



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



Workshop Announcement

## **Barriers to global standardization of clinical laboratory testing: reference materials and regulations**

**To be rescheduled in 2021**

Differences in country or region specific reference materials and regulatory requirements are challenges to implementing global metrological traceability of clinical laboratory methods. ISO standards with JCTLM certified reference materials, reference measurement procedures and protocols provide tools for global standardization. Workshop topics will address technical and regulatory issues, impact of new biomarkers and technologies, approaches to prioritization of tests for standardization, and conclude with issuing recommendations for improved approaches to achieve globally standardized patient test results.

Information and registration: [to be revised](#)

Presented under the auspices of:



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# PROGRAMME OVERVIEW

## DAY ONE

### **PART 1: What are the problems we will address at this workshop?**

- Medical impact of non-standardized test results
- Suitability / availability of existing reference systems
- Regulatory barriers to standardization

### **PART 2: What is needed to address the barriers to standardization?**

- Global agreement on desirable features of standardization.
- Defining stakeholders and their needs
- Standardization for tests based on new technologies
- Measurand characterization and prioritization for development of reference systems
- IVD manufacturer needs
- Convergence and simplification of regulations to implement standardization protocols

## DAY TWO

### **PART 3: Breakout sessions: How do we get to a better state?**

- (1) Coordination and maintenance of a global standardization infrastructure
  - Identification and roles of international / national stakeholders
  - Use of EQA to monitor effectiveness of standardization activities
  - Reaching global consensus on fit-for-purpose reference materials and measurement procedures
  - Best practices for prioritization of measurands and activities
- (2) Global coordination of national metrology institutes (NMIs)—moving from regional to global focus
  - Strengthening collaboration among all standardization stakeholders
  - JCTLM listing and ISO requirements for reference materials, measurement procedures, and labs
  - How to improve definition / characterization of reference materials by NMIs
  - How to improve labelling and documentation of reference materials and measurement procedures
- (3) Improving the regulatory environment to facilitate global standardization
  - Globalizing regulations—opportunities for collaboration on common regulations
  - Converging regulations to facilitate global implementation of new/replenished RMs and RMPs
  - Simplify regulations to approve recalibration to achieve international standardization
  - Global coordination to implement new standardization processes

### **PART 4: Breakout session reports and recommendations**

- Present and discuss recommendations from breakout groups
- Develop overall workshop recommendations for publication and follow up actions

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