

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: SKML

JCTLM Member status: Stakeholder Member

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Period covered: 2024 – 2025

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

(Please describe what activities your organization has undertaken related to the implementation of reference measurement systems in laboratory medicine during the last two years, including but not limited to information on: the production of certified reference materials; the development of reference measurement methods; or the establishment of calibration (reference) measurement services. Outline the measurement area(s)/measurands covered, and provide a listing of the relevant technical/scientific publications.)

SKML is a not for profit EQA organisation based in the Netherlands, aiming to organise EQA schemes which are suitable to monitor the successful implementation of metrological traceability of all relevant measurands in laboratory medicine within the scope of clinical chemistry including haematology, cytology, microbiology, immunology and clinical pharmacology including toxicology.

For that purpose SKML aims to use samples with proven commutability and target value assignment using reference method procedures and/or reference materials. SKML uses a multi sample reporting format allowing to distinguish between bias and imprecision as difference sources of inaccuracy.

SKML has an active scientific policy by organising scientific research by its section and SKML employed PhD students

In 2024-2025 SKML was involved in the following projects related to the JCTLM ambitions.

- Changing the value assignment of the SKML scheme for albumin from method group consensus to related to reference material
- Commutability assessment of the SKML coagulation scheme for PT and APTT
- Commutability assessment of the SKML scheme for ferritin
- Regrouping methods groups in the SKML ferritin scheme, based on three different generation of the WHO reference material used in the different IVDs for ferritin, leading to predictable difference in between method metrological traceability
- Commutability assessment of the SKML m-protein scheme
- Active Participation in the EQALM initiatives HALMA and COMET

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

- Development and production of a commutable candidate secondary reference materials for ferritin
- Value assignment of the albumin in urine EQA scheme related to the newly available reference material rather than the current consensus approach

3. Promoting traceability in laboratory medicine

(Please describe activities your organization has undertaken during the last two years for promoting traceability in laboratory medicine including but not limited to a listing of your publication(s), presentation(s) and other communication(s) on traceability at international and national conferences or congresses, or other forums for clinical laboratory medicine)

SKML publications in 2024-2025 related to JTLM goals are:

Thelen MHM, van Schrojenstein Lantman M. When bias becomes part of imprecision: how to use analytical performance specifications to determine acceptability of lot-lot variation and other sources of possibly unacceptable bias. *Clin Chem Lab Med.* 2024 Feb 8;62(8):1505-1511. doi: 10.1515/cclm-2023-1303. PMID: 38353157.

van Schrojenstein Lantman M, Grobben R, van Herwaarden AE, van Berkel M, Schaap J, Thelen M. To rule-in, or not to falsely rule-out, that is the question: evaluation of hs-cTnT EQA performance in light of the ESC-2020 guideline. *Clin Chem Lab Med.* 2024 Feb 7;62(6):1158-1166. doi: 10.1515/cclm-2023-1226. PMID: 38353154.

Van Rossum HH, Holdenrieder S, Yun YM, Patel D, Thelen M, Song J, Unsworth N, Partridge K, Moore M, Cui W, Ramanathan L, Meng QH, Ballieux BEPB, Sturgeon C, Vesper H. External quality assessment-based tumor marker harmonization simulation; insights in achievable harmonization for CA 15-3 and CEA. *Clin Chem Lab Med.* 2024 Sep 20. doi: 10.1515/cclm-2024-0696. Epub ahead of print. PMID: 39299928.

van Schrojenstein Lantman M, van Berkel M, Kuijper P, Langelaan M, Brouwer N, Thelen M. Clinical Decision-Making Suffers from Inequivalent Measurement Results and Inadequate Reference Intervals. *Clin Chem.* 2024 Nov 4;70(11):1383-1392. doi: 10.1093/clinchem/hvae129. PMID: 39288014.

Swinkels DW, van Schrojenstein Lantman M, Matlung HL, Weykamp C, Thelen M. Equivalence in clinical assessment of iron status requires ferritin assay standardisation before harmonisation of ferritin reference intervals. *Lancet Haematol.* 2024 Oct;11(10):e721. doi: 10.1016/S2352-3026(24)00245-X. PMID: 39362739.

Van Rossum HH, Holdenrieder S, Yun YM, Patel D, Thelen M, Song J, Unsworth N, Partridge K, Moore M, Cui W, Ramanathan L, Meng QH, Ballieux BEPB, Sturgeon C, Vesper H. External quality assessment-based tumor marker harmonization simulation; insights in achievable harmonization for

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

(Please describe your participation in laboratory networks, forums or professional/technical committees linked to reference measurements system development/implementation, and contributions to JCTLM Working Group activities.)

SKML participates in the following IFCC WGs related to standardisation:

WG-HbA₂/HbF

WG-hGH

WG-FIT

WG PT/INR

WG-NB

WG-TMH

WG-FCE

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)

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.