HBM4EU project

How to prepare your data for sharing

Sylvie Remy/Liese Gilles

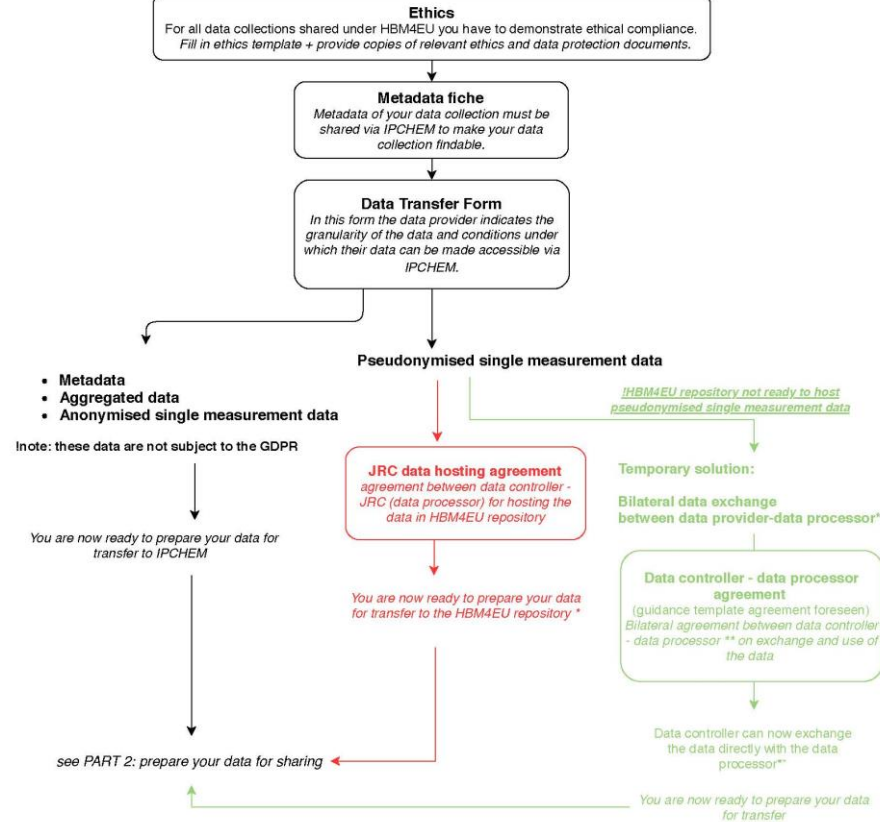2nd HBM4EU Training School 2018

Sharing data with HBM4EU

Steps for data providers:
1. Prepare and submit documents for data sharing
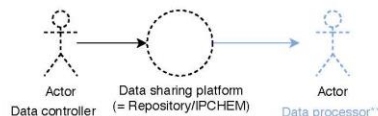2. Prepare your data for sharing

Process of sharing data:
What are the steps for data providers

Data provider

Part 1: Prepare and submit documents for data sharing

Ethics
For all data collections shared under HBM4EU you have to demonstrate ethical compliance.
Fill in ethics template + provide copies of relevant ethics and data protection documents.

Metadata fiche
Metadata of your data collection must be shared via IPCHEM to make your data collection findable.

Data Transfer Form
In this form the data provider indicates the granularity of the data and conditions under which their data can be made accessible via IPCHEM.

Pseudonymised single measurement data

- **Metadata**
- **Aggregated data**
- **Anonymised single measurement data**

!note: these data are not subject to the GDPR

!HBM4EU repository not ready to host pseudonymised single measurement data

You are now ready to prepare your data for transfer to IPCHEM

JRC data hosting agreement
agreement between data controller - JRC (data processor) for hosting the data in HBM4EU repository

You are now ready to prepare your data for transfer to the HBM4EU repository *

Temporary solution:

Bilateral data exchange between data provider-data processor*

Data controller - data processor agreement
(guidance template agreement foreseen)
Bilateral agreement between data controller - data processor ** on exchange and use of the data

Data controller can now exchange the data directly with the data processor**

see PART 2: prepare your data for sharing

You are now ready to prepare your data for transfer

**Data processor is the data user, who can process the data on behalf of the data controller.
*HBM4EU repsitory is a secured and restricted part of IPCHEM

Actor
Data controller

Data sharing platform
(= Repository/IPCHEM)

Actor
Data processor**

Actor
Data controller

Actor
Data processor**

Process of sharing data:
What are the steps for data providers

Ethics	Metadata	Data transfer Agreement

For all datasets (anonymised as well as pseudonymised) used for research under HBM4EU it is required that you demonstrate ethical approval of the study by submitting required ethics documents to the:

project coordinator (Marike Kolossa: HBM4EU@uba.de)

ethics coordinator of the project (Lisbeth Knudsen: liek@sund.ku.dk)

Required ethics documents:

- Ethics template

- Template of the informed consent form

- Copy of information leaflet

- Copy of ethical approval

- Copy of data protection approval (if applicable)

- ...

