



# How to request and get access to HBM data generated under T8.1 of the HBM4EU project

## Table of Contents

<b>Definitions:</b> .....	2
<b>Procedures during HBM4EU</b> .....	3
<b>Accessing aggregated data:</b> .....	3
<b>Accessing (Pseudonymous) single measurement data</b> .....	4
<b>Use of the data for activities described in HBM4EU D10.10 or D10.12</b> .....	5
<b>Use of the data for activities other than those described in HBM4EU D10.10 or D10.12</b> ..	5
<b>Procedures after HBM4EU?</b> .....	6
<b>Accessing aggregated data</b> .....	6
<b>Accessing pseudonymous single measurement data</b> .....	6

Responsible author	Liese Gilles,	E-mail	<a href="mailto:liese.gilles@vito.be">liese.gilles@vito.be</a>
Short name of institution	VITO	Phone	+3214335219
Co-Authors	Greet Schoeters, Eva Govarts, Sylvie Remy, Laura Rodriguez Martin		



## Definitions:

- **Single measurement data:** personal data on the level of single individuals.
- **Aggregated data:** descriptive data statistics (mean, percentiles, etc.) calculated from single measurement data.
- **Pseudonymisation:** the processing of personal data in such a manner that the personal data can no longer be attributed to a specific individual without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person. (see figure 1).
- **Anonymisation:** the processing of personal data in such a manner that the data can no longer be attributed to a specific individual. The data subject is not or no longer identifiable via any means possible. The processing of such anonymous information, including for statistical or research purposes is therefore not subjected to the GDPR. (See figure 1).
- **Data Owner:** The entity that holds the legal ownership of data, and as such can authorise or deny access to data from IP perspective. The Data Owner may or may not be distinct from the Data Controller.
- **Data Provider:** The entity (mandated by the Data Owner and/or engaged by the Data Controller) in charge of the collection, acquisition, production, management, quality control and/or publication and dissemination of data; this definition may include Commission Services, EU Agencies and third parties. The Data Provider may or may not be distinct from the Data Owner and/or Data Controller.
- **Data Controller:** Controller<sup>1</sup> means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data.
- **Supplying Data Controller:** a Data Controller who submits data into the Central Data Platform.
- **Receiving Data Controller:** a Data Controller who gets access to (subsets of) the data from the Central Data Platform.
- **Data Processor:** Processor<sup>1</sup> means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the data controller.
- **Central Data Platform:** a central database system containing the data collected for the Aligned Studies. This platform is used for exchanging data between the Data Controllers. It is hosted and managed by VITO, that is considered to be Data Processor in this data exchange process.

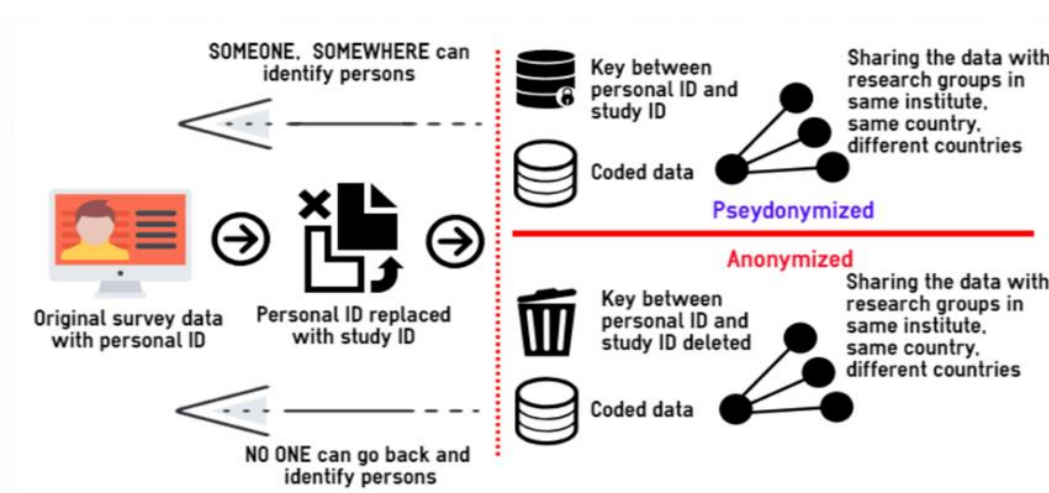


Figure 1: Pseudonymisation vs. Anonymisation.

