suspend, terminate or otherwise restrict or prohibit access to the Track in the case of a critical and time-sensitive situation (critical and time-sensitive situations include but not limited to malware issues, hacking attempts and other security issues). Track Provider will give the Institution information on the reasons for this access restriction/prohibition and a reasonable sufficient notice period depending on the context of the situation.

4.12

Parties are fully and exclusively responsible for ensuring that:

- (i) only properly authorized representatives of Party are permitted access to the Track;
- (ii) that all such representatives are fully aware of and comply with all of the obligations, terms and conditions of this Agreement and the Individual Terms of Use.

4.13

Parties and all of Parties' representatives permitted access to the Track, are required to keep contact information accurate and up-to-date and should not share passwords, certificates or other sensitive information, let any third party access any Party account, or do anything else that might jeopardize the security of the Track.

4.14

Parties are required to notify Track Provider and de-authorize the account of any current or former representative who is no longer authorized by Party to access the Track, including due to termination of such party's employment, contract, etc.

4.15

Parties agree that they are fully responsible for the use (and/or misuse) of the Track by its representatives in a manner not permitted under this Agreement.

4.16

Track Provider may, at Track Provider's sole discretion, provide support to Institution at times and in manners as mutually agreed by the Parties, including but not limited to:

- (i) Updates and fixes to the Track;
- (ii) Answers to technical questions regarding the Track;
- (iii) Technical support for the Track.

5 Term, Termination

5.1

The term of this Agreement shall commence on the Effective Date and shall continue until terminated.

5.2

Either Party may terminate this Agreement at any time by providing at least thirty (30) days written notice thereof to the other Party.

5.3

In the event of termination, Institution will immediately discontinue use of the Track and delete any software associated with the Track.

5.4

The provisions of Sections 5.1, 5.2, 5.3, 6, 7, 8, 9, 10, 11, 12, 13 and 14 shall survive any termination of this Agreement.

6 Publications, Results, Intellectual Property

Track Provider does not hold any right, including intellectual property rights, to any results of the Project unless otherwise agreed to in the Project Agreement.

In scientific publications it may be mentioned that "This research was performed on the RAILWAY Personal Health Train infrastructure provided by Medical Data Works, Maastricht, The Netherlands" or an equivalent attribution. However, such an attribution is not mandatory.

7 Confidentiality

7.1

Neither Party will disclose to any third party, or use for any purpose except carrying out the activities under this Agreement, any of the other Party's Confidential Information for a period of five (5) years after the initial disclosure of such Confidential Information, provided that the recipient Party's obligation shall not apply to information that: a. was known to the receiving Party and not already subject to any obligation of confidentiality of the disclosing Party; b. is or becomes generally known or publicly available

without any breach of this Agreement; c. has been obtained from a third party under no obligation of confidentiality; d. has been independently developed by a Party; e. is disclosed pursuant to the requirement of any law or regulation or the order of any court of competent jurisdiction; or f. is approved for release in writing by an authorized representative of the other Party.

7.2

Neither Party will use the other's name or logo in any press release or product advertising, or for any other promotional purpose, without first obtaining the other's written consent.

8 Warranty

The Track is provided "as is". To the extent admissible by law, Track Provider provides no warranties as to its function and its use. Track Provider does not warrant that the Track will function uninterrupted or error-free.

The Train and/or the Station are provided "as is". To the extent admissible by law, Institution provides no warranties as to its function and its use. Institution does not warrant that the Station and/or Train will function uninterrupted or error-free.

9 Limitation of Liability

The total Party's liability for damages to the other Party under this agreement in a given Project finally awarded shall be no more than the compensation which is paid to Track Provider to provide the Track in that Project, provided such damage was not caused by a willful act or gross negligence Parties are not liable for indirect, incidental, special or consequential damages.

10 Severability

In the event any provision of this Agreement is determined to be invalid or unenforceable, the remainder of this Agreement shall remain in force as if such provision were not a part.

11 Successors

This Agreement will be binding upon and will inure to the benefit of the Parties hereto and their respective representatives, successors and assigns except as otherwise provided herein.

12 Governing law

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. Any legal proceedings or communication shall take place in the English language or in a mutually agreed other language.

13 Compliance With Laws

13.1

Parties will comply with all applicable provisions of law and other rules and regulations of any and all governmental authorities. Institution acknowledges that Track Provider is subject to the EU GDPR regulations and to fully cooperate with Track Provider in meeting its obligations hereunder.

13.2

Parties will be bound by the ethical principles underlying EU GDPR regulations. Parties shall ensure that all Research, and all use of the Track, is conducted in accordance with the highest reasonable standards of scientific integrity and in compliance with all requirements of applicable laws, rules and regulations, including those regarding patient data privacy.

14 Entire Agreement

This Agreement sets forth the entire understanding between the Parties with respect to the subject matter hereof and merges and supersedes all prior agreements, discussions and understandings, express or implied, concerning such matters. Any modifications or amendments to this Agreement will not be effective unless both Parties agree to it in writing.

15 Notices

All notices in connection with this Agreement shall be in writing and may be given by regular or email in the English language. For purposes of this Agreement, a notice shall be deemed effective upon receipt. The contact names and addresses for notices in connection with this Agreement are:

For Track Provider:

[TRACK PROVIDER NOTICES]

For Institution:

[INSTITUTION NOTICES]

16 Project Description, Agreement and Compensation for Track Use

16.1

Before a Project can use the Track, a Project Agreement shall be concluded the Members of the Project.

16.2

Before a Project can use the Track, a description of the Project shall be provided to Track Provider by the Leading Member.

16.3

The aforementioned description of the Project shall contain at least

- (i) A list of Members involved in the Project and who the Leading Member is
- (ii) A list of Stations and a description of the data elements that they contain
- (iii) A description of the Trains being deployed in the Project

16.4

Unless agreed otherwise, based on the said Project description, Track Provider shall prepare for the Leading Member a quote for the compensation required for the use of the Track.

16.5

Unless agreed otherwise, after and only after acceptance of the quote by the Leading Member, the Track can be used for the Project.

17 Signature

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date by their duly authorized representatives.

[TRACK PROVIDER]

Date:

[TRACK PROVIDER LEGAL REPRESENTATIVE]

[INSTITUTION]

Date:

[INSTITUTION LEGAL REPRESENTATIVE]