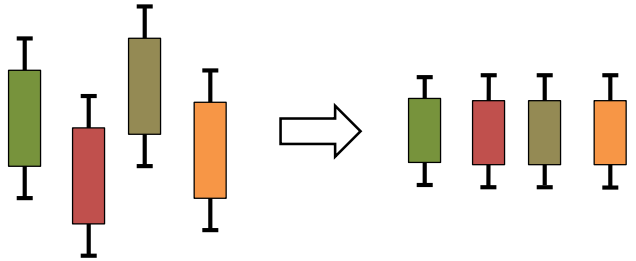
International Consortium for Harmonization of Clinical Laboratory Results



An Update

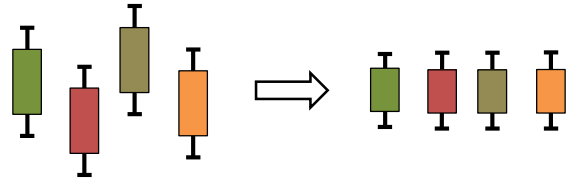
Gary L. Myers, PhD
Council Chair - ICHCLR

Presentation Outline

- Formation and objectives
- Governance structure
- Current activities

Measurands for which reference measurement procedures exist or can be developed

International Consortium for Harmonization of Clinical Laboratory Results



Formation

- In 2010 AACC convened an international leadership conference that focused on the status and challenges to achieve harmonized results from clinical laboratories on a global basis.
- The ICHCLR was created in 2013 to fulfil the recommendations from that conference

Clinical Chemistry 57:8
1108–1117 (2011)

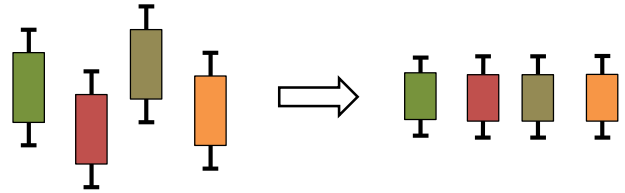
Special Report

Roadmap for Harmonization of Clinical Laboratory Measurement Procedures

W. Greg Miller,[1*] Gary L. Myers,[2] Mary Lou Gantzer,[3] Stephen E. Kahn,[4] E. Ralf Schönbrunner,[5] Linda M. Thienpont,[6] David M. Bunk,[7] Robert H. Christenson,[8] John H. Eckfeldt,[9] Stanley F. Lo,[10] C. Micha Nübling,[11] and Catharine M. Sturgeon[12]

Available at www.harmonization.net under the Resources tab

International Consortium for Harmonization of Clinical Laboratory Results



The primary objectives of the ICHCLR are:

- to improve the harmonization of results from clinical laboratory measurement procedures for measurands that do not have reference measurement procedures

- to provide a resource center for information on global activities to harmonize and standardize clinical laboratory measurement procedures

ICHCLR Governance

Council

AACC Better health through laboratory medicine.