! no work for HBM4EU can commence before the coordinator and Lisbeth Knudsen receive confirmation that the study has been approved by your in-country ethics committee

Process of sharing data:
What are the steps for data providers

Ethics	Metadata	Data transfer Agreement

Metadata - "a set of data that describes and gives information about other data"
Collects information about your dataset NOT actual data
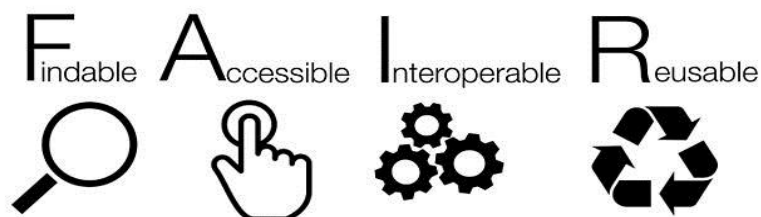
Metadata of all HBM data sets used in HBM4EU must be integrated into the IPCHEM portal website and made accessible to all user groups to ensure that the datasets are findable. The metadata shall be provided by filling out the **HBM4EU metadata template.**

Process of sharing data:
What are the steps for data providers

Ethics	Metadata	Data transfer Agreement

Using this form, the Data Contact Point communicates the conditions under which they agree to make chemical monitoring data, together with the associated metadata, accessible via IPCHEM and via the HBM4EU repository.

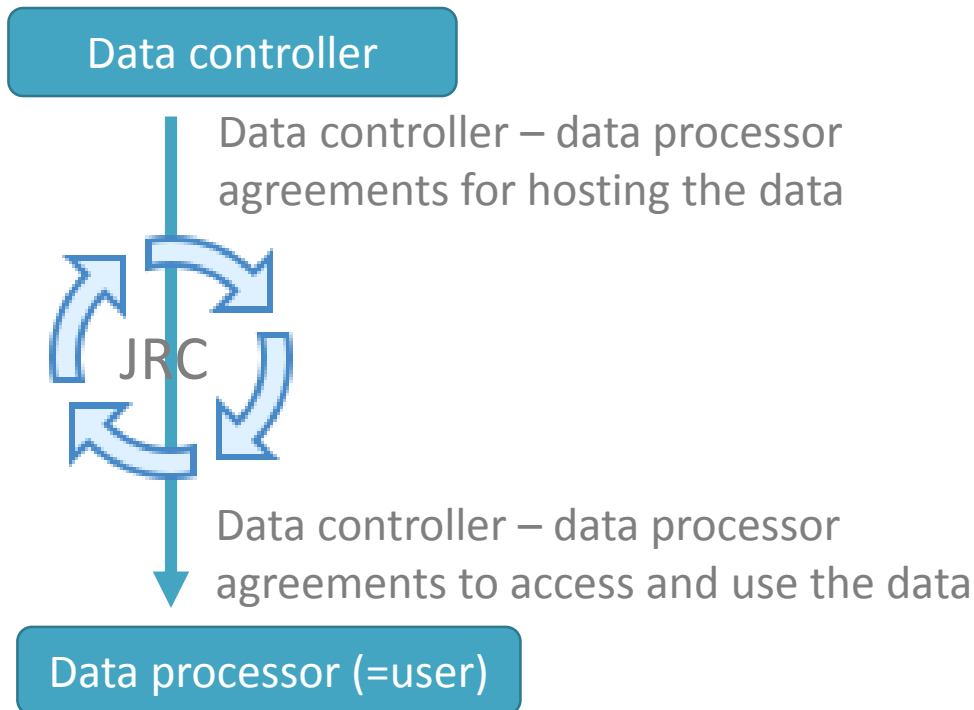| Aggregated or Single measurement data	Format	Share	Accessible via	HBM4EU project group	EU Commission and EU Agencies	EU National bodies	General Public
Aggregated data *(that can be considered anonymous)*	**HBM4EU format**	☐ YES	☐ IPCHEM portal website	☐ YES	☐ YES	☐ YES	☐ YES
				☐ NO	☐ NO	☐ NO	☐ NO
			☐ HBM4EU repository				
		☐ NO					
	Own format	☐ YES	☐ IPCHEM portal website	☐ YES	☐ YES	☐ YES	☐ YES
				☐ NO	☐ NO	☐ NO	☐ NO
			☐ HBM4EU repository				
		☐ NO					
Anonymised Single Measurement Data	**HBM4EU format**	☐ YES	☐ IPCHEM portal website	☐ YES	☐ YES	☐ YES	☐ YES
				☐ NO	☐ NO	☐ NO	☐ NO
			☐ HBM4EU repository				
		☐ NO					
	Own format	☐ YES	☐ IPCHEM portal website	☐ YES	☐ YES	☐ YES	☐ YES
				☐ NO	☐ NO	☐ NO	☐ NO
			☐ HBM4EU repository				
		☐ NO					
Pseudonymised Single Measurement Data[3]	**HBM4EU format**	☐ YES	☐ HBM4EU repository				
		☐ NO					
	Own format	☐ YES	☐ HBM4EU repository				
		☐ NO					

