



The Medical Informatics Platform Service Agreement and Software Licenses

BETWEEN

Centre hospitalier universitaire vaudois (hereinafter : “CHUV”).

AND

CENTRE: NAME – ADRESS (hereinafter: the “CENTRE”)

PREAMBLE

WHEREAS the Medical Informatics Platform (MIP) is an innovative IT solution using open source software that provides an interface for various investigators (clinicians, neuroscientists, epidemiologists, researchers, health managers) enabling them to access and analyze medical data currently locked in hospitals or medical research CENTRES;

WHEREAS the MIP was developed as part of the sub-project 8 and SGA3 Service category 5 (SC5) of the Human Brain Project, an EU funded H2020 FET Flagship Project, to unlock access to hospital data while preserving data privacy;

WHEREAS the HBP Flagship Project was launched as part of the European Commission's Future and Emerging Technologies (FET) scheme in October 2013 and is scheduled to run for ten years;

WHEREAS the MIP is available in multiple variants:

- a “MIP LOCAL” which is installed in the CENTRES and contains pseudonymized data that can only be accessed and analyzed by the accredited staff from within the CENTRE

- a “MIP federated node” which is installed on a server in the CENTRE and contains anonymized data. It can be connected to other MIP-Federated Nodes in other hospitals/centers or VMs on EBRAINS. Upon signed agreement between data providers from the MIP network, accredited investigators can query multiple MIP federated nodes and obtain aggregate results. Queries of the MIP-Federated Nodes do not allow to copy or upload any data, nor to see individual patient’s data.

- a “MIP federated node VM” which is set-up on the EBRAINS Research Infrastructure (hosted by the Swiss National Supercomputing Center CSCS) as a secured Virtual Machine, dedicated to CENTER and contains anonymized data. It can be connected to other MIP-Federated Nodes in other hospitals/centers or on EBRAINS. Upon signed agreement between data providers from the MIP network, accredited investigators can query multiple MIP federated nodes and obtain aggregate



results. Queries of the MIP-Federated Nodes do not allow to copy or upload any data, nor to see individual patient's data.

WHEREAS EBRAINS is the HBP legacy as a sustainable European Research Infrastructure, that was launched in 2020 during HBP SGA3, the HBP's last specific grant agreement, currently hosted on the Swiss National Supercomputing Centre (CSCS) and on other FENIX HPC centers;

WHEREAS the clinical impact of the MIP specifically addresses EU health priorities to reduce the burden of major health challenges, like brain diseases, by leveraging transnational federated data analysis without sharing of the actual data, informing personalized medicine and treatment;

WHEREAS the Centre Hospitalier Universitaire Vaudois (CHUV) is attached to the Department of health and social action of the State of Vaud;

WHEREAS, subject to the approval of the State government, the General Manager of CHUV is entitled to decide about collaborations with other health institutions and to sign collaboration agreements legally binding for CHUV;

WHEREAS CHUV is the legal entity responsible for the development of the Medical Informatics Platform and the management of the infrastructure within the framework of the HBP SGA3 SC5 of the Human Brain Project;

NOW, THEREFORE, the Parties agree as follows:

SUBJECT MATTER

This AGREEMENT binds the Parties in the context of the INSTALLATION and USE of the Medical Informatics Platform for research only.

It is covering the DISTRIBUTION, INSTALLATION and USE of the Medical Informatics Platform in the CENTRE.

This AGREEMENT does not cover any aspect of data sharing or data transfer. These aspects are covered in different contracts, the "Data Sharing Agreement" and "Data Transfer Agreement".

DEFINITION OF TERMS

AGREEMENT means the Medical Informatics Platform Service Agreement and Software Licenses;

CENTRE means any hospital, clinic, research institute or university entering into this AGREEMENT where the Medical Informatics Platform is installed pursuant to the terms of this AGREEMENT;

EXTERNAL USER means an end user accredited by the MIP data management for the MIP FEDERATE NETWORK.