The Korean Society for Laboratory Medicine

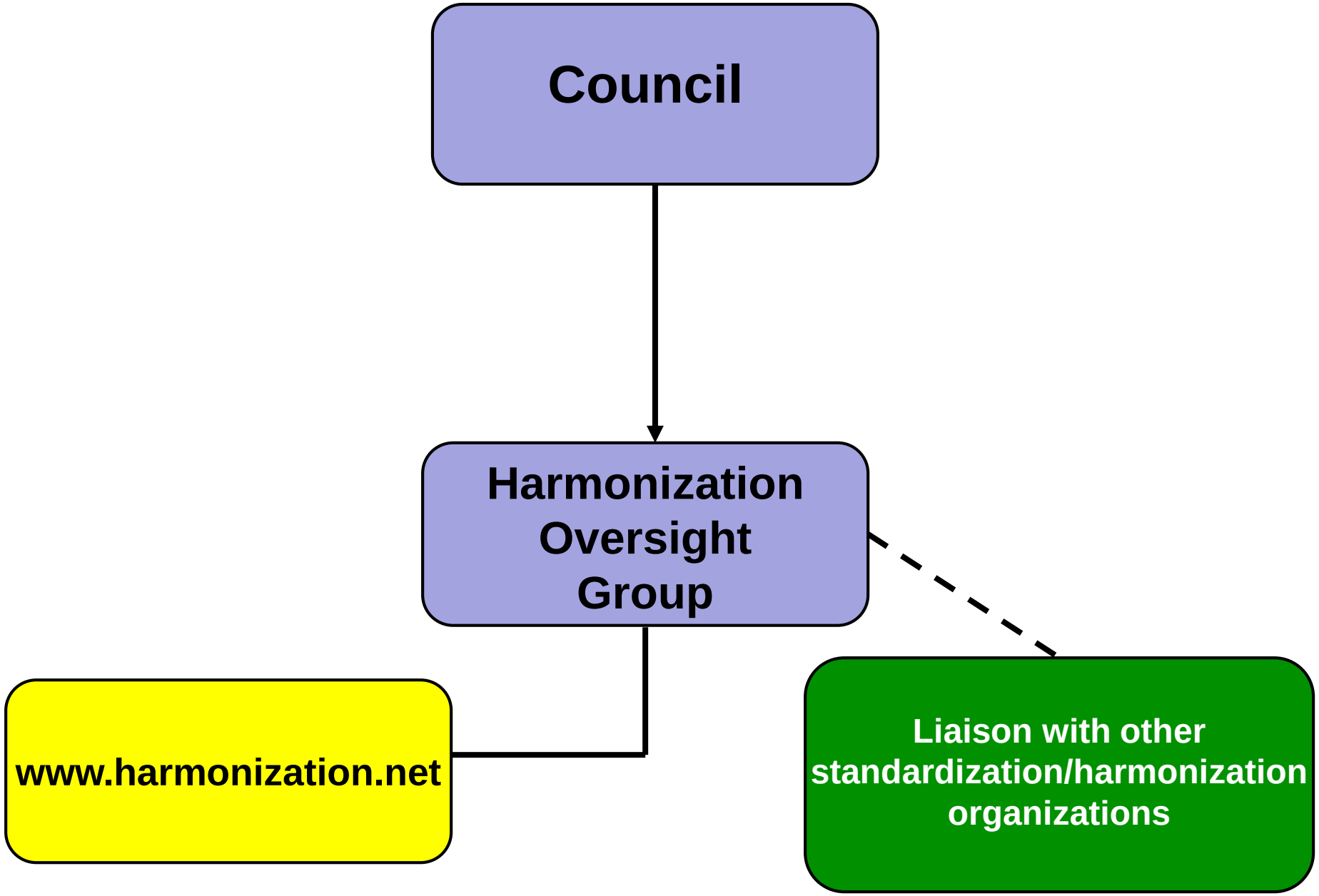
COLLEGE of AMERICAN PATHOLOGISTS

JCCLS 特定非営利活動法人 日本臨床検査標準協議会
JAPANESE COMMITTEE FOR CLINICAL LABORATORY STANDARDS

IFCC International Federation of Clinical Chemistry and Laboratory Medicine

(Serves as ICHCLR Secretariat)

