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:** International Consortium for Harmonization of Clinical Laboratory Results (ICHCLR)

**JCTLM Member status:** Stakeholder

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**Period covered:** 2018 – 2019

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.)

   A proposal for an ISO standard, ISO DIS 21151:2019 "In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for international harmonization protocols intended to establish metrological traceability of values assigned to end user calibrators and human samples” originated from the ICHCLR and will be an important new tool to achieve equivalent results among different measurement procedures when no suitable certified reference material or reference measurement procedure is available. This new standard can be used by the JCTLM to list harmonization protocols to achieve metrological traceability and equivalent results among medical laboratory measurement procedures.

2. **Planned activity(ies) in support of standardization in laboratory medicine**
   (Please outline R&D project(s) and/or programme(s) planned by your organization in the next two years including information on: new measurement area(s)/measurands of interest for your organization; new CRMs and renewals of materials; development of methods (new measurands and improved measurement technique/principle); and extensions of your calibration measurement service(s) portfolio.)

   The ICHCLR’s Council approved using a portion of the ICHCLR fund balance to support start-up costs for new projects to standardize/harmonize results for high priority measurands conducted by other organizations. The funding is intended to support the following types of activity: an initial meeting of a working group to develop the detailed experimental design for a project; an initial experiment to launch a project. The expectation is the working group will obtain additional funding from other sources to complete the project.
An application to apply for start-up funds is available at www.harmonization.net. Applications for funding will be reviewed by the HOG and approved by the Council.

The ICHCLR initiated a pilot project to explore the feasibility to aggregate EQA, or PT, data from commutable samples to provide feedback to in-vitro diagnostics (IVD) manufacturers and the clinical laboratory community regarding the status of harmonization of results for various measurands. The initial task force requested and received EQA results for creatinine from four EQA programs: NOKLUS (Sverre Sandberg), SKML (Cas Weykamp and Eline van der Hagen), NEQAS (Finlay MacKenzie), CAP (Greg Miller). Aggregation of the pilot data supports feasibility of this approach and identified a need to automate the process of accumulating EQA data from different providers. The pilot results were presented at the EQALM meeting October 17-18, 2019. The ICHCLR and the EQALM, a Stakeholder Member of ICHCLR, signed an MOU on August 15, 2019 to collaborate together to expand the pilot project and develop the program to aggregate EQA data from commutable samples on a global basis.

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)

The ICHCLR joined the JCTLM as a Stakeholder member in 2018. This membership will enable the ICHCLR to better collaborate with JCTLM on topics of mutual interest to advance harmonization of results and promote traceability on a global basis.

The ICHCLR maintains the website www.harmonization.net as a global portal for information on harmonization activities. At this time, 104 of the most frequently ordered measurands have been evaluated and recommendations for harmonization have been posted to the “Measurand” section of the web site. Information on harmonization status and priority for harmonization of a measurand is available by clicking on the measurand name. Links to organizations and resources for harmonization of measurands that are actively in progress or in a continuing status are being added to the Measurand table. Information when JCTLM resources are available is also provided. The website functionality was enhanced to allow sorting of the Measurand table and printing the table with any sort applied.

The ICHCLR and the IFCC Scientific Division are organizing a workshop: Barriers to global standardization of clinical laboratory testing: reference materials and regulations on May 29-30, 2020 in Seoul, Korea immediately following the IFCC WordLab Congress. This workshop will address the technical and regulatory barriers to implementing global metrological traceability of clinical laboratory measurement procedures. Workshop topics will address technical and regulatory issues with potential solutions, how to address new biomarkers and technologies, considerations for prioritization of tests for standardization, and conclude with published recommendations for improved approaches to achieve globally standardized patient test results. The workshop announcement and details are available at the ICHCLR and IFCC websites.
Presentations:

1. AACC Annual Meeting, Chicago, 29 July – 2 August 2018. Symposium organized by the ICHCLR and the Joint Committee for Traceability in Laboratory Medicine. Session Title: Why are Harmonized Results Difficult to Achieve?
   - Regulatory Challenges in Achieving Harmonization of Results; Gary Myers
   - How to Implement a Harmonization Protocol in the Absence of Higher Order Reference System Components; Greg Miller

2. European Organization for External Quality Assurance Providers in Laboratory Medicine (EQALM), 2018 Symposium, Zagreb, Croatia, 18-19 October 2018.
   - Future challenges in EQA, with special emphasis on harmonization and commutability; Greg Miller

   - The Standardization Journey and the Path Ahead; Greg Miller

4. IFCC General Conference, Budapest, Hungary, 10-11 November 2018
   - International Consortium for Harmonization of Clinical Laboratory Results; Greg Miller

Publications:


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.)

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 JCTLM Executive Committee should consider how the JCTLM will incorporate the new ISO guide: ISO DIS 21151:2019 “In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for international harmonization protocols intended to establish metrological traceability of values assigned to end user calibrators and human samples” so that harmonization protocols to achieve metrological traceability and equivalent results among medical laboratory measurement procedures can be approved and listed in the JCTLM database.

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 authorizes 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.