

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: Ref4U – Laboratory for Toxicology – Ghent University

JCTLM Member status: Stakeholder Member

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Period covered: 2024 – 2025

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

Ref4U's activities support the efforts to develop and implement a measurement infrastructure for SI-traceable "measurands" in Laboratory Medicine (EN/ISO 17511).

Ref4U, as a reference laboratory, conducts SI-traceable reference measurement procedures as listed in the database of the "Joint Committee for Traceability in Laboratory Medicine (JCTLM)". It offers services to the in vitro diagnostic industry, metrological institutes, organizers of external quality assessment and other interested parties. An overview of these services, including the associated reference measurement procedures, is given in the JCTLM database. For these measurement services Ref4U is accredited by BELAC (ISO 17025 and ISO 15195), see also the certificate with accompanying scope.

Ref4U, by representation of Dr. Van Uytfanghe, is active as a partner in the EMN on Traceability in Laboratory Medicine, the JCTLM task force on reference measurement system implementation and COMET.

Ref4U is as reference laboratory very actively involved in the activities of the IFCC Committee for Standardization of Thyroid Function Tests (C-STFT). The mission statement of the C-STFT is to document and improve the standardization status and intrinsic quality of current thyroid hormone immunoassays. One of the tasks was to develop reference measurement systems for the most commonly determined thyroid hormones (TT4, TT3, FT4, FT3 and TSH). Activities are now focused on the implementation of these reference measurement systems: (i) by establishing a network of FT4 reference laboratories; (ii) by ensuring sustainability of TSH harmonization; (iii) by dissemination of the work of the C-STFT so that new research (e.g. in establishing regional reference intervals) will be linked to the standards set by the C-STFT; (iv) supporting IVD manufacturers in implementing the standardized FT4 and harmonized TSH assays.

Ref4U supports activities of other IFCC working groups/committees as well by means of providing reference measurement services or as a corresponding member.

Additional research activities are focused on the implementation of the principles of standardization beyond the field of clinical chemistry, more particular in the field of toxicology, with current focus on the measurement of the direct alcohol biomarker phosphatidylethanol.

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

The focus of the activities of Ref4U with regard to standardization in laboratory medicine will be on:

1. A continuation of the previous mentioned activities within the C-STFT.
2. Providing reference measurement services to the in-vitro diagnostic industry, and other interested parties.

3. Ref4U also aims to further develop and validate candidate reference measurement procedures for SI-traceable measurands.
4. Ref4U will continue to promote standardization in the field of toxicology.
5. Ref4U will continue its activities within the EMN on Traceability in Laboratory Medicine.
6. Ref4U will continue its activities within the JCTLM task force on reference measurement system implementation
7. Ref4U will continue its activities in COMET.

3. Promoting traceability in laboratory medicine

Publications

1. Cowper B, Lyle AN, Vesper HW, Van Uytfanghe K, Burns C. Standardisation and harmonisation of thyroid-stimulating hormone measurements: historical, current, and future perspectives. *Clin Chem Lab Med*. 2024 Jan 31;62(5):824-829. doi: 10.1515/cclm-2023-1332. PMID: 38295422.
2. Panteghini M, Camara JE, Delatour V, Van Uytfanghe K, Vesper HW, Zhang T. Feasibility of Metrological Traceability Implementation Using the Joint Committee on Traceability in Laboratory Medicine Database Entries Including the Fulfillment of "Fit-for-Purpose" Maximum Allowable Measurement Uncertainty. *Clin Chem*. 2024 Nov 4;70(11):1321-1333. doi: 10.1093/clinchem/hvae131. PMID: 39316470.
3. Cavalier E, Bhattoa HP, Heijboer AC, Lombardi G, Delatour V, Van Uytfanghe K, Makris K, Jørgensen NR, Herrmann M, Pikner R, Lukas P, Vasikaran SD, Fraser CG; IFCC-IOF Committee on Bone Metabolism. Assessment of measurement uncertainty of immunoassays and LC-MS/MS methods for serum 25-hydroxyvitamin D. *Clin Chem Lab Med*. 2025 Aug 12;63(10):1981-1991. doi: 10.1515/cclm-2025-0554. PMID: 40785082.

Presentations by (chaired by) Dr. Van Uytfanghe

1. "Standardisation biologique et nouvelles techniques de dosage des hormones thyroïdiennes."; Annual bioclinical symposium, December 7 and 8 2023 in Paris under the auspices of the SFMN. An
2. "Harmonization of thyroid-stimulating hormone measurements - an historical overview and outlook for the future", EFLM webinar, in May 2025, available online.
3. "20 years of standardization of thyroid function testing - the success and the outlook", IFCC webinar entitled, December 18th, 2025.
4. "Challenges to adopt a new reference system: the case of thyroid hormones", JCTLM Members & Stakeholders Meeting and Workshop, December 1-2, 2025

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

Ref4U is a partner in the FT4 Reference Laboratory Network (RLN), established under the auspices of the C-STFT. Other members are: the Centers for Disease Control and Prevention (CDC, Atlanta, USA), the Reference Material Institute for Clinical Chemistry Standards (ReCCS, Japan) and the Radboud University Medical Center of Nijmegen (Nijmegen, the Netherlands).

5. Open questions and suggestions to be addressed by 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.