ICHCLR Governance



Harmonization Oversight Group Members

Chair
Greg Miller, PhD

Vice Chair
Eun-Hee Lee, MD, PhD

Philippe Gillery, MD, PhD

Amrom Obstfeld, MD, PhD

Andy Hoofnagle, MD, PhD

Joseph Passarelli, MS

Anja Kessler, PhD

Masato Maekawa, MD, PhD

Melissa Snyder, PhD

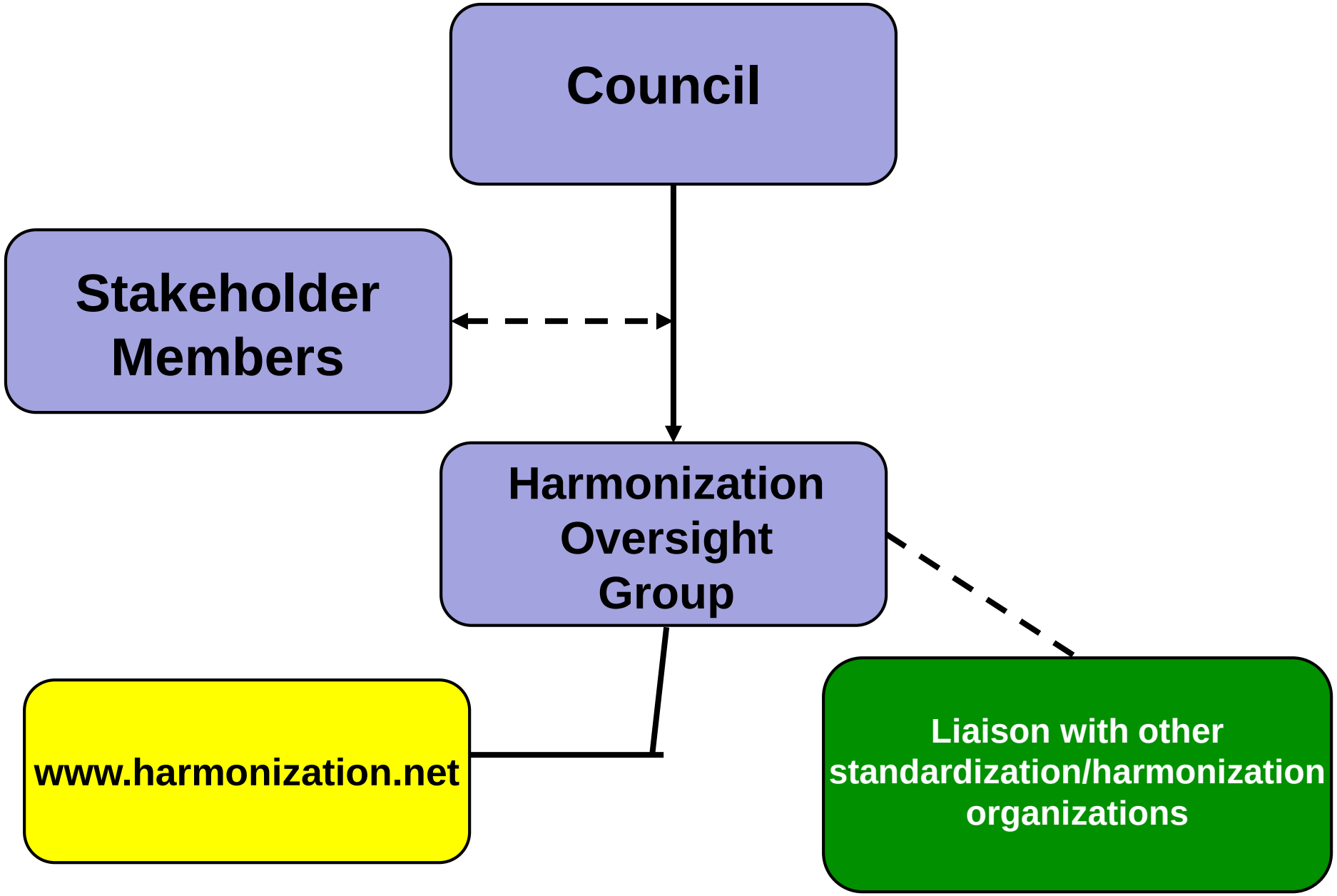
Ross Molinaro, PhD

Stephen R. Master, MD, PhD

Ian Young, MD

Yeo-Min Yun, MD, PhD

ICHCLR Governance



Stakeholder Members

Australasian Association of Clinical Biochemists (AACB)

European Organization for External Quality Assurance Providers in Laboratory Medicine (EQALM)

INSTAND e.V.

