HBM4EU science and policy for a healthy future

HORIZON2020 Programme
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Standard Operation Procedure

HBM4EU-QA-004

Reporting of results of Interlaboratory Comparison Investigations (ICI) and External Quality Assurance Schemes (EQUAS)

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Validation status:	~~Basic / Single lab / Multi-lab~~ / Not applicable
Accredited:	~~Yes~~ / No

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1 Aim and application area

This SOP is one out of four SOPs describing how Interlaboratory Comparison Investigations (ICIs) and External Quality Assurance Schemes (EQUAS) are done in HBM4EU:

HBM4EU-SOP-QA-001 "Organisation of Interlaboratory Comparison Investigations (ICI) and External Quality Assurance Schemes (EQUAS) of interlaboratory studies"

HBM4EU-SOP-QA-002 "Preparation of control materials for Interlaboratory Comparison Investigations (ICI) and External Quality Assurance Schemes (EQUAS)"

HBM4EU-SOP-QA-003 "Evaluation of results from Interlaboratory Comparison Investigations (ICI) and External Quality Assurance Schemes (EQUAS)"

HBM4EU-SOP-QA-004 "Reporting of results of Interlaboratory Comparison Investigations (ICI) and External Quality Assurance Schemes (EQUAS)"

This SOP describes how the results of an ICI or EQUAS study are described in a report that will be distributed to the participants and the HBM4EU QAU. For drafting this SOP, requirements as outlined in ISO/IEC 17043:2010, "Conformity assessment – General requirements for proficiency testing" have been taken into account.

A template report has been drafted to ensure harmonised reporting of ICI/EQUAS studies, and is available as separate document.

2 Definitions

All definitions have been compiled in HBM4EU-SOP-QA-001, and the reader is referred to that SOP.

3 Procedures

In line with ISO/IEC 17043, the report will include:
- Name and address of organizer
- Names of persons involved in approval of the report
- Date of issue of the report
- A report number and description
- Procedure for the organization of the ICI / EQUAS
- Description of applied methods and procedures (e.g. homogeneity/stability testing)
- Codes and results of the individual participating laboratories
- Statistical data and summary
- Description of applied statistics
- Data on methods as applied by the participating laboratories
- Discussion and graphical presentations of results

3.1 General

3.1.1 Anonymity

In the report, laboratories are mentioned by code, not by their name. A list of laboratories that participated in the ICI / EQUAS study can be included as appendix to the report as long as laboratories cannot be linked to the code through the text or results or by any other means.

3.1.2 Deviations from the ICI / EQUAS SOPs

When due to unforeseen circumstances the organizer deviates from the procedures as described in the ICI / EQUAS SOPs, and this has an impact on the characteristics of the control materials, evaluation of the data, or outcome of the study, this has to be described and included in the report.

3.2 Title page

The title page includes at least:

- Title of ICI / EQUAS study
- Name of author(s)
- Report number
- Date of issue
- Name and address of the organizer

3.3 Summary

The report contains a summary that includes at least:

- Description of the control material
- Outcome of the homogeneity and stability assessment of the control material
- Number of participating laboratories
- Information on the number of false positives and false negatives
- Performance of the laboratories
- Conclusions and recommendations (optional)

3.4 Introduction

The introduction of the report includes at least:

- Description and aim of the ICI / EQUAS study
- Information on the biomarkers included in the scope of the ICI / EQUAS (rational for inclusion, concentrations etc.).

3.5 Control materials

Information on the control materials includes at least:

- Information on material used; matrix, target biomarkers and target concentrations
- Information on how the materials were prepared
- Information/results on the homogeneity study (procedure, results, statistics, conclusion)
- Information/results on stability of the control material (procedure, results, statistics, conclusion)
- Information on shipment of the test samples (composition of sample set, date/conditions of shipment)

3.6 Statistical evaluation of results

The report contains a section on the evaluation procedure/statistics used, and includes:

- reference to literature and guidelines used for statistical analysis
- way of calculation of the consensus value (ICI) or expert value (EQUAS)
- rationale of the chosen target standard deviation
- way of calculation of the uncertainty of the assigned value
- way of calculation of the Z-score
- information on the classification of results of the individual laboratories

3.7 Results and discussion

The results and discussion section includes at least:

- The number of participating laboratories and how many of those submitted results
- Detailed data on the results and outcome of the ICI / EQUAS including:
    - number of results used for statistical calculations
    - number of false positives and false negatives
    - laboratory codes and results
    - consensus value and its uncertainty (only for ICI)
    - calculated Z-scores
    - graphical presentation of results (concentration vs lab code; Z-score in increasing order vs lab code)
    - discussion of results and performance of the laboratories
    - optional: discussion on the methods and any observed associations between performance and methods

3.8 Conclusion

The conclusions includes at least:

- Number of participating laboratories
- Techniques used for analysis
- Occurrence of false positives/false negatives
- Performance of laboratories for the analysis

3.9 Appendices

The following appendices are included in the report:

- List of countries and number of laboratories for each country that participated in the ICI/EQUAS round
- Overview table of results and statistical parameters of homogeneity study
- Overview table of results and statistical parameters of stability study
- Copy of letter of invitation
- Copy of letter/instructions sent together with test samples
- Overview table of analysis results of the individual laboratories
- Overview table of performance of laboratories
- Optional: table with the scope and LOQs of the laboratory's method

3.10 Revision of an issued report

In case a revision of an earlier issued report is made, this needs to include:

- a new/unique report number
- reference to the original report
- explanation/comment on reason for drafting the revision

4 References

HBM4EU-SOP-QA-001 "Organisation of Interlaboratory Comparison Investigations (ICI) and External Quality Assurance Schemes (EQUAS) of interlaboratory studies"

HBM4EU-SOP-QA-002 "Preparation of control materials for Interlaboratory Comparison Investigations (ICI) and External Quality Assurance Schemes (EQUAS)"

HBM4EU-SOP-QA-003 "Evaluation of results from Interlaboratory Comparison Investigations (ICI) and External Quality Assurance Schemes (EQUAS)"

ISO/IEC 17025. 2005. General Requirements for the Competence of Calibration and Testing Laboratories.

ISO/IEC 17043, 2010, Conformity assessment – General requirements for proficiency testing.

ISO/IEC 13528.2015. Statistical methods for use in proficiency testing by interlaboratory comparison