International Consortium
for Harmonization of Clinical Laboratory Results

International Federation of Clinical Chemistry and Laboratory Medicine

JCTLM
Accurate results for patient care

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

During the JCTLM Members and Stakeholders Meeting

BIMP 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 more effectively achieve standardized results 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
- 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, the International Consortium for Harmonization of Clinical Laboratory Results and the Joint Committee for Traceability in Labortory Medicine. Organizing committee: Philippe Gillery, Christa Cobbaert, Greg Miller, Gary Myers, Joe Passarelli, Robert Wielgosz, Ian Young, Elvar Theodorsson.

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