HBM4EU science and policy for a healthy future

HORIZON2020 Programme
Contract No. 733032 HBM4EU

Criteria for selecting candidate laboratories to analyse HBM4EU samples

Information extracted from Deliverable Report D 9.3: Database of candidate laboratories for the 1st prioritisation round of substances

WP 9 - Laboratory analysis and quality assurance

Uploaded by Coordinator: 28 September 2017

Entity	Name of person responsible	Short name of institution	Received [Date]
Coordinator	Marike Kolossa	UBA	13/09/2017
Grant Signatory	Argelia Castaño	ISCIII	04/09/2017
Pillar Leader	Argelia Castaño Greet Schoeters	ISCIII VITO	13/09/2017
Work Package Leader	Argelia Castaño and Marta Esteban	ISCIII	04/09/2017
Task leader	Marta Esteban	ISCIII	04/09/2017

Responsible author	Octavio Pérez Luzardo	E-mail	octavio.perez@ulpgc.es
Short name of institution	ULPGC	Phone	+ 34 928 451 424
Co-authors	Marta Esteban and Argelia Castaño		

Table of contents

1 Authors and Acknowledgements

Lead authors

Octavio Pérez Luzardo, Universidad Las Palmas de Gran Canaria (ULPGC)

Marta Esteban López, Institute of Health Carlos III (ISCIII)

Argelia Castaño Calvo, Institute of Health Carlos III (ISCIII)

Contributors

Pillar 2 leader:

Argelia Castaño. Institute of Health Carlos III (ISCIII)

Partners in task 9.2:

- Juan José Ramos, Silvia Gómez, Susana Pedraza, Sara González, Helena García and Miguel Motas. Institute of Health Carlos III (ISCIII)
- Jean-Philippe Antignac. French National Institute for Agricultural Research (INRA)
- Ovnair Sepai. UK Department of Health - Public Health England (DH)
- Dagnė Janarauskienė and Rosita Balčienė. Lithuanian National Public Health Surveillance Laboratory (NPHSL)
- Jana Klanova. Masaryk University (MU)
- Katrin Vorkamp. Aarhus University (AU)

Task leaders in WP9:

- Marta Esteban López. Institute of Health Carlos III (ISCIII)
- Cathrine Thomsen, Norwegian Institute of Public Health (NIPH)
- Holger Koch. Institute for Prevention and Occupational Medicine of the German Social Accident Insurance (IPA)
- Thomas Göen, Friedrich-Alexander-Universität Erlangen-Nürnberg (IPASUM)
- Thomas Lundh. University of Lund (ULUND)
- Jana Hajslova. University of Chemistry and Technology (VSCHT)

Partners in WP9:

- Enrique Cerquier and Line S. Haug. Norwegian Institute of Public Health (NIPH)
- Monika Kasper-Sonnenberg. Institute for Prevention and Occupational Medicine of the German Social Accident Insurance (IPA)
- Adrian Covaci, University of Antwerp (UAntwerp)
- Löic Rambaud. Santé publique France (ANSP)
- Hans Mol. RIKILT Wageningen UR (RIKILT)

Chemical group leaders (CGLs):

- Marike Kolossa, Ulrike Doyle, Till Weber. Umweltbundesamt (UBA)
- Robert Barouki. Institut National de la Sante et de la Recherche Medicale (INSERM)
- Maria Uhl. Umweltbundesamt GMBH (EAA)
- Jana Klanova. Masaryk University (MU)
- Milena Horvat. Institut Jozef Stefan (JSl)
- Alessandro Alimonti. Istituto Superiore Di Sanita (ISS)
- Greet Schoeters. Vlaamse Instelling Voor Technologisch Onderzoek N.V. (VITO)
- Tiina Santonen. Finnish Institute for Occupational Health (FIOH)
- Lisbeth Knudsen. University of Copenhagen (UCPH)

2 Introduction

The objective of the task 9.2 was to elaborate a list of candidate laboratories for the substances selecteded in the 1st HBM4EU round of prioritisation for:

- Performing chemical analysis of biomarkers
- Developing new analytical methods
- Supporting Quality Assurance/Quality Control (QA/QC) program in WP9

These candidate laboratories could take part in the activities of HBM4EU after their subsequent successful participation in the Interlaboratory Comparisin Investigations (ICIs) and External Quality Assurance Scheme (EQUAS) (biomarker analysis) or after being selected according to the criteria defined by experts (new analytical methods and QA/QC support).

3 Criteria definition

The first draft of the criteria for selecting the candidate laboratories was discussed within the QAU (23/03/2017). After that, the QAU associated members and other WP9 partners were included in the discussions.

The QAU members decided to define a primary criterion for each section as a direct exclusion criterion. This was presented and approved by the Management Board. Then, the data received would be evaluated according to the scoring defined for each of the criteria and consequently, obtaining the final score for each laboratory (Table 1-3). The evaluation of data for each section and group would be evaluated separately. Regarding the section covering analysis of the different biomarkers, data for each group of chemicals would be considered separately.

Criteria for selecting candidate laboratories to analyse HBM4EU samples

KNOW – HOW	Exclusive	1st level	2nd level	Scoring system
Experience analysing human samples	X			
Experience in the target matrix/biomarker		x		5: experience in matrix and biomarker 3: experience in matrix or biomarker
Participation in human biomonitoring surveys/studies – sample size[1]		x		5: >1000 participants 3: 250 - 1000 participants 1: <250 participants
Participation in human biomonitoring surveys/studies – target population		x		5: general population, mother/children 3: occupational, highly exposed
QA/QC AND BIOSAFETY				
Successful participation in Interlaboratory Comparison Exercises[2] (ICIs) for the target matrix/biomarker		x		5: in the last 3 years 3: in > 3 years
Successful participation in External Quality Assurance Schemes[3] (EQUAS) for the target matrix/biomarker in the last 3 years		x		5: in the 3 years 3: in 2 years
Accreditation by ISO/IEC 17025 norm			x	3: yes in human samples 1: in biological samples or others
Not accredited but there is a QA/QC system in the laboratory covering the: - Control of the instruments, standards, reagents, etc. - Traceability of the samples - Data protection - Biosafety practices and facilities (chemical fume hoods, biological safety cabinets, chemical hygiene plan, SOP for chemical handling, etc.)		x		5: if yes in all options 3: if yes in the 2 first options (control and traceability)
Existence of a SOP for the analysis of the target matrix/biomarker		x		5
CAPACITY				
Analysis capacity per month		x		Taking as 100% the maximum number of samples of the answers received: 5: 100-50% 3: <50%
Storage capacity			x	Taking as 100% the maximum capacity of the answers received: 3: 100-50% 1: <50%
Time required for starting the analysis considering the time for fulfilling the legal and/or the required internal procedures		x		5: ≤ 4 weeks 3: > 4 weeks
Cost of the analysis			x	Taking as 100% the maximum cost of the answers received: 3: <75% 1: 100-75%

[1] *This criterion will be only applied in case it is necessary to select laboratories with high capacities with regards to the number of samples to be analysed*

[2] *ICIs: is a measure to harmonise analytical methods and their application and in this way improving the comparability of analytical results.*

[3] *EQUAS: is a measure to improve the accuracy of analytical results. For this purpose, control material is analysed in reference laboratories. The accuracy is evaluated by comparing results with the assigned values calculated from the results of the reference laboratories.*