GDPR means the General Data Protection Regulation 2016/679;

INSTALLATION means the process of downloading and installing the SOFTWARE on the CENTRE IT infrastructure and servers or on EBRAINS;



LICENSES refers in parts to the licenses listed in Annex I of the present agreement, and comprises the individual licenses as made available individually by the components, software, and systems used or packaged by the MIP, each applicable in their current versions and subsequent changes and amendments;

MEDICAL INFORMATICS PLATFORM (MIP) means an IT platform comprising a suite of open source software, including a front-end interface for EXTERNAL USERS designed to allow privacy preserving data analysis within and across hospitals/CENTRES in Europe, based on the use of the MIP software by the CENTRE;

MIP means the Medical Informatics Platform made available by CHUV under the terms of this Agreement to the CENTRE;

MIP LOCAL means the MIP platform installed in the CENTRE, which contains pseudonymized data from the CENTRE and can only be accessed by accredited users from the CENTRE.

MIP FEDERATED NODE means the MIP software installed in the CENTRE, or on a dedicated VM on EBRAINS, which contains anonymized data from the CENTRE and can be connected to the MIP FEDERATE NETWORK upon authorization by the CENTER and remains under its control.

MIP FEDERATE NETWORK means the network of all authorized, active and connected MIP federated nodes;

MIP IT TEAM means the team from CHUV or its partners supporting the installation and maintenance of MIP in the CENTRE or on EBRAINS;

PACKAGE means the suite of SOFTWARE and the instructions to install the SOFTWARE on the CENTRE IT infrastructure or EBRAINS VM;

SERVICE or **SERVICES** refers to the services provided to CENTRE by CHUV pursuant to the SLA;

SERVICE LEVEL AGREEMENT (SLA) means the agreement attached in ANNEX II defining the SERVICES to be provided by CHUV and its partners to the HOSPITAL;

SOFTWARE means the suite of open source software listed in the Deployment Pack, contained in the MIP, including all UPDATES and UPGRADES of such open source software

SYSTEM means the information system made available through the MIP.

ARTICLES

1 SCOPE

Pursuant to the terms of this AGREEMENT, CHUV and, on its behalf, the MIP IT TEAM will provide CENTRE with:

- The PACKAGE;
- The LICENSES;



- The SERVICES

2 LICENSES

CHUV distributes, makes available free of charge to the CENTRE and installs the SOFTWARE on the CENTRE's dedicated server or on EBRAINS, pursuant to the terms of the LICENSES.

CENTRE is entitled to copy, reproduce, distribute, modify, translate, create derivative works out of, the SOFTWARE (or the resulting derivative work) in any medium, with or without modifications, in source form, provided it strictly complies with the terms of the LICENSES, meaning that the CENTRE shall ensure that:

- a) The SOFTWARE carries prominent notices stating that CENTRE modified it, giving a relevant date;
- b) The SOFTWARE must carry prominent notices stating that it is released under the LICENSES and any conditions added under the LICENSES.
- c) CENTRE must license the entire SOFTWARE (including all derivative works), as a whole, under the LICENSES to anyone who comes into possession of a copy of the SOFTWARE.
- d) If the SOFTWARE has interactive user interfaces, each must display appropriate legal notices.

All appropriate copyright and other proprietary notices and legends shall be retained on the SOFTWARE, and CENTRE shall maintain and reproduce such notices on all authorized copies of the SOFTWARE and related documentation including in any scientific publications.

3 SERVICES

CHUV provides to CENTRE the SERVICES listed in the SERVICE LEVEL AGREEMENT.

Such SERVICES may be, at all times, delegated by CHUV to a third party, subject to prior information of the CENTRE.

4 CENTRE RIGHTS AND OBLIGATIONS

CENTRE is responsible for providing the required IT infrastructure and specifications dedicated for the MIP to be installed and commit, if required, IT resources for the INSTALLATION, in compliance with the applicable data protection regulations.

CENTRE shall accept the INSTALLATION of the SOFTWARE locally on its IT infrastructure dedicated to MIP, in case INSTALLATION of a MIP instance (local or federate) on the CENTRE's premises was selected.

CENTRE is responsible for ensuring that the MIP is used for research purposes only. The MIP was not designed as a clinical diagnostic software. CENTRE is also responsible for ensuring that any data stored on the local MIP, has been pseudonymised according to current standards and that any data stored in the MIP FEDERATED NODE has been anonymized.



The research results obtained from data hosted on the MIP by CENTRE remain the CENTRE's property.

CENTRE is responsible for complying with the terms of the LICENSES.

5 TERM AND TERMINATION

This AGREEMENT is valid for six (6) years.

Either Party may terminate this AGREEMENT by serving a thirty (30) days written notice by certified mail to the other Party.

This AGREEMENT shall be automatically terminated in the event of termination of the HBP Flagship Project or its legacy, the EBRAINS RI.