<sup>1</sup> As defined and/or described in REGULATION (EU) 2016/679 (GDPR)

## Procedures during HBM4EU

The HBM data generated under HBM4EU in the aligned studies of T8.1 and co-financed by HBM4EU will become available as both aggregated data and single measurement data.

### Accessing aggregated<sup>2</sup> data:

Human biomonitoring data resulting from T8.1 activities co-funded by HBM4EU are made publicly available and accessible in aggregated format through [IPCHEM](#) by the end of the HBM4EU project. See section 3.1. During HBM4EU, access to the aggregated data is restricted to HBM4EU project partners<sup>3</sup>, EU Commission, EU Agencies, and EU National bodies who can access and download the data for use after log-in to the IPCHEM website. To enable login to the IPCHEM website authorization with the EU id is necessary. If not done before, an EU LOGIN should be created using this link: <https://ecas.ec.europa.eu/cas>.

When data with access restricted to the HBM4EU project partners<sup>3</sup>, EU Commission and EU Agencies and EU National bodies are used, the Data Provider is entitled to request the inclusion of 2 co-authors in scientific publications or abstracts of results considering the provided data.

*Note: Due to the delays caused by covid-19, it will be verified whether it is possible to extend the project specific IPCHEM user group i.e. "HBM4EU project partners" with 6-12 months.*

#### TEMPORARY SOLUTION:

Currently, IPCHEM is improving their data module to host aggregated HBM data. As interim solution, until the aggregated data can be integrated and accessed through IPCHEM, the aggregated data are made available to HBM4EU consortium partners through the internal HBM4EU webpages. These internal webpages require log-in<sup>4</sup> by users and are restricted to HBM4EU consortium partners (Grant signatories and their LTPs) and shall not be distributed further without permission of the Data Controller or Data Provider. EU Commission, EU Agencies and EU National bodies cannot access the internal HBM4EU webpages. They can obtain access to the aggregated data by submitting a request to HBM4EU. [DATAMANAGEMENT@vito.be](mailto:DATAMANAGEMENT@vito.be). The data can be used only to reach HBM4EU objectives. The WP leader verifies the fit of the purpose with HBM4EU objectives and checks whether the same analyses are not yet performed by other consortium partners. When the data are used the Data Provider is entitled to request the inclusion of 2 co-authors in scientific publications or abstracts of results considering the provided data.

The provisional deadline as from when aggregated data of the aligned studies become available is August 2020. Please note that the aggregated data of the different data collections will become available step-by-step as some chemical analysis are delayed because of covid-19. A timeline of when the data becomes available can be consulted on the online library of the HBM4EU website. This overview will be updated monthly.

Once the aggregated data are integrated and accessible via IPCHEM the data will be removed from the internal HBM4EU webpages.

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<sup>2</sup> Data aggregated with the HBM4EU aggregation script can be considered anonymous data and therefore not subjected to the GDPR.

<sup>3</sup> The project specific IPCHEM user group "HBM4EU project partners" includes all Grant signatories and LTP's. The option to make the data in IPCHEM accessible to the HBM4EU project group follows indications of Articles 10 and 11 of the IPCHEM Data Policy and related to "Use of IPCHEM for projects on chemical monitoring data". This extraordinary project-specific accessibility rules can only last temporarily for the duration of the HBM4EU project. Upon the dissolution of the Project the data generated, collected or analysed in the course of the Project will have to be made accessible to IPCHEM User Groups according to the Open Data Principles and the Exceptional Accessibility Regimes described in Articles 4-7 of the IPCHEM Data Policy.

<sup>4</sup> Log-in credentials to access the internal webpages can be requested by clicking "how to request access" button on the home page of the public HBM4EU website.

## Accessing (Pseudonymous) single measurement data

### ORIGINAL SCENARIO AS PLANNED AT THE START OF HBM4EU TO EXCHANGE PSEUDONYMIZED SINGLE MEASUREMENT DATA:

To exchange pseudonymised data within HBM4EU, the [HBM4EU data repository](https://ipchem.jrc.ec.europa.eu/share/) (<https://ipchem.jrc.ec.europa.eu/share/>) was set up as an option under IPCHEM. The HBM4EU data repository is part of the IPCHEM platform and ensures safe transfer, storage and access of the data only to authorised accounts. As JRC is currently revising its legal procedures to enable the exchange of pseudonymised data and ensure compliance with the GDPR, an alternative solution for accessing and exchanging HBM4EU co-funded data was necessary.