Korean Association of External Quality Assessment Service (KEQAS)

Qualab Biotech Co., Ltd.

Reference Institute for Bioanalytics (RfB)

Roche Diagnostics

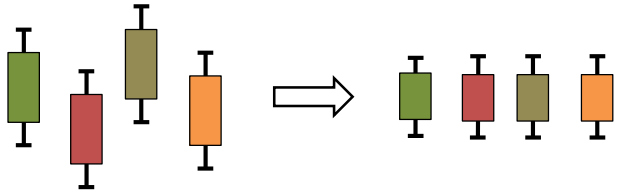
Royal College of Pathology of Australasia Quality Assessment Programs (RCPAQAP)

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Siemens Healthcare Diagnostics

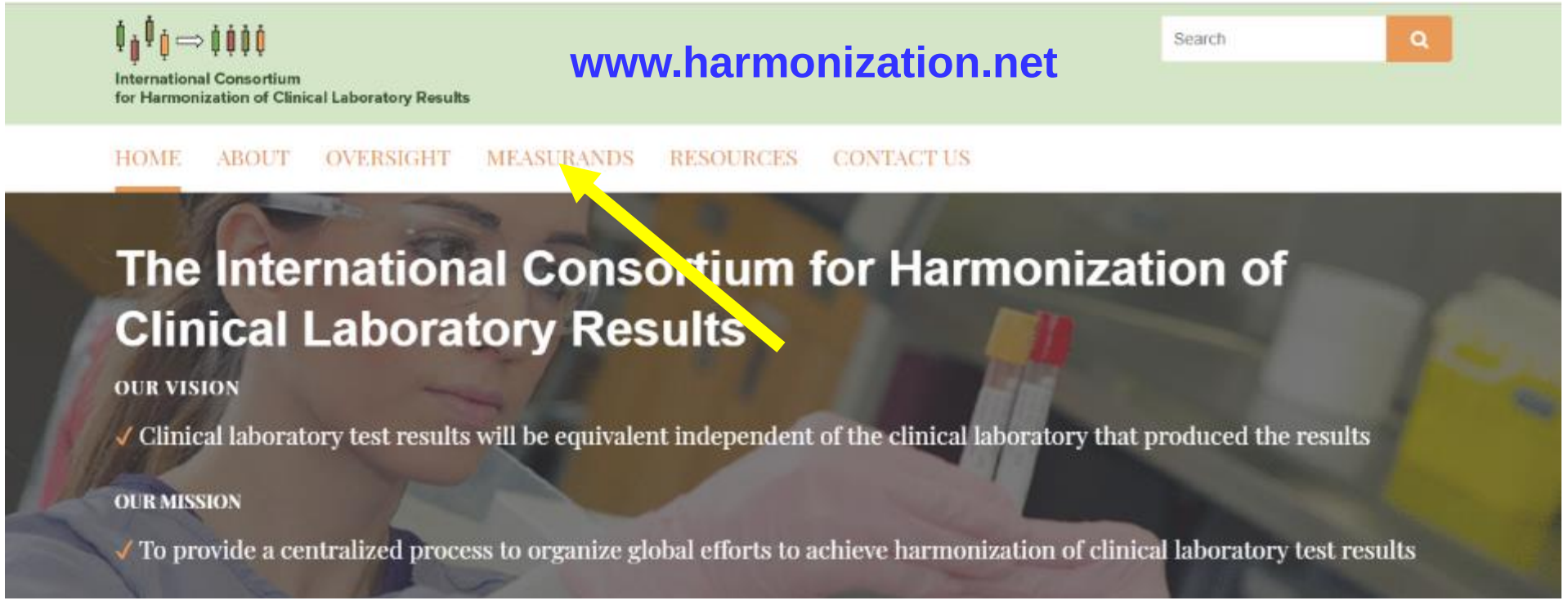
Zybio, Inc.