In the event of termination of this AGREEMENT, CHUV will stop providing the SERVICES.

6 REPRESENTATIONS AND WARRANTIES

Each of the Parties represent and warrant that they have the unrestricted rights and authority:

- a) to enter validly into this AGREEMENT;
- b) to validly represent the party to this AGREEMENT;
- c) to perform all undertakings under or in connection with this AGREEMENT;

and represent and warrant that this AGREEMENT constitutes a valid, legal and binding obligation of the Parties, enforceable against the parties in accordance with its terms.

7 NO WARRANTIES

The SOFTWARE is provided to the CENTRE "AS IS" without any warranty of any kind.

The Parties make no warranties, either explicit or implied, with respect to the MIP, the SOFTWARE, and/or the SERVICES and/or as to any matter including but not limited to, warranties of ownership, novelty, patentability, originality, accuracy, non-infringement, merchantability, quality or fitness of the MIP and/or the SOFTWARE, the SERVICES for a particular purpose.

The SERVICES are provided by CHUV to the CENTRE without any warranty and without any obligation of result.

8 LIABILITY

Each Party shall only be liable towards the other in the event of fraud or gross negligence resulting in direct damages for the other party. Any other liability incurred by a party as a result of a breach of the obligations contained in this AGREEMENT and/or as a result of the MIP, the SOFTWARE and/or the SERVICES is excluded.



9 APPLICABLE LAW AND PLACE OF JURISDICTION

This AGREEMENT shall be governed by the laws of Switzerland.

All disputes concerning intellectual property arising under this AGREEMENT shall be submitted to mediation in accordance with the WIPO Mediation Rules. The place of mediation shall be Lausanne unless otherwise agreed upon. The language to be used in the mediation shall be English unless otherwise agreed upon. If, and to the extent that, any such dispute has not been settled pursuant to the mediation within 60 calendar days of the commencement of the mediation, the courts of Lausanne shall have exclusive jurisdiction.

For all other disputes arising under this AGREEMENT, which cannot be solved amicably, the courts of Lausanne shall have exclusive jurisdiction.

10 AMENDMENT

This AGREEMENT may be amended by CHUV from time to time, and by a written instrument only. Any amendments to this AGREEMENT, its provisions, or annexes shall be executed separately by each of the parties hereto. The parties to this agreement shall be notified of such amendments with a SIXTY (60) days notice period.

11 ASSIGNMENT

CHUV shall be entitled to assign this AGREEMENT or delegate its obligations under this AGREEMENT either in whole or in part, with prior written notice to CENTRE.

CENTRE shall not assign this AGREEMENT or its obligations under this AGREEMENT without prior written approval given by CHUV.

12 MISCELLANEOUS

This AGREEMENT supersedes any and all prior agreements or understandings relating to the subject matter hereof.

Neither Party shall be entitled to commit the other Party to any obligation in connection with this AGREEMENT, without the prior written consent of the other Party.

This AGREEMENT may be signed in counterparts, and by either party on separate counterparts, each which shall be deemed original, but all of which together constitute one and the same instrument.

Nothing whatever in this AGREEMENT shall be construed as conferring rights to use in advertising, publicity, or otherwise the name and logo of either party or any of its respective marks or name of employees.

The terms of this AGREEMENT are severable such that if any term or provision is declared by a court of competent jurisdiction to be illegal, void, or unenforceable, the remainder of the provisions shall continue to be valid and enforceable.



IN WITNESS WHEREOF, the Parties hereto have executed this AGREEMENT as one of the date first written above.

Signed for and on behalf of:

CHUV

by Prof. Philippe Ryvlin

Title: Chef du Département des Neurosciences Cliniques, DNC

Date:

Signed for and on behalf of:

CHUV

by M Nicolas Rosat

Title: Deputy Director of the Department of Information Systems

Date:

Signed for and on behalf of

CENTRE

by: _____

Title:

Date:

Annex I: Licenses

Annex II: Service Level Agreement

**ANNEX I Licenses**

MIP Components	Licenses	Storage
Data Quality Control tool	Apache-2.0 License	https://github.com/HBPMedical/DataQualityControlTool
MIPMAP	GPL-3.0 License	https://github.com/HBPMedical/MIPMap
MRI parallel neuromorphometric pipeline	Apache-2.0 License	https://github.com/HBPMedical/mri-parallel-nmm-pipeline
NMM Pipeline - Nifti Organiser	Apache-2.0 License	https://github.com/HBPMedical/nmm-pipeline-nifti-organizer
NMM Pipeline - Output Merge	Apache-2.0 License	https://github.com/HBPMedical/nmm-pipeline-output-merge
HBP-MIP DataCatalogue	GPL-3.0 License	https://github.com/HBPMedical/DataCatalogue
Exareme	MIT License	https://github.com/HBPMedical/exareme
portal-frontend	GNU AFFERO GENERAL PUBLIC LICENSE Version 3	https://github.com/HBPMedical/portal-frontend
portal-backend	GNU AFFERO GENERAL PUBLIC LICENSE Version 3	https://github.com/HBPMedical/portal-backend
General	GNU General Public License v. 3	https://www.gnu.org/licenses/gpl-3.0.en.html



ANNEX II - Service Level Agreement (SLA)

1 Definitions

CLAIM means a claim submitted by CENTRE to CHUV with respect to the SOFTWARE pursuant to this SLA;

EXTERNAL CONNECTIVITY is bi-directional network traffic that can be sent and received from a public IP address ensuring a remote access;

INCIDENT is an unplanned interruption to or reduction in the quality of the IT service provided by the MIP, including the failure of a configuration item that has not yet affected service (ITIL 2011);

MIP LOCAL means the MIP software installed in the CENTRE, which contains pseudonymized data from the CENTRE and can only be accessed by users from the CENTRE.

RELEASE means a collection of hardware, software, documentation, processes or other components required to implement one or more approved changes, update or upgrade to the SOFTWARE. The contents of each RELEASE are managed and tested as a unit, and deployed as a single entity.

SUPPORT means the services by which CHUV or its partners may provide assistance to CENTRE to resolve issues with the MIP.

Definitions of the MIP Installation and License Agreement are hereby incorporated by reference.

2 SERVICES

The SERVICES will be provided to CENTRE for the duration of the Term of the MIP Installation and License Agreement. The SLA can be updated independently from the renewal or update of the MIP Installation and License Agreement.

The SERVICES include:

- **SUPPORT:**
 - Level 1;
 - Level 2;
 - Level 3.
- **End-user Assistance:**
 - User access management;
 - User and technical documentation.



- INCIDENT Management:
 - INCIDENT report;
 - Root-cause analysis;
 - INCIDENT resolution.
- Availability Management:
 - Design service for availability;
 - Availability testing;
 - Availability monitoring and reporting.
- SOFTWARE Maintenance:
 - SOFTWARE maintenance;
 - RELEASE planning;
 - Emergency SOFTWARE release planning;
 - RELEASE management.

3 Support

There are three levels of support.

Level 1	<p>The first level support attempts to collect as much information and diagnostics about the INCIDENT as possible and best effort to resolve the issue on the spot.</p> <p>Every INCIDENT or user demand has to be reported to the first level support, which is responsible for managing the CLAIM. If the first level support is not able to resolve the INCIDENT right away, it will escalate the INCIDENT to the second level support.</p>
Level 2	<p>The second level support is devoted to INCIDENT and problem resolutions.</p> <p>If the second level support is not able to resolve the INCIDENT, it will escalate the INCIDENT to the third level support.</p>
Level 3	<p>The third level support is constituted by all third parties involved in the development of the SOFTWARE. If the CHUV HBP MIP Team cannot fix the underlying cause of the INCIDENT, it escalates to the relevant open source software communities.</p>

3.1 First-level Support

The first level support is provided by the HBP High Level Support Team.

Contact address is support@humanbrainproject.eu.

Opening hours are from 9:00 to 17:00 Central European Time except bank holidays (federal and cantonal (Vaud)).



3.2 Second-level Support

The second level support is provided by the CHUV HBP MIP team.

In cases when the first level support team cannot resolve an INCIDENT, it provides a request for support to the second level support team.

The second level support provides SERVICE in its domain of competencies. The SERVICE is provided on a best-effort basis during the opening hours from 9:00 to 17:00 Central European Time except bank holidays (federal and cantonal (Vaud)).

3.3 Third Level Support

The third level support is provided by the CHUV HBP MIP team.

In cases when the second level support team cannot resolve an INCIDENT, it provides a request for support to the third level support team.

The third-level support team consists of the experienced members of the CHUV MIP team involved in the development of the MIP platform. They have all the necessary competencies to resolve the most complex INCIDENTS.

