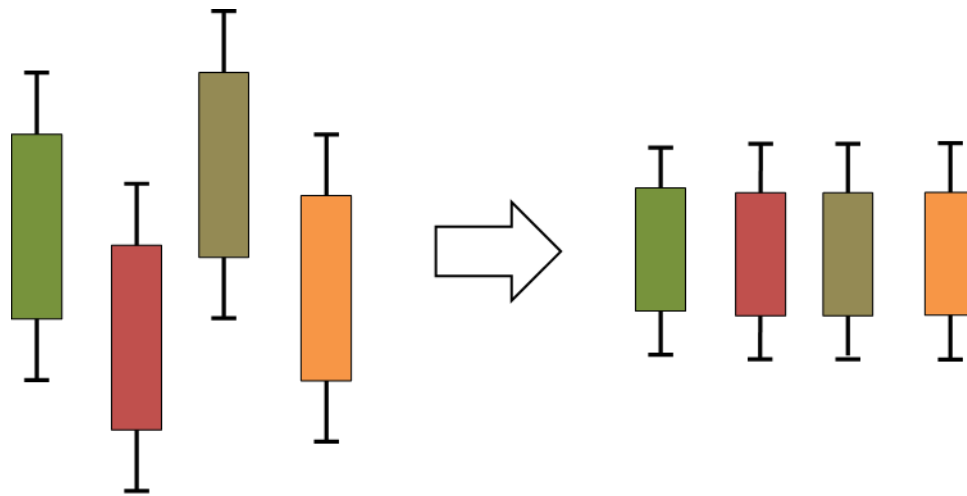


International Consortium for Harmonization of Clinical Laboratory Results: An Update



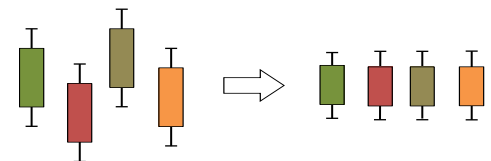
JCTLM Members' & Stakeholders' Meeting

30 November – 1 December 2015

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. Sturgeon¹²