International Consortium for Harmonization of Clinical Laboratory Results



Current Activities:

- **Prioritize measurands needing harmonization/maintain the website www.Harmonization.net**
- **ISO DIS 21151:2019 Guidance for harmonization protocols**
- **Project to aggregate External Quality Assurance (EQA) data from commutable samples from global EQA providers**
- **Funding for start-up harmonization projects**
- **ICHCLR/IFCC Workshop 2020**



Our specific objectives

✓ to improve the harmonization of results from clinical laboratory measurement procedures for measurands (analytes) that do not have reference measurement procedures

✓ to provide a resource center for information on global activities to harmonize and standardize clinical laboratory measurement procedures

Organization

Operating Procedures for the International Consortium for Harmonization of Clinical Laboratory Results describe the program. The governing body is a Council made up of organizations from around the world that contribute financially to support the administration of the program. A Harmonization Oversight Group (HOG) is responsible to manage the harmonization activities.

Interested stakeholders may become Stakeholder Members of the consortium to support and contribute to the harmonization activities.

The IFCC is the secretariat for administration of the program.

Council Members

American Association for Clinical Chemistry

College of American Pathologists

International Federation of Clinical Chemistry and Laboratory Medicine

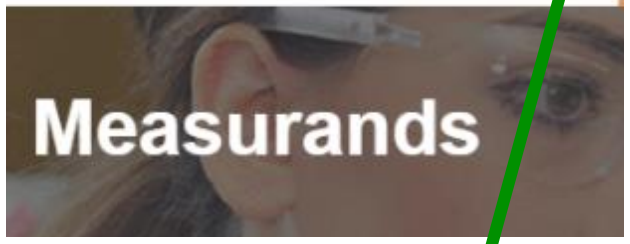
Japanese Committee for Clinical Laboratory Standards