### ALTERNATIVE SOLUTION FOR ACCESS AND EXCHANGE OF HBM4EU CO-FUNDED DATA OF THE ALIGNED STUDIES:

A central data platform has been set up at VITO to host pseudonymous single measurement data co-funded by HBM4EU collected within the framework of the aligned studies. Data from the aligned studies are pooled together in one database and specific extracts<sup>5</sup> of the database can be made accessible through a [webportal](#) upon request. Access to these data extracts is regulated on individual user level and requires log-in authentication.

A DPIA (Data Protection Impact Assessment) has been performed for the central data platform and is available on request at [VITO HBM4EU Data Management team](#). The DPIA identifies the privacy risks of the processing of personal data and defines measures that are implemented to reduce the identified risks and is mandatory under GDPR legislation.

To host the aligned study data a bilateral Data Controller – Data Processor agreement was established between each aligned study partner (Data Controller) and VITO (Data Processor), allowing VITO to host the single measurement data in a central data platform and to pool the data. These processing agreements end at the end of HBM4EU (31/12/2021). After this date the Data Controller and Data Processor declare to maintain a copy of the data for a period of 10 years to enable reproducibility testing of the results and the agreements will continue to apply for these archiving and reproduction activities. See box 2.

When pseudonymous individual data obtained from the central data platform are used in scientific publications or abstracts the "[HBM4EU publication policy](#)" should be followed. In this, the same rules apply for the data platform as initially documented for the "HBM4EU repository" (see Box 1).

#### Box 1: Publication of results based on data obtained from the HBM4EU central data platform:

The procedures described in the HBM4EU publication policy shall be followed considering submission of any papers for publication and/or abstracts for conferences. At latest 30 calendar days prior to submission of any papers for publication considering data that are provided to HBM4EU partners via the HBM4EU repository, the lead author shall contact the Data Owner/Data Provider by sending a title, abstract, and author list. The Data Owner/Data Provider is entitled to request to include 2 co-authors in scientific publications of results considering the provided data. It is advised to consult the Data Owner/Data Provider as early as possible.

For publication and communication of results other than scientific publications or abstracts the "Strategy for making new HBM4EU results available from the aligned studies" should be followed. The document is available in the online library of the HBM4EU website.

<sup>5</sup> Extracts of the pooled database with limited variables are made available to adhere to the [data minimization principle](#) laid down in the GDPR Article 5(1)(c).

How to get access to the pseudonymous single measurement data of the aligned studies depends on the purpose of use of the data. More information in the sections below.

### Use of the data for activities described in HBM4EU D10.10 or D10.12.

Use of pseudonymous single measurement data for activities described in HBM4EU D10.10 “Statistical analysis plan for the co-funded studies of WP8” and D10.12 “Update Statistical Analysis Plan for the aligned studies including the strategy to connect to effect markers and health data” are covered under the Collaboration Agreement (CA). This agreement has been signed between all Supplying Data Controllers and all Receiving Data Controllers and allows access and use of the data by those partners detailed in D10.10 and 10.12 that signed the CA as **receiving Data Controller** and for those activities as detailed in D10.10 and D10.12. **The CA is valid until the end of HBM4EU (31/12/2021).** At the end of this Agreement the Supplying Data Controllers declare to maintain a copy of the data for a period of 10 years after the end date of this Agreement, to enable reproducibility testing of the results. The Receiving Data Controller destroys his copy of the data after a period of maximum 2 years after the project has ended. See box 2.

Extracts<sup>6</sup> of the pooled database that are required for a specific research question will be made accessible for the Receiving Data Controller via the [Webportal](#). Access to these data extracts is regulated on individual user level and requires log-in authentication. After log-in to the [webportal](#) the data user can download this specific extract of the pooled database in encrypted format. The webportal is managed by VITO. Log-in accounts are created and provided by VITO to validated users.

Extracts can only be made available when the CA is signed by all parties. The provisional deadline as from when extracts of pseudonymous single measurement data of the aligned studies becomes available is August 2020. Please note that data of the different data collections will become available step-by-step as chemical analysis are delayed because of covid-19.

