INNODIA IVZW INTERNATIONAL NON-PROFIT ORGANIZATION
HERESTRAAT 49, ONDERWIJS EN NAVORSING 1BIS
BOX 902 - 3000 LEUVEN (BELGIUM)
info@innodia.org www.innodia.org

INNODIA DATA USE AGREEMENT (DUA)

This Data Use Agreement (this "**Agreement**") is entered into as of its date of last signature (the "**Effective Date**"), by and between (Recipient) with offices at (Recipient's Address) and INNODIA, an international non-for-profit organization with registered office in Herestraat 49, Onderwijs en Navorsing 1bis, box 902, 3000 Leuven (Belgium), registered under number 0792.991.133 (RLE Leuven), represented by Chantal Mathieu ("**INNODIA**"). (Recipient) and INNODIA are each referred to herein as a "Party" and collectively as the "Parties."

Definitions

INNODIA iVZW – the international non-for-profit organization with registered office in Herestraat 49, Onderwijs en Navorsing 1bis, box 902, 3000 Leuven (Belgium), registered under number 0792.991.133 (RLE Leuven), represented by Chantal Mathieu, hereafter "**INNODIA**"

INNODIA.Projects – the Innodia project and the Innodia Harvest project funded by the European Commission under respectively the Grant Agreement No. 115797 and the Grant Agreement No. 945268, The Hemsley Charitable Trust, JDRF, and EFPIA partners as a global partnership between academic institutes, industry, and patients, gathering their knowledge and experience, with one common goal to eradicate type 1 diabetes. These projects ended respectively on 31 October 2023 and on April 30th, 2024, hereafter **"INNODIA.Projects"**

INNODIA.Projects Partners – all academic or industrial partners who were parties to the INNODIA.Projects and who might be parties to the License Agreement (cumulative conditions), which was signed to allow INNODIA **iVZW** to be the Licensee of the Data, empowered to give access to those data for research use and effective as of 21 January 2025.

INNODIA Projects Data Access Committee (DAC) – The body responsible for evaluating and approving Data Access Requests.

Data – The pseudonymized biomedical research Data collected under INNODIA.Projects, including immunomic, genotypic, lipidomic, metabolomic, metagenomic, proteomic, transcriptomic, CGM, and eCRF Data.

Recipient – The authorized researchers involved in the project as approved by the DAC and listed under this Agreement.

Aggregated Data – Processed Data where individual-level information is not accessible, preventing re-identification.

Foreground IP – Intellectual property developed by the Recipient using the Data, including research findings, models, and methodologies.

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1. Scope and Purpose

- INNODIA grants the Recipient access to aggregated and/or anonymized Data analysis results for the purpose of the research project as approved by the DAC **only.**
- The Recipient have to use the Data for Research use only, i.e. for the purpose of advancing scientific understanding of Type 1 Diabetes (T1D) and to support efforts in finding new ways to predict and prevent the progression of the disease.
- This Agreement outlines the conditions governing access to Data generated under INNODIA.Projects, ensuring compliance with ethical, legal, and scientific standards.
- INNODIA may provide Data only after approval from the INNODIA Data Access Committee (DAC) and in accordance with the License Agreement.
- The Recipient shall not download, extract, or retain pseudonymized raw data; access is restricted to a secure INNODIA research environment.
- This Agreement is non-transferable and non-sublicensable.

2. Data Classification and Compliance

- The Data includes pseudonymized research data covering immunomic, genotypic, lipidomic, metabolomic, metagenomic, proteomic, transcriptomic, and clinical data, including continuous glucose monitoring (CGM) and electronic case report form (eCRF) data.
- The Data is classified as sensitive biomedical research data and is subject to strict confidentiality and legal protections.
- Access is limited to the INNODIA secure environment, and data cannot be copied, transferred, or stored externally.
- All analyses have to produce only aggregated, non-personal results, ensuring no individual participant can be identified.
- The Recipient shall not attempt to re-identify participants or infer personal details.
- As the outputs are statistical summaries or grouped datasets, they do not fall under the General Data Protection Regulation (GDPR).

