

## Draft template for biennial activity report from JCTLM Member organizations

All JCTLM Members are invited to attend the Members' and Stakeholders' Meeting, which is held once every two years, and submit a report of their activities in support of traceability in laboratory medicine over the preceding period.

For that purpose this template document provides guidance to JCTLM Members for drafting their biennial activity report. Organizations are invited to provide the information below for submission to the Executive Committee.

**Organization Name:** EQALM

**JCTLM Member status:** Stakeholder Member

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**Period covered:** 2024 – 2025

### 1. Major achievement(s) in support of standardization in laboratory medicine

EQALM is a cooperation of EQA organisations aiming to improve quality in laboratory medicine. An important aspect of that ambition is the establishment by EQALM members of EQA schemes capable to check and monitor the claimed metrological traceability of IVDs. That purpose requires EQA schemes using samples with proven commutability and value assignment in JCTLM listed reference method procedures (RMPs) and/or reference materials (RMs) where possible and feasible.

EQALM actively promotes and coordinates participation of its member organisations in projects aiming to assess EQA sample commutability and EQA value assignment traceable to RMPs and RMs. With regard to this, two projects are worth mentioning:

#### COMET-project

EQALM is an Associated Partner in the EU project COMET (Manufacturing of commutable calibrators and quality control materials for standardisation and post-market surveillance of IVD tests).

The scope of this project is to establish the necessary metrological infrastructure to provide calibration services to External Quality Assessment (EQA) providers and IVD manufacturers to evaluate and improve accuracy and harmonisation of medical test results. It also aims at improving the availability of commutable Certified Reference Materials (CRMs) and EQA materials for standardisation and post-market surveillance of IVD tests. This will help the in vitro diagnostic industry meet the requirements of the In Vitro Diagnostic Medical Devices Regulation (IVDR) regarding calibration and performance verification of IVD tests.

EQA providers play an important role in this project. Also, the EQALM Central Database plays a crucial role. For more information on this project see: <https://projects.lne.eu/jrp-comet/>

In 2024- 2025 three work packages have been started, and EQALM invited its members to share their EQA materials so that these can be examined for commutability. The aim is to identify the sample formats and matrices associated with the highest commutability level for the following measurands:

- Multiparameter, including glucose, testosterone, calcium, total cholesterol, HDL-cholesterol, triglycerides, total protein, ALT and CK
- Neonatal bilirubin
- POCT for Glucose

EQALM has received funding from the Swiss State Secretariat for Education, Research and Innovation (SERI).

### **The HALMA initiative**

Combining results from various EQA providers may provide a powerful tool to monitor harmonization of measurement procedures in the medical laboratory. Therefore, the International Consortium for Harmonization in Laboratory Medicine (ICHCLR) and The European Organisation for External Quality Assurance Providers in Laboratory Medicine (EQALM), have joined forces for an initiative called HALMA. The acronym stands for HARmonization of measurands in Laboratory Medicine through data Aggregation and aims to collect and aggregate results from different EQA providers that use commutable samples. The purpose is to evaluate and assess harmonization of measurands through aggregated EQA data on an international basis. This program is an expansion of a feasibility study reported here.

In a first stage, EQA data from Albumin, Creatinine and Calcium will be collected into the EQALM Central data base.

### **2. Planned activity(ies) in support of standardization in laboratory medicine**

Continuation of beforementioned projects COMET and HALMA

### **3. Promoting traceability in laboratory medicine**

- Promotion of COMET and HALMA initiative at the EQALM annual symposia held in October 2024 in Vienna and October 2025 in Leiden
- Stressing the importance of metrological traceability in a series of EQA papers in the context of medicine, published as:

Buchta C, Marrington R, De la Salle B, Albarède S, Badrick T, Bietenbeck A, Bullock D, Cadamuro J, Delatour V, Dusinovic E, Geilenkeuser WJ, Gidske G, Griesmacher A, Haliassos A, Holzhauser D, Huggett JF, Karathanos S, Pezzati P, Sandberg S, Sarkar A, Solsvik AE, Spannagl M, Thelen M, Restelli V, Perrone LA. Behind the scenes of EQA - characteristics, capabilities, benefits and assets of external quality assessment (EQA). Clin Chem Lab Med. 2025 Jan 6. doi: 10.1515/cclm-2024-1289. Epub ahead of print. PMID: 39753377.

