

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



Workshop Announcement

Reference materials and regulations for global standardization / harmonization of clinical laboratory testing

29-30 May, 2020 - SEOUL, KOREA

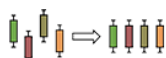


Immediately following IFCC WorldLab 2020 - <http://www.seoul2020.org/2020/home>

This workshop will address the need to establish global metrological traceability of clinical laboratory methods using ISO standards with JCTLM certified reference materials, reference measurement procedures and harmonization protocols, rather than via country or region specific reference materials or requirements. Workshop topics will address technical and regulatory issues, impact of new biomarkers and technologies, approaches to prioritization of measurands for harmonization, and conclude with recommendations for improved approaches to achieving harmonization of results.

Information and registration: seoul@ifcc2020.org

Presented under the auspices of



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



DRAFT PROGRAMME

DAY ONE – May 29

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
- Other barriers to harmonization

PART 2: What is needed to address the barriers to harmonization?

- Global agreement on desirable features of standardization / harmonization.
- Defining stakeholders and their needs
- Harmonization / standardization for tests based on new technologies
- Measurand characterization
- How to prioritize development of new or improved reference materials and measurement procedures
- IVD manufacturer needs
- Impact of new and evolving biomarkers

DAY TWO – May 30

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

- (1) Coordination and maintenance of a global standardization / harmonization infrastructure
 - Identification and roles of international / national stakeholders
 - Use of EQA to monitor effectiveness of standardization / harmonization 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 harmonization
 - Globalizing regulations—opportunities for collaboration on common regulations
 - Facilitating implementation of new or replenished reference materials and measurement procedures
 - Global coordination to implement new standardization/harmonization processes (technical, education)

PART 4: Breakout session reports and recommendations

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

Organizing committee: Philippe Gillery (IFCC), Christa Cobbaert (IFCC), Jim Pierson-Perry (IFCC), Gary Myers (ICHCLR), Greg Miller (ICHCLR)