

# Infrastructure Individual Terms of Use

The infrastructure (Track) is offered by Medical Data Works B.V., with its principal office at Dr Tanslaan 12, 6229 ET, Maastricht, The Netherlands (“MDW”). Your access to and use of the Track is subject to the terms and conditions described in this agreement (“Terms of Use”), which may be amended by MDW by posting a revised Terms of Use on the website [www.medicaldataworks.com](http://www.medicaldataworks.com).

Your use of the Track is governed by and subject to the terms of two agreements. One is the Infrastructure User Agreement, an agreement executed between MDW and a third party (“Institution”). This Institution has informed MDW that you are one of its authorized users of the Track. The second agreement is a Project Agreement which describes the Project for which you use the Track.

By using the Track, you acknowledge and agree to adhere to these Terms of Use. You also acknowledge and agree that the Institution has shared the Infrastructure User Agreement and the Project Agreement with you, that you are bound by these agreements, and that you will comply with all such terms in your use of the Track at all times.

## 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. MDW is not 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 “Identifiers”**

Clinical Data that directly or indirectly identifies a specific person.

### **1.8 “Member”**

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

### **1.9 “Leading Member”**

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

### **1.10 “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.

### **1.11 “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.

### **1.12 “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.

### **1.13 “Terms of Use”**

The terms of use described in this document

### **1.14 “Infrastructure User Agreement”**

An agreement between Institution and MDW describing the terms and conditions for using the Track.

### **1.15 “Track”**

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

### **1.16 “Track Provider”**

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

### **1.17 “Distributed Learning”**

Learning from Clinical Data where no Clinical Data leaves the Station and only anonymous statistical data is communicated on the Track. Federated Learning is a synonym of Distributed Learning.

### 1.18 Content

Any information content entity including but not limited to Institution Data, Clinical Data, Confidential Information, software, code, results, agreements, documents, etc. which is present in the Track, Station and/or Train.

### 1.19 “Effective Date”

The date of the last signature.

## 2 Preamble

MDW implements a privacy preserving distributed infrastructure as proposed by the Personal Health Train, please see here: [www.personalhealthtrain.org](http://www.personalhealthtrain.org).

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.

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

You desire to use the Track for one or more Project(s) in behalf of an Institution. As an individual user, you are subject the terms and conditions in this document.

## 3 Revisions, Updates and Changes

MDW reserves the right to modify, amend and update these Terms of Use at any time and for any reason. New versions will be published at [www.medicaldataworks.com](http://www.medicaldataworks.com).

## 4 Acceptable Use

### 4.1

You shall only use the Track for the Project(s) in which your Institution participates and for which your Institution has authorized you.

### 4.2

You shall not

1. Collect or extract data not necessary for the Project.

2. Give your login details to someone else.
3. Ask someone else for their login details.
4. Share any other sensitive information like data, certificates, keys, etc. with someone else other than described in the Project Agreement
5. Attempt to decipher data, keys and/or software used in the Track other than described in the Project Agreement.
6. Impair proper working of the Track for instance by unreasonably or disproportionately overloading the network or infrastructure associated with the Track.
7. Upload malware, viruses or other malicious code.
8. Take any action that violates or threatens the Track and its security.
9. Knowingly infringe on MDW's or third party intellectual property rights.
10. Facilitate or encourage violations of these Terms of Use.

### 4.3

Access to and use of the Track is at your own risk and is subject to these Terms of Use, the Project Agreement, the Infrastructure User Agreement and all applicable laws and regulations.

### 4.4

MDW reserves the right to remove your access to the Track.

## 5 Content

### 5.1

You and/or your Institution are entirely responsible for all Content that you make available or use through the Station, Train or Track.

### 5.2

MDW reserves the right to monitor the Content of the Track.

### 5.3

MDW may, at its sole discretion, block, remove and edit Content of the Track if MDW determines that this Content is in conflict with the

1. Terms of Use
2. Project Agreement
3. Infrastructure Use Agreement
4. Law and regulations and/or other relevant terms and conditions
5. Legitimate interests of MDW including but not limited to liability, compliance etc.
6. Legitimate interests of any other party including but not limited to patient privacy, confidentiality, intellectual property, liability, compliance, etc.

MDW will notify you of any action in this regard.

#### 5.4

You acknowledge that MDW does not archive Content nor has any responsibility or liability for the deletion or failure to store any Content.

## 6 Privacy of data subjects

### 6.1

You must ensure that all Content you share via the Track does not contain Clinical Data and/or Identifiers and/or any other information that may harm the privacy of data subjects.

### 6.2

You must notify MDW immediately if you become aware that any Content of the Track contains Clinical Data, Identifiers and/or any other information that may harm the privacy of data subjects.

### 6.3

You must follow all applicable laws regarding confidentiality, privacy and/or data protection including the EU General Data Protection Regulation (GDPR) and/or any other laws similar to the GDPR and applicable in the Project.

## 7 Notifications and Feedback

### 7.1

You must notify MDW if you become aware of any situation that may violate the Terms of Use, the Project Agreement or the Infrastructure Use Agreement. This includes you becoming aware of other individual Track users not complying with these Terms of Use.

### 7.2

It is appreciated if you give MDW feedback on the Track which may include bug reports, issues, suggestions for improvement etc. When giving feedback you must ensure that the feedback

1. Does not contain confidential information
2. Can be disclosed by MDW
3. Can be used by MDW without compensation

MDW reserves the right but has no obligation to act on your feedback.

## 8 Account and License

### 8.1

You must register for and create an account with MDW

## 8.2

You must use your Institution's email address to register and provide MDW with contact information as requested.

## 8.3

You must keep your contact information up to date.

## 8.4

You must not provide any false information.

## 8.5

You must not create an account for anyone else.

## 8.6

You must notify MDW and deactivate your account when you are no longer authorized to by your Institution to participate in the Project including but not limited to you ending your employment relation with your Institution.

## 8.7

After account registration and acceptance, MDW grants you a free, personal, limited, non-exclusive, non-transferable, revocable license and right to use the Track for the Project(s).

## 8.8

You must not use the Track or any tool, software, etc. associated with the Track for any other use unless permission is granted by MDW or is released for that use under an applicable open-source or other license.

## 9 Termination

MDW reserves the right to terminate your access and use of the Track in accordance with these Terms of Use.

## 10 Compliance With Laws

### 10.1

You will comply with all applicable provisions of law and other rules and regulations of any and all governmental authorities. You acknowledge that MDW is subject to the EU GDPR regulations and to fully cooperate with MDW in meeting its obligations hereunder.

### 10.2

You will be bound by the ethical principles underlying EU GDPR regulations. You shall ensure that the 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.

## **11 Governing law**

In case of any dispute over the interpretation or the execution of this Agreement, you and MDW undertake to make every effort to settle the dispute by amicable agreement. If you and MDW are unable to settle a dispute arising out of or in connection with this Terms of Use, 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.