Process of sharing data:
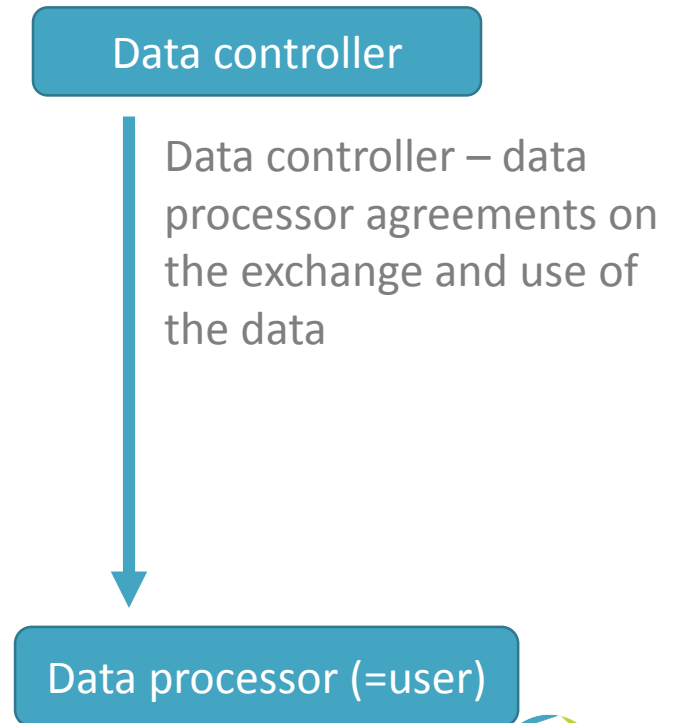# *What are the steps for data providers*

Data controller - Data processor Agreement

! Pseudonymized individual data – Subjected to GDPR

→ Data controller – data processor agreement required

Temporary solution

Data controller

Data controller – data processor agreements for hosting the data

JRC

Data controller – data processor agreements to access and use the data

Data processor (=user)

Data controller

Data controller – data processor agreements on the exchange and use of the data

Data processor (=user)

Data harmonisation

Data provider

Part 2: Prepare your data for sharing

HBM4EU harmonised data format
Facilitates higher comparability and increased use of data collection

Fill in biomarkerlist
In this list you have to indicate which metabolites you want to share data from.

Fill in data template
Based on your biomarkerlist you will receive a personalised data template. Harmonise your data using the HBM4EU codebook and fill in the data template.

single measurement data*
Your data is ready to be shared

Aggregated data

Run R-script
Run the HBM4EU developed R-script on your single measurement data in your personalised data template to generate harmonised aggregated data.

Your data is ready to be shared

Own data format

Single measurement data*
Your data is ready to be shared

Aggregated data

Fill in aggregated data template
In this template you can fill in the aggregated data you have available

Your data is ready to be shared

note: Pseudonymised single measurement data has to be shared via HBM4EU repository (secured and restricted part of IPCHEM)

General advantages:

- Comparability of data
- Facilitate statistical analysis of <u>pooled data collections</u>
- Comparison between data collections
- Step forward in EU HBM (~Nhanes)
- …

Advantages of harmonised aggregated data:

- We know how the data were processed!
- One common way to deal with values < LOD or LOQ
- Same descriptive statistics are calculated
- Comparability

Harmonization of single measurement data:

Harmonisation of aggregated data: *R-script*
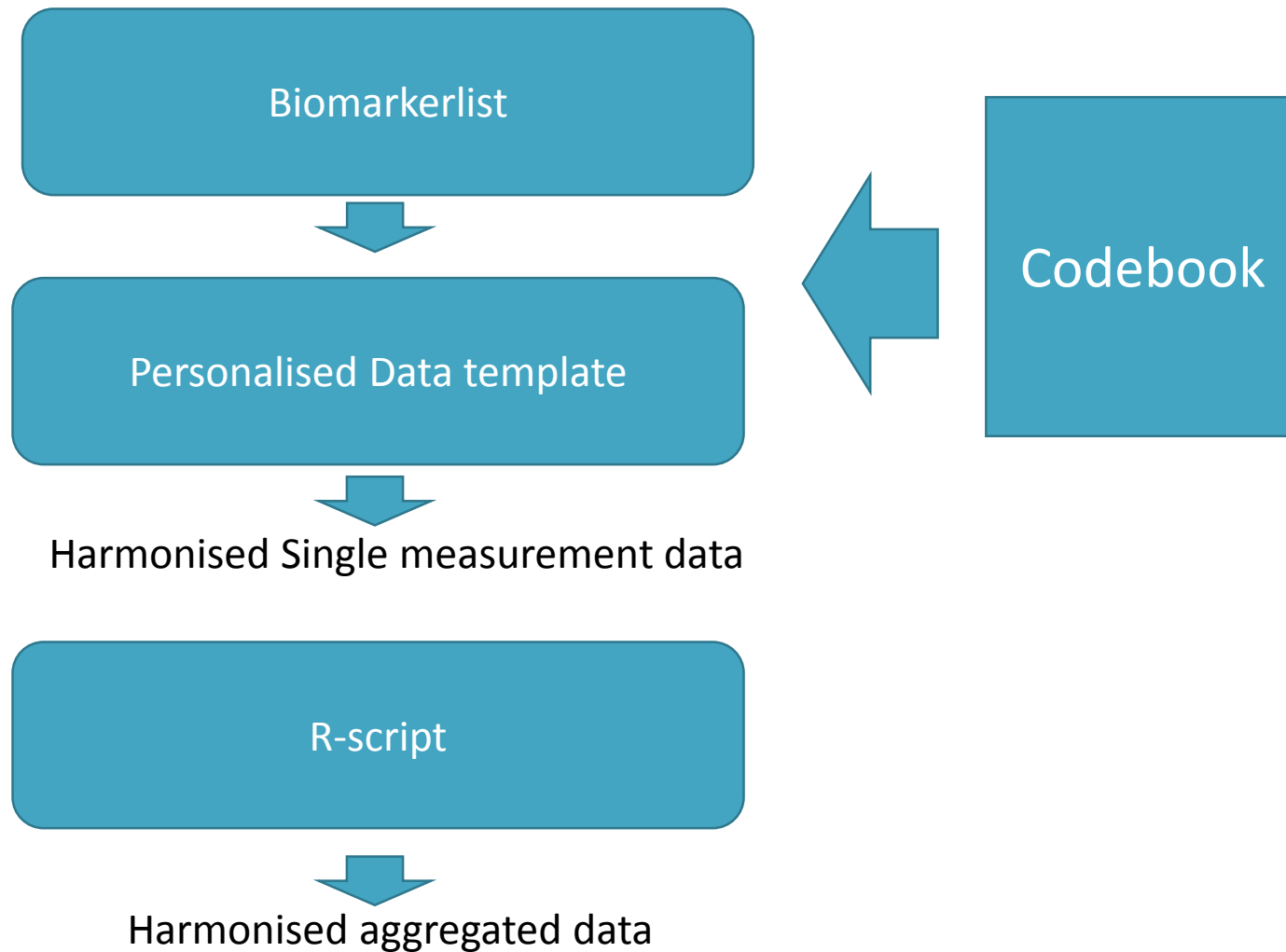
How will we obtain Harmonised aggregated data?

Data template for individual data = input file for an R-script to generate harmonised aggregated data

Output = Descriptive statistics including:

✓ N of subjects

✓ Arithmetic mean + SD

✓ Geometric mean + 95% CI

✓ percentiles with CI

✓ …

Stratified for gender, age, BMI, smoking, level of education,…?

Open for input!

->Tailored to the needs of the WP's within HBM4EU

*Aggregated data **own format***

Template **to facilitate the provision of aggregated data in your own format**. The template is to provide guidance on the desired descriptive statistics for the aggregated data that can be used within the project.

We ask data providers to fill in the aggregated data that they have available.

Thank you for your attention

If you have any questions about data management

Don't hesitate to contact the HBM4EU data management team!

HBM4EU.datamanagement@vito.be

All documents can be found on the **internal webpages** of the HBM4EU website:

https://www.hbm4eu.eu/private/work-package-webpage/data-management-and-analysis/data-management/

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Speaker's information

Liese Gilles works as R&D researcher at VITO Flemish institute for technological innovation, Mol, Belgium. In HBM4EU she is involved in data management (WP10) and the alignment of studies (WP8).