If appropriate, in cases when the source of the incident is a third-party component, third-level support team may propose integration of an alternative solution to the development team. In these cases, the development team decides on whether and when the change will be released, subject to internal HBP MIP development project coordination and prioritization.

The SERVICE is provided on a best-effort basis during the opening hours from 9:00 to 17:00 Central European Time except bank holidays (federal and cantonal (Vaud)).

4 End-user Assistance

Users of the MIP can contact the first level support for assistance.

Assistance includes support in using the MIP, simple modifications of parameters, corrections to the DATA or any other request related to the MIP usage that the user or super-user cannot respond by his own means. The CLAIM should be accompanied by the expected solution deadline.

5 INCIDENT Management

CENTRE raises an INCIDENT by contacting the MIP first level support using the e-mail address provided in section 2 of this SLA. The first level support registers the INCIDENT and provides its reference (ticket number) to the CENTRE.

The first-level support provider analyses root-cause of the INCIDENT and resolves it in the scope of its responsibilities and its domain of competence. In cases when it cannot resolve the INCIDENT, the first level support provider escalates the INCIDENT to the second-level support (CHUV HBP MIP team) and informs the end-user about the escalation.



The second level support provider analyses root-cause of the INCIDENTS escalated by the first-level support and resolves it in the scope of its responsibilities and its domain of competence. In cases when it cannot resolve the INCIDENT, the second-level support provider escalates the INCIDENT to the third-level support.

The third-level support provider analyses root-cause of the INCIDENT and resolves it in the scope of its responsibilities. The third-level support provider is an engineer experienced with the development of the HBP MIP who has all necessary competencies to resolve the most complex INCIDENTS. The third-level support provider is responsible for coordinating the plans for emergency software releases with the HBP MIP software development team.

6 Availability Management

The CHUV HBP MIP team is responsible for designing the procedures and technical features to maximise the MIP availability levels.

The CHUV HBP MIP TEAM shall continuously monitor MIP availability, identify the areas where it must be improved, and implement measures for the availability maximization. The identification of areas for improvement and implementation of measures for improvement are done on a best-effort basis.

7 SOFTWARE MAINTENANCE

7.1 Maintenance Window

The maintenance windows planned for releasing MIP UPDATES or UPGRADES will be communicated in advance. There can be several releases per year.

7.2 Emergency RELEASES

Between the planned HBP MIP software maintenance windows, important and/or urgent corrections shall be released in the scope of emergency software RELEASES, subject to internal HBP MIP development project coordination and prioritization.

7.3 EXTERNAL CONNECTIVITY

To guarantee a maximum level of platform availability, CENTRE shall provide to CHUV HBP MIP engineers upon request with a secure temporary EXTERNAL CONNECTIVITY with credentials for the MIP execution environment during the maintenance release windows, or intermittently on-demand, within a reasonable timeframe, for un-planned emergency operations.

In cases where CENTRE's data centre security policy strictly forbids any remote access and/or super-user credentials to third-party personnel, CENTRE and CHUV HBP MIP team will define a specific operation procedure.

7.4 RELEASE management

During the Term, RELEASES will be deployed in the CENTRE's private execution environment (MIP LOCAL) either by the CHUV HBP MIP team or by the CENTRE's IT responsible.



CENTRE shall install the RELEASES or allow MIP IT TEAM to proceed to the installation of the RELEASES.

The same terms of the LICENSES contained in the MIP Installation and License Agreement will apply to the RELEASES.

8 EXCLUSIONS

This SLA does not apply to any INCIDENTS:

- occurring during maintenance of the SOFTWARE;
- due to factors outside CHUV's reasonable control (for example, a general network failure, a network or device failure at the CENTRE);
- due to failure of CENTRE to provide EXTERNAL CONNECTIVITY to the MIP IT TEAM to MIP LOCAL or to the CENTRE server;
- resulting from CENTRE's or third-party hardware or software, including VPN devices that have not been tested and found to be incompatible by the MIP IT TEAM;
- resulting from actions or inactions of CENTRE or third parties;
- caused by CENTRE's use of the SOFTWARE after the MIP IT TEAM advised CENTRE to modify its use of the SOFTWARE, and CENTRE did not modify its use as advised;
- due to any act or omission of CENTRE or CENTRE's employees, agents, contractors, or vendors, or anyone gaining access to the SOFTWARE by means of CENTRE's passwords or equipment.