



**International Consortium  
for Harmonization of Clinical Laboratory Results**



## **Workshop on overcoming challenges to global standardization of clinical laboratory testing: reference materials and regulations**

**During the JCTLM Members and Stakeholders Meeting**

**BIPM in Paris, 6-7 December, 2021**

The workshop will develop and publish recommendations how the laboratory medicine community can address challenges related to reference materials and regulations to achieve standardized results more effectively on a global basis. Demonstrating commutability of matrix-based certified reference materials (CRMs) remains a significant challenge, and CRMs that have not been validated for commutability with clinical samples may invalidate calibration hierarchies of end-user measuring systems. In addition, matrix-based CRMs from different providers are expected to demonstrate equivalent performance in calibration hierarchies. Increasing availability of commutable and equivalent matrix-based CRMs for more analytes remains a key challenge. Regulations to enable use of IVD devices differ between countries and frequently do not include a simplified process for recalibration to achieve standardized results worldwide. Developing harmonized and simplified regulations that will enable faster and less costly recalibration of end-user measuring systems to conform to internationally agreed standardization/harmonization initiatives will improve patient care and safety.

Draft program:

## Part 1: Challenges for laboratory medicine

- Introduction; workshop goals.
- What are the medical needs for standardized results from laboratory tests?
- How does the laboratory meet the medical needs; what are the challenges to achieve standardized results?
- How do IVD manufacturers implement metrological traceability?
- Availability and suitability of matrix-based CRMs; an IVD industry view.
- Discussion of preceding.

## Part 2: Challenges for reference systems

- National Metrology Institute challenges; how to coordinate effort.
- Reference system development and how to collaborate with IVD manufacturers.
- New metrological traceability tools; ISO 21151 harmonization protocol, IFCC recommendations for correction for non-commutability of matrix-based CRMs.
- Discussion of preceding

## Part 3: Challenges for regulatory organizations

- European Union regulations
- Food and Drug Administration, United States, regulations
- National Institutes for Food and Drug Control, China, regulations
- International Medical Device Regulators Forum
- Discussion of preceding

Part 4: Develop workshop recommendations for publication and follow up actions.

Organized by the IFCC Scientific Division and the International Consortium for Harmonization of Clinical Laboratory Results. Organizing committee: Philippe Gillery, Christa Cobbaert, Greg Miller, Gary Myers, Joe Passarelli, Robert Wielgosz, Ian Young, Elvar Theodorsson.

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