Korean Society for Laboratory Medicine

International Consortium
for Harmonization of Clinical Laboratory Results

HOME ABOUT OVERSIGHT

Search

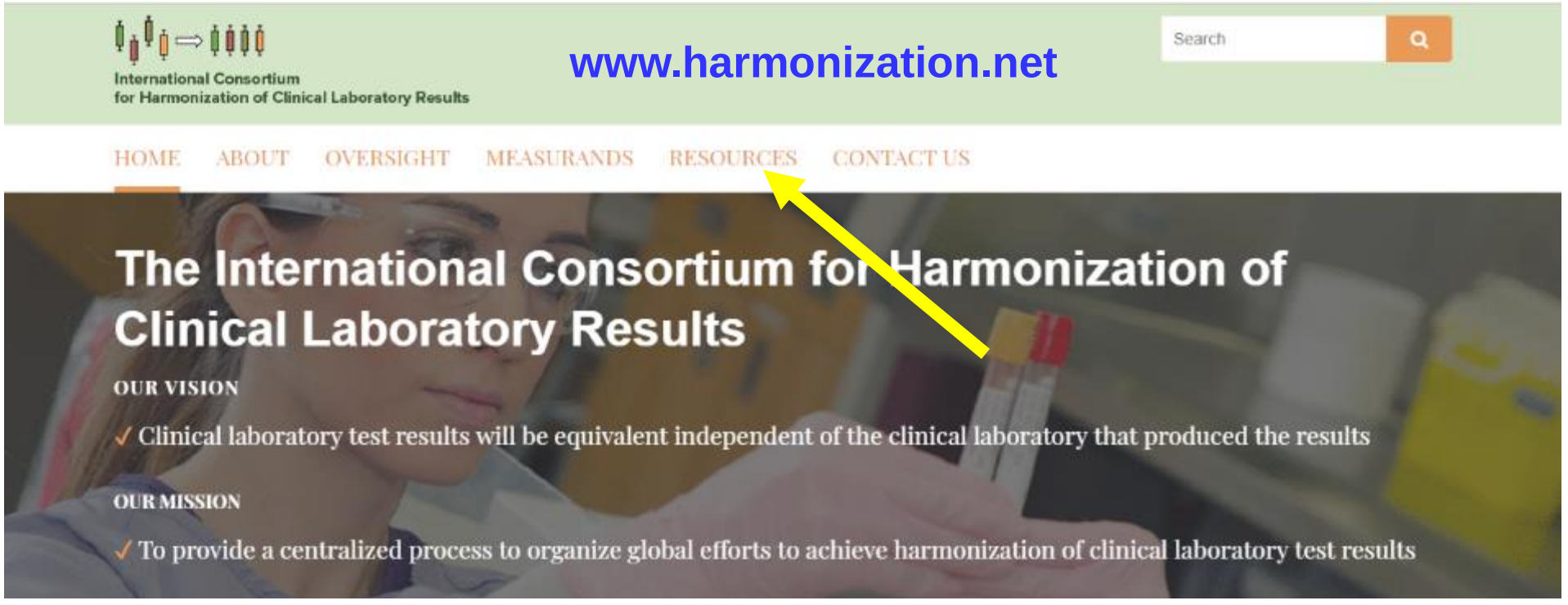


Measurand	Resources	Organization
Alanine Aminotransferase (ALT)	JCTLM	IFCC EU-JRC (IRMM)
Albumin		NKDEP IFCC JSCC
Albumin	JCTLM	
Alkaline Phosphatase (ALP)	JCTLM	IFCC
Alpha Fetoprotein		
Amylase	JCTLM	IFCC
Anti-DNA antibody (qualitative)		
Anti-DNA antibody (quantitative)		
Anti-Hepatitis B Surface Antigen (Anti-HBsAg)	WHO	

Alanine Aminotransferase (ALT)

The IFCC has developed reference measurement procedures for AST and ALT enzymes. The IFCC reagent formulation is generally used by IVD manufacturers with some adaptation for the technology of a given instrument system. Standardization is thus easily achievable. The harmonization issue is whether or not pyridoxyl-5-phosphate (P5P) is included in reagents from IVD manufacturers. P5P is needed to fully activate the enzymes in situations when a patient has a deficiency in this vitamin as may occur in kidney failure and other conditions. A technical issue is that adding P5P to reagents reduces the reagent stability. Consequently P5P is supplied in a separate container to be mixed at the time a reagent is put into use. Furthermore, laboratories may prefer not to add P5P because there may be reagent waste in lower testing volume situations. Some countries do not typically include P5P and in other countries there is a mix of inclusion and exclusion in reagents. Differences in vitamin deficiency between countries may contribute to different practices. The ICHCLR recommends that manufacturers make available reagents that include P5P so that laboratories can determine if their population would benefit from its use in the reagents. A medium priority was assigned because these two analytes are well standardized except for the P5P inclusion and the need for P5P may vary among different regions of the world.

Schumann G, Bonora R, Ceriotti F, Ferard G, Ferrero CA, Franck PF, et al. IFCC primary reference procedures for the measurement of catalytic activity concentrations of enzymes at 37 degrees C. International Federation of Clinical Chemistry and Laboratory Medicine. Part 4. Reference procedure for the measurement of catalytic concentration of alanine aminotransferase. Clin Chem Lab Med. 2002;40:718-24.



Our specific objectives

✓ to improve the harmonization of results from clinical laboratory measurement procedures for measurands (analytes) that do not have reference measurement procedures

✓ to provide a resource center for information on global activities to harmonize and standardize clinical laboratory measurement procedures

Organization

Operating Procedures for the International Consortium for Harmonization of Clinical Laboratory Results describe the program. The governing body is a Council made up of organizations from around the world that contribute financially to support the administration of the program. A Harmonization Oversight Group (HOG) is responsible to manage the harmonization activities.