Buchta C, Marrington R, De la Salle B, Albarède S, Badrick T, Berghäll H, Bullock D, Coucke W, Delatour V, Geilenkeuser WJ, Griesmacher A, Henriksen GM, Huggett JF, Luppä PB, Pelanti J, Pezzati P, Sandberg S, Spannagl M, Thelen M, Restelli V, Perrone LA. Behind the scenes of EQA - characteristics, capabilities, benefits and assets of external quality assessment (EQA). Clin Chem Lab Med. 2025 Jan 6. doi: 10.1515/cclm-2024-1290. Epub ahead of print. PMID: 39753241.

Buchta C, Marrington R, De la Salle B, Albarède S, Albe X, Badrick T, Berghäll H, Bullock D, Cobbaert CM, Coucke W, Delatour V, Geilenkeuser WJ, Griesmacher A, Henriksen GM, Huggett JF, Juhos I, Kammel M, Luppá PB, Meijer P, Pelanti J, Pezzati P, Sandberg S, Spannagl M, Thelen M, Thomas A, Zeichhardt H, Restelli V, Perrone LA. Behind the scenes of EQA - characteristics, capabilities, benefits and assets of external quality assessment (EQA). Clin Chem Lab Med. 2025 Jan 6. doi: 10.1515/cclm-2024-1291. Epub ahead of print. PMID: 39753204.

Buchta C, De la Salle B, Marrington R, Aburto Almonacid A, Albarède S, Badrick T, Bullock D, Cobbaert CM, Coucke W, Delatour V, Faria AP, Geilenkeuser WJ, Griesmacher A, Huggett JF, Janovská V, Kammel M, Kessler A, Körmöczy GF, Meijer P, Miranda A, Patel D, Pezzati P, Sandberg S, Schennach H, Schweiger CR, Schwenoha K, Spannagl M, Sung H, Thelen M, Weykamp C, Zeichhardt H, Restelli V, Perrone LA. Behind the scenes of EQA - characteristics, capabilities, benefits and assets of external quality assessment (EQA). Clin Chem Lab Med. 2025 Jan 6. doi: 10.1515/cclm-2024-1293. Epub ahead of print. PMID: 39753240.

Buchta C, De la Salle B, Marrington R, Albarède S, Badrick T, Bicker W, Bietenbeck A, Bullock D, Delatour V, Dequeker E, Flasch M, Geilenkeuser WJ, van Hellemond J, Huggett JF, Janovská V, Kaiser P, Kammel M, Kessler A, Laudus N, Luppá PB, Morandi PA, O'Connor G, Panteghini M, Pezzati P, Rosendahl J, Sandberg S, Scheiblauer H, Skitek M, Spannagl M, Stavelin A, Thelen M, Unterberger U, Zeichhardt H, Restelli V, Perrone LA. Behind the scenes of EQA-characteristics, capabilities, benefits and assets of external quality assessment (EQA). Clin Chem Lab Med. 2025 Jan 6. doi: 10.1515/cclm-2024-1292. Epub ahead of print. PMID: 39754494.

#### **4. Reference laboratory networks /collaborations focusing on developing /implementing reference measurement systems**

Projects mentioned under 1 and 2 have the intention to contribute to this.

#### **5. Open questions and suggestions to be addressed by JCTLM**

(Suggestions on issues related to standardization and metrological traceability that should be considered by the JCTLM)

The EQALM annual report can be found at [www.eqalm.org](http://www.eqalm.org).

Note: The information of this report will be accessible publicly on the relevant JCTLM Members webpage, unless the author of the report states otherwise. In the case the organization does not authorize the publication of the report in part or full, the author will add a statement to clarify which part(s) of the report will /will not be rendered public.