Protocol title

WP10 Data management and analysis

Task 10.4 Statistical analysis

Substance group X

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| --- | --- | --- | --- |
| Date |  | | |
| Responsible author |  | E-mail |  |
| Short name of institution |  | Phone |  |
| Co-authors |  | | |

# Background

Provide background literature regarding the research hypothesis.

# Objective

Explain the objective of the study protocol with stating the specific research question.

# Methods

## Study design

Overview of studies that are needed for this study protocol.

Define inclusion/exclusion criteria.

Describe overall study design: e.g. meta-analysis, pooled analysis, children/adolescents/adults/…, case control, …

## Exposure variables and accompanying variables

Describe the exposure variables (specific metabolites) and accompanying variables (age, sex, SES, NUTS,…) needed to explore this specific research hypothesis.

Add a full list of variables that are required for your research question in table 1 in the appendix of this study protocol. For the accompanying variables also information on needed resolution should be thought of very well (e.g. age in years, months, weeks, …).

*Remark: Within WP10, VITO and ISGLOBAL have constructed a harmonized codebook specifying exposure variables, the main accompanying variables (e.g. sex, age, …) and other accompanying variables (e.g. food consumption, …).once your protocol is finalized ISGLOBAL will assist you in* developing a protocol specific harmonized codebook. As probably a lot of the variables that you list in table 1 were already specified in other protocols or in the basic codebook. ISGLOBAL will suggest using the same codings as used in other protocols. This allows the data collections to reuse their previously harmonized data.

## Statistical analysis

Explain the statistical methods that will be used.

Describe your strategy to handle missing values (both for exposure as accompanying variables), analytical models you will use, sensitivity analysis you will perform, …

Indicate the level of data needed for the study protocol, e.g. individual, aggregated data (specify the conditions / summary statistics that are needed), summary estimates (e.g. slope of the regression line with 95% confidence interval), …. Specify if you will do meta- and/or pooled analysis, and set out the minimal requirements of data comparability to enable these analyses.

Specify substance specific issues that are important to consider in the statistical analyses.

# Organisation, publication and time schedule

## Organisation

Explain which data collection(s) will be invited to participate:

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| --- | --- | --- |
| **Name Data collection** | **Responsible Institute** | **Contact person** |
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Specify who will coordinate the study protocol.

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| --- | --- |
| **Responsible person:** | ………….. |

Indicate that each data collection should assign e.g. 1 researcher to join the study protocol working group.

Explain what you need from each data collection: individual or aggregated data, summary estimates, …

Explain who will do the statistical analyses:

|  |  |
| --- | --- |
| **Name:** | **Institute:** |
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Explain where the source data will be stored. Specify that data transfer agreements should be signed by the data owner/provider; data use agreements should be signed by the persons that actually will have access to the data Template Supplying data controller – Receiving data controller Agreements can be found on the project website: <https://www.hbm4eu.eu/result/data/>.

## Publication

The procedures described in the HBM4EU publication policy shall be followed considering submission of any papers for publication and/or abstracts for conferences. Considering data use, the HBM4EU data policy sets the requirements of acknowledgement of the Data Owner/Data Provider. At latest 30 calendar days prior to submission of any papers for publication considering data that are provided to HBM4EU partners, the lead author shall contact the Data Provider by sending a title, abstract, and author list. The 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 Provider as early as possible.

Specify which publication(s) will results from this study protocol.

List of potential co-authors and their contribution to the manuscript.

## Time schedule

Clarify the working plan in a time schedule, e.g. describe the different steps that will be taken and put a timing on it, including a timing for writing a paper of the results.

## Permissions and ethical issues

To obtain permission to use the data, the lead data user has to submit a proposal, containing among others the purpose of data use, named lead data user and other data users, the required studies, variables, sampling time frame, a start and end data to perform the analyses,… 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. Upon approval of the proposal, the protocol responsible shall complete and sign a supplying data controller- receiving data controller agreement with all supplying data controllers. Upon signed agreement, the data can be exchanged bilaterally between supplying data controller and receiving data controller using a secure transfer method. The data shall be used to perform the data analyses for the purpose specified in the approved proposal. Data analyses and presentation of papers should adhere to good epidemiological practice and the STROBE guidelines. By receiving and using data within the frame of HBM4EU all involved parties accept the HBM4EU Data Policy. This includes, but is not limited to, protection of the study participants identity, safeguard to not share the data with unauthorized people, commitment to not store the data on any place that is accessible by others (unauthorized people), commitment to follow the procedures regarding publication and/or dissemination of results. All details are available in the documents mentioned above.

# References

Reference list

# Appendix

Table 1: List of obligatory and optional variables.

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| Variable name | Description of variable | TYPE | UNIT | Obligatory/Optional | Remark |
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