Interested stakeholders may become Stakeholder Members of the consortium to support and contribute to the harmonization activities.

The IFCC is the secretariat for administration of the program.

Council Members

American Association for Clinical Chemistry

College of American Pathologists

International Federation of Clinical Chemistry and Laboratory Medicine

Japanese Committee for Clinical Laboratory Standards

Korean Society for Laboratory Medicine

Document

Workshop Announcement

The ICHCLR and IFCC Scientific Division will host a workshop on barriers to global standardization of clinical laboratory testing: reference materials and regulations in Seoul 29–30 May, 2020 following the IFCC WorldLab conference.

Read more

Content

Council/HOG Meeting Summaries

Council/HOG Meeting Summaries

Read more

Content

ICHCLR Activity Reports

ICHCLR Activity Reports

Read more

Document

Application for financial support

The ICHCLR provides start-up financial support for standardization/harmonization projects conducted by other organizations.

Read more

Document

Toolbox of technical procedures for developing a process to achieve harmonization for a measurand

Read more

External link

Roadmap for Harmonization of Clinical Laboratory Measurement Procedures Clinical Chemistry 2011 v. 57, p. 1108–1117.

Read more

External link

Status of the Roadmap for Harmonization in 2018

Read more

Document

International Consortium for Harmonization of Clinical Laboratory Results: Operating Procedures

Read more

External link

AACB harmonization activities

Read more

Document

AACC/AdvaMedDx/FDA Forum on Regulatory Issues in Harmonization, 2013

Read more

Document

AACC White Paper on the Need to Harmonize Clinical Laboratory Test Results, 2015

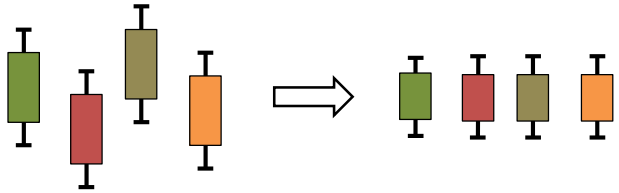
Read more

Document

AACC Position Statement on Harmonization of Clinical Laboratory Test Results, 2013

Read more

International Consortium for Harmonization of Clinical Laboratory Results



Current Activities:

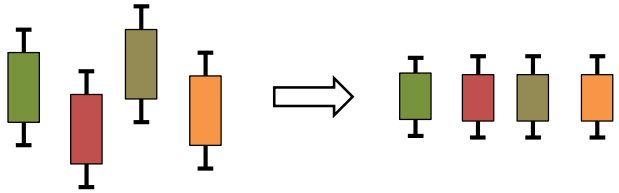
- Prioritize measurands needing harmonization/maintain the website www.Harmonization.net
- **ISO DIS 21151:2019 Guidance for harmonization protocols**
- Project to aggregate External Quality Assurance (EQA) data from commutable samples from global EQA providers
- Funding for start-up harmonization projects
- ICHCLR/IFCC Workshop 2020

ISO DIS 21151:2019 *"In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin -* ***Requirements for international harmonization protocols intended to establish metrological traceability of values assigned to end user calibrators and human samples".***

A proposal for an ISO standard for international harmonization protocols originated from the ICHCLR and will be an important new tool to achieve equivalent results among different measurement procedures when no certified reference material or reference measurement procedure is available.

Dr. Miller will cover this in more detail in the next presentation.

