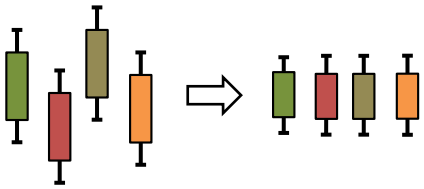


International Consortium
for Harmonization of Clinical Laboratory Results

Terms of Reference for the working group: Commutability

A working group under the joint task force to monitor harmonization of measurands in laboratory medicine through data aggregation (HALMA).

The purpose of this document is to clarify the terms of reference for the working group (WG) on commutability of samples used by EQA programs.

Members

Greg Miller - USA

VIncent Delatour - France

Sverre Sandberg - Norway

finlay MacKenzie - UK

Background

The European Organization for External Quality Assurance Providers in Laboratory Medicine (EQALM) and the International Consortium for Harmonization of Clinical Laboratory Results (ICHCLR) have joint task force to monitor harmonization of measurands in laboratory medicine through data aggregation (the HALMA task force).

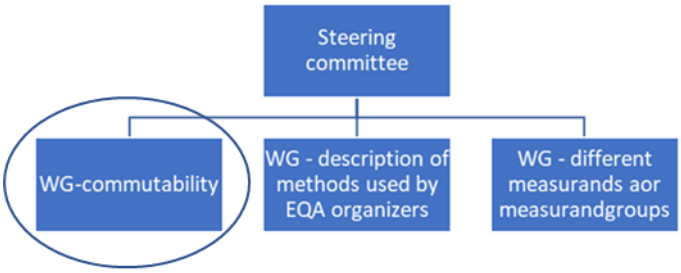
Purpose of HALMA

The primary purpose is to assess harmonization of the IVD industry through aggregated EQA data for different measurands on an international basis. Harmonization will be assessed by providing information on differences between peer group target values of measurement procedures and a true value, or between peer group target values when no true value is available.

Organizational structure of HALMA

The HALMA task force will be led by a steering committee and will have specific working groups for dedicated tasks including the WG on description of methods used by EQA organizers.

The working groups are established with a chair who is responsible to organize the work and a group of dedicated experts (people with expertise and experience in the topic). The chair is appointed by the steering committee.



The circle indicates that these terms of reference are for this working group.

Tasks and purpose of the working group on Commutability

Members

Members of the working group are appointed by the chair of the working group.

Purpose

The main purpose of this WG is to define the minimum criteria and evidence to accept that samples used in an EQA scheme are, with a high probability, sufficiently commutable to represent measurement procedure performance for authentic patient specimens.

Tasks for the WG:

1. Define what is adequate commutability for EQA samples to enable data to be successfully aggregated from different EQA providers.
2. Specify the minimum evidence to be provided by EQA providers to document that their samples meet the adequate commutability specification defined in Task 1.
3. Collaborate with EQA providers to determine if the specifications are achievable and the evidence is reasonably available.

The WG should collaborate with the different measurand WG's to clarify commutability requirements as applicable to different categories of measurands. The WG should coordinate with the IFCC WG on Commutability in Metrological Traceability for consistency in specifications.

Publications

Publications from the WG must be reviewed and approved by the steering committee before submission. The WG should deal with practical implementation.

Useful knowledge

Useful knowledge on commutability characteristics of EQA samples to enable data to be suitably aggregated among different EQA schemes can be found in the feasibility project (Feasibility for

aggregation of commutable external quality assessment results to evaluate metrological traceability and agreement among results. Clin Chem Lab Med 2021;59:117-25).