### Use of the data for activities other than those described in HBM4EU D10.10 or D10.12.

Use of pseudonymous single measurement data by HBM4EU project partners, EU Commission and EU Agencies or EU National bodies for activities/purposes other than those described in D10.10 and D10.12 must follow the procedure as outlined below:

- Write a research protocol specifying the research question or hypothesis that will be evaluated and detailing the subset of data required for this (a template for developing a research protocol is available in the online library of the HBM4EU website).
- Sign a bilateral Supplying Data Controller – Receiving Data Controller agreement with each of the Supplying data controllers whose data you want to access (a [template](#) agreement is available in the online library of the HBM4EU website).
- The requesting data user (Receiving Data Controller) should submit the Research protocol and the signed Supplying Data controller – Receiving Data controller agreement(s) to the HBM4EU data management team ([HBM4EU.DATAMANAGEMENT@vito.be](mailto:HBM4EU.DATAMANAGEMENT@vito.be)). VITO will provide an account for the specific Receiving Data Controller and will grant access to the subset of data for which approval has been obtained via the [webportal](#). The VITO Data Platform manager shall ensure that only the necessary subset of data (adherence to data minimization) is accessible for the Receiving Data Controller. The provisional deadline as from when extracts of pseudonymous single measurement data of the aligned studies becomes available is August

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<sup>6</sup> Extracts of the pooled database with limited variables are made available to adhere to the [data minimization principle](#) laid down in the GDPR Article 5(1)(c).

2020. Please note that data of the different data collections will become available step-by-step as chemical analysis are delayed because of covid-19.

*Note: Because the data are co-funded by the EC as part of the HBM4EU project, requests from EU Commission and EU Agencies or EU National bodies cannot be refused by the Data Controller if the use purpose specified in the research protocol is in line with environment and health research. Requests from HBM4EU project partners cannot be refused by the Data Controller if the research is in line with HBM4EU project objectives and laid down in the annual work plans.*

## Procedures after HBM4EU?

### Accessing aggregated data

By the end of the project, all aggregated data should be integrated in [IPCHEM](#). During the project access was restricted to HBM4EU project partners EU Commission and EU Agencies, and EU National bodies. Due to the delays caused by covid-19, it will be verified if it is possible to extend the project specific IPCHEM user group “HBM4EU project partners” with 6-12 months. After the HBM4EU project (or its possible extension), the HBM4EU user group will no longer exist in IPCHEM. The aggregated data will then become publicly available through IPCHEM.

When publicly available data are used, a reference to the data should be included in scientific publications or abstracts. In the “License of use” that can be found on the metadata page of each data collection, the Data Owner can specify conditions for data use.

### Accessing pseudonymous single measurement data

As mentioned in the processing and collaboration agreement, the central data platform at VITO will be maintained for 10 years after the HBM4EU project to enable reproducibility testing of the results and both agreements will continue to apply for these archiving and reproduction activities only. As a consequence, when the HBM4EU project ends (31/12/2021) VITO is no longer allowed to provide access to extracts of the pseudonymous single measurement data of the aligned studies hosted in the central data platform.

It should be decided what will happen with the central data platform that contains EU wide recent HBM data to ensure continued access to the data after the HBMEU project (or its possible extension). If VITO’s role is extended in another EU contract or partnership the procedures will need to be revised and new agreements established in the frame of the next project.

*Note: Due to the delays caused by covid-19, it has to be verified if it is possible to extend both agreements with 6 months.*

**Box 2: Extract from Data processing agreement and Collaboration agreement:**

**ART2 Processing agreement:**

ARTICLE 2: DURATION OF THE PROCESSING

This Agreement shall enter into force upon signature of both parties until the end of HBM4EU (31/12/2021) for the processing activities under HBM4EU. After this date the Data Controller and Data Processor will maintain a copy of the data for a period of 10 years to enable reproducibility of the results and this Agreement will continue to apply for these archiving and reproductions.

**ART2 Collaboration Agreement:**

ARTICLE 2: DURATION OF THE PROCESSING

This Agreement shall enter into force upon signature of all the Supplying Data Controllers or at the latest by 30/04/2020 until the end of HBM4EU (31/12/2021). At the end of this Agreement the supplying Data Controllers declare to maintain a copy of the data for a period of 10 years after the end date of this Agreement, to enable reproducibility of the results.

The Receiving Data Controller destroys his copy of the data after a period of maximum 2 years after the project has ended.