International Consortium for Harmonization of Clinical Laboratory Results



Current Activities:

- Prioritize measurands needing harmonization/maintain the website www.Harmonization.net
- ISO DIS 21151:2019 Guidance for harmonization protocols
- **Project to aggregate External Quality Assurance (EQA) data from commutable samples from global EQA providers**
- Funding for start-up harmonization projects
- ICHCLR/IFCC Workshop 2020

ICHCLR/EQALM project to aggregate EQA data from commutable samples from global EQA providers

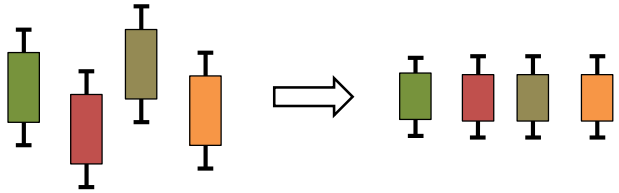
- The HOG initiated a pilot project to explore the feasibility to aggregate EQA, or PT, data from commutable samples to provide feedback regarding the status of harmonization of results for various measurands

- Aggregation of the pilot data supports feasibility of this approach and identified an approach to automate the process of accumulating EQA data from different providers.

- The pilot results were presented at the EQALM meeting October 17-18, 2019.

- The ICHCLR and the EQALM signed an MOU on August 15, 2019 to collaborate to expand the pilot project and develop the program to aggregate EQA data from commutable samples on a global basis

International Consortium for Harmonization of Clinical Laboratory Results



Current Activities:

- Prioritize measurands needing harmonization/maintain the website www.Harmonization.net
- ISO DIS 21151:2019 Guidance for harmonization protocols
- Project to aggregate External Quality Assurance (EQA) data from commutable samples from global EQA providers
- **Funding for start-up harmonization projects**
- ICHCLR/IFCC Workshop 2020

Funding for Start-up Harmonization Projects

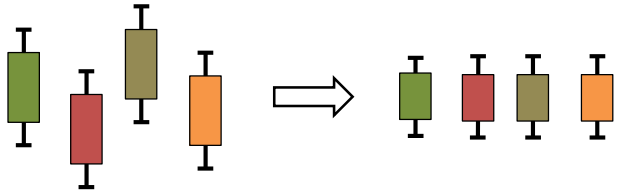
- The ICHCLR will make available funding to support start-up costs for new projects to standardize/harmonize results for high priority measurands conducted by other organizations ($5-15 K).

- The funding is intended to support the following types of activity: an initial meeting of a working group to develop a detailed experimental design for a project; an initial experiment to launch a project.

- The expectation is the working group will obtain additional funding from other sources to complete the project.

- An application to apply for start-up funds is available at www.harmonization.net under the Resources tab.

International Consortium for Harmonization of Clinical Laboratory Results



Current Activities:

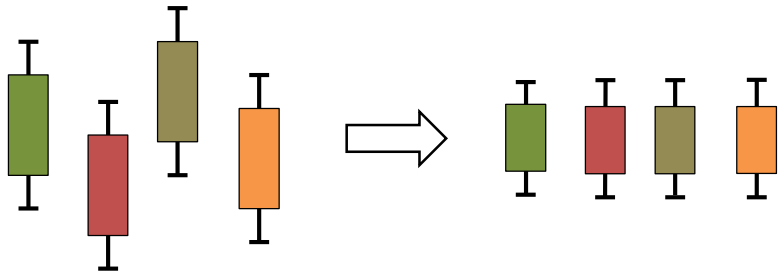
- Prioritize measurands needing harmonization/maintain the website **www.Harmonization.net**
- ISO DIS 21151:2019 Guidance for harmonization protocols
- Project to aggregate External Quality Assurance (EQA) data from commutable samples from global EQA providers
- Funding for start-up harmonization projects
- **ICHCLR/IFCC Workshop 2020**

ICHCLR/IFCC Workshop: Barriers to global standardization of clinical laboratory testing: reference materials and regulations

- The ICHCLR and the IFCC Scientific Division are organizing a workshop on May 29-30, 2020 in Seoul, Korea immediately following the IFCC WordLab Congress.

- 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.

- The workshop announcement and program details are available at the ICHCLR and IFCC websites.



Thank You!!