3. Confidentiality and Security

The Recipient agrees to:

- **Limit Access** – Only authorized personnel working on the approved research project may access the Data.
- **Ensure Data Protection** – Data must be accessed and used only within the INNODIA secure platform.
- **Maintain Non-Disclosure** – Data shall not be shared, distributed, or disclosed to third parties.

- **Secure Data Handling** – The Recipient must implement industry-standard security protocols, including encryption and controlled access.
- **Report Incidents** – Any breach of confidentiality or security incidents must be immediately reported to INNODIA.
- **No Re-Identification** – The Recipient shall not attempt to combine Data with external sources in an effort to re-identify individuals.

Failure to comply may result in revocation of access, legal action, and liability for damages.

4. Artificial Intelligence (AI) Model Training Restriction

The Recipient shall not use the Data provided under this Agreement for the training, fine-tuning, or development of Artificial Intelligence (AI) models unless, upon completion of the training phase, the AI models operate independently of the original Data, ensuring that:

1. The AI models do not require ongoing access, reference, or reliance on the original Data for their operation, inference, or further development.
2. The AI models do not retain or reconstruct any personally identifiable, pseudonymized, or sensitive elements of the original Data.
3. No derivative AI models shall allow for re-identification of participants or reconstruction of the original dataset through direct or indirect means.
4. The Data shall not be stored, transferred, or embedded in external AI training systems, databases, or machine learning repositories beyond the permitted use specified in this Agreement.

INNODIA reserves the right to audit AI-related projects to verify compliance with this clause. Any breach will result in immediate termination of access, revocation of data usage rights, and may lead to legal liability under applicable agreements and regulations.

5. Attribution and Publication

The Recipient must properly acknowledge INNODIA and INNODIA.Projects Partners in any publications, presentations, or reports derived from the Data.

Before publication, a manuscript draft or summary of results must be submitted to INNODIA for review to ensure compliance with data use policies, confidentiality agreements, and ethical guidelines.

INNODIA reserves the right to request modifications to prevent misrepresentation or misuse.

The Recipient shall not claim ownership of the original Data but retains rights over new analyses or methodologies developed.

If required, results, scripts, and methodologies shall be deposited in the INNODIA repository to support reproducibility.

Non-compliance with these attribution and publication rules may result in termination of data access and exclusion from future collaborations.

6. Duration of the Agreement

This Agreement takes effect on the Effective Date and remains valid for 12 months, unless terminated earlier.

Upon termination, the Recipient must cease all access to the Data and delete any derivative datasets that are not stored within the INNODIA platform. The Recipient shall be free to download the aggregated results generated from the INNODIA platform.

INNODIA may revoke access at any time in case of breach of agreement, security risks, or non-compliance.

Extensions may be granted upon written request, subject to INNODIA and DAC approval.

7. Intellectual Property Rights

All Intellectual Property (IP) rights in the original Data remain the exclusive property of INNODIA and its INNODIA.Projects Partners.

The Recipient shall not claim ownership or seek patents on the original Data.

Any new findings, models, or methodologies (Foreground IP) developed using the original Data belong to the Recipient, subject to:

1. Data Integrity – The Recipient must ensure accuracy and avoid misrepresentation of the Data.
2. Attribution – INNODIA and its partners must be credited.
3. Non-Exclusive Use – New IP must not restrict INNODIA's right to use similar knowledge.
4. Open Science Requirements – If the Recipient's research falls under Open Science (e.g., funded by grants requiring open access, or subject to institutional policies), then results, scripts, and methodologies must be shared publicly via recognized open-access repositories — unless INNODIA provides a formal exemption.

8. Cost Coverage

The Recipient agrees to cover reasonable costs associated with Data access and analysis, as specified in Annex XX.

9. Termination and Liability

INNODIA may immediately terminate access in case of Agreement violations.

The Recipient shall indemnify INNODIA against any claims, damages, or liabilities resulting from misuse of the Data.

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Signature Page

By signing below, the Recipient agrees to these terms.

INNODIA

_____

Name: **MANUELA BATTAGLIA**
Function: Managing Director

Place: _____

Date: _____

DATA REQUESTOR

_____

Name:
Function:

Place: _____

Date: _____

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Annexes:

Annex 1. Data Description

- **Immunomic data:**
  Flow cytometry data are available as raw FCS files. Extracted cell population counts based on manual gating are provided in Excel files. Gating strategy information is saved as images embedded in PDF files.

- **Genotyping data:**
  Raw genotyping data are available in PLINK and VCF formats, along with HLA data in text files organized by haplotypes in 4- and 2-digits format.

- **Lipidomic data:**
  Data were generated using ultra-high-performance liquid chromatography coupled to a quadrupole time-of-flight mass spectrometer (UHPLC-QToF-MS). Raw positive and negative ion mode .mzML files and processed extracted summaries for both ion modes are available.

- **Metabolomic data:**
  Data were generated using two-dimensional gas chromatography coupled to a time-of-flight mass spectrometer (GC×GC-ToF-MS). Raw data are provided in .peg format, and processed data are available in a .csv file.

- **Metagenomic data:**
  Metagenomic data were generated by sequencing DNA using a 2 × 150 bp paired-end protocol on an Illumina platform. Raw *fastq* files are available, along with processed results files containing matrices of counts and relative abundances for microbial profiles (GMMs), functional profiles (KOs), and taxonomic profiles (MGSs), provided in Excel and .tsv formats. Supplementary information about the experimental design and analysis is available in PDF format.

- **Proteomic data:**
  Proteomic data include mass spectrometer binary files in .RAW format and supplementary information in CSV, Excel, and text files. These include measured peptide sequences, the accession numbers of the proteins associated with the peptides, and the corresponding gene names.

- **Transcriptomic data:**
  Raw and processed RNA-seq data are available as .fastq files. Sequence files were generated on a NovaSeq 6000 sequencing platform using a paired-end protocol.

- **mi/smallRNA data:**
  This dataset includes raw .fastq files for both targeted and untargeted miRNAs, as well as normalized count tables for targeted miRNAs. Data were generated using HTG EdgeSeq sequencing, which employs a targeted sequencing approach for validating microRNA expression.

- **eCRF data:**
  - Demographic and clinical data collected as part of the INNODIA project are available in a relational database. An extract version of the following variables will be made available in a CSV file:
  - Patient_ID
  - BMI
  - Age
  - Medical history
  - Eligibility status and criteria
  - MMTT or OGTT values

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- HbA1C value
- C-peptide
- HLA typing

(Other variables included in the database may be added to the extracts upon request.)

- **CGM data:**
  Continuous glucose monitoring data are available as CSV exports from Clarity for 17 individuals.

In more detail, the eCRF relational database includes:

- BMI
- Age
- Medications
- Medical history
- Eligibility status and criteria
- Summary of family medical history
- Family relationship status for participants in the study (e.g., UFM parents of ND child)
- MMTT and OGTT metadata (including compliance with the MMTT/OGTT protocol)
- HbA1C values
- Insulin treatment regimen for ND participants
- Yearly questionnaires for UFMs
- Sample collection and processing metadata
- DBS metadata
- Uploaded results from selected laboratories (e.g., C-peptide, autoantibodies, proinsulin)
- CGM data for some UFMs (17 individuals)

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Annex 2. **Annex 2**. Cost Coverage (if applicable) – See the INNODIA DATA BROCHURE

The Cost Coverage Annex will be finalized once the Data Requestor will define the Data Access needs (virtual machine size and data storage capacity).

If Data Analysis will be requested, this will also be quoted according to the pieces in the Brochure.

Invoicing Schedule
The invoicing for selected services will follow the schedule below:

- **Access** – upon contract signature, annually
- **Virtual Private Machine & Results Storage** – at the end of each month
- **Services** – prior to the delivery of results
- **Any additional requests** beyond the agreed scope will be invoiced separately on a case-by-case basis.

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Annex 3. Data Access Request Form (DARF) - approved by DAC – Separate .pdf

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Annex 4. Institutional and Researcher Information

- Principal Investigator (PI) details (name, affiliation, contact information).

Please provide the list of authorised personnel (including email addresses) accessing the data