

JCTLM Members and Stakeholders biennial meeting and workshop

Overcoming challenges to global standardization of clinical laboratory testing: reference materials and regulations

A workshop organized by the IFCC Scientific Division, the International Consortium for Harmonization of Clinical Laboratory Results (ICHCLR) and the Joint Committee for Traceability in Laboratory Medicine (JCTLM)

Dates: 6-10 December 2021

Location: Virtual sessions

Format: Two 2-hour discussion sessions on three separate topics with a final combined session to develop workshop recommendations

Workshop goals:

The workshop will develop and publish recommendations how the laboratory medicine community can address challenges related to reference materials and to country and region specific regulations to more effectively achieve standardized results on a global basis.

Achieving equivalent results in laboratory medicine is reliant in part on development and global availability of commutable certified reference materials. Ensuring such materials are available for more analytes is a key challenge, which when met will allow the application of fit-for-purpose calibration hierarchies to more end-user measuring systems.

Regulations to enable use of IVD devices differ between countries and regions and can be a challenge to implementing international standardization programs. This workshop focuses on the situation when recalibration of existing end-user measuring systems is needed to conform to internationally agreed standardization goals. Developing harmonized and simplified regulations for this situation will enable faster and less costly standardization of results to improve patient care and safety.

Organizing committee: Philippe Gillery, Christa Cobbaert, Greg Miller, Gary Myers, Joe Passarelli, Robert Wielgosz, Ian Young, Elvar Theodorsson

Programme

Session 1: What are the needs and logistical challenges for standardized results?

Virtual sessions for discussions and developing recommendations will be held on:

- a. **6 December at 5 pm - 7 pm; Paris time (CET, UTC+1).**
- b. **7 December at 8 am - 10 am; Paris time (CET, UTC+1).**

Background pre-recorded presentations available for consultation prior to discussion sessions will be:

1. Introduction; workshop goals and outcome
2. What are the medical needs for standardized results from lab tests?
3. What are the challenges to achieve standardized results?
4. How do IVD manufacturers implement metrological traceability?
5. What is the availability and suitability of matrix-based CRMs? An IVD industry view.

Session 2: What are the challenges for CRM producers?

Virtual sessions for discussions and developing recommendations will be held on:

- a. **7 December at 5 pm - 7 pm; Paris time (CET, UTC+1).**
- b. **8 December at 8 am - 10 am; Paris time (CET, UTC+1).**

Background pre-recorded presentations available for consultation prior to discussion sessions will be:

6. How to coordinate the effort among different NMIs to meet the needs of IVD manufacturers
7. How to bring IVD manufacturers into the process to develop commutable CRMs for use in calibration hierarchies according to ISO 17511
8. New metrological traceability tools; ISO 21151 harmonization protocol and IFCC recommendations for correction for non-commutability of matrix-based CRMs
9. How to prioritize needs for harmonization/standardization of measurands

Session 3: What are the challenges to meet regulatory requirements in different countries or regions?

Virtual sessions for discussions and developing recommendations will be held on:

- a. **8 December at 5 pm - 7 pm; Paris time (CET, UTC+1).**
- b. **9 December at 8 am - 10 am; Paris time (CET, UTC+1).**

Background pre-recorded presentations available for consultation prior to discussion sessions will be:

10. EU regulations
11. US FDA regulations
12. China CMDE regulations
13. IMDRF role in promoting collaboration in regulations

Session 4: Develop workshop recommendations for publication and follow up actions

The virtual session for discussions and developing recommendations will be held on:

- 10 December at 12 - 2 pm; Paris time (CET, UTC+1)**

The workshop website can be found at:

<https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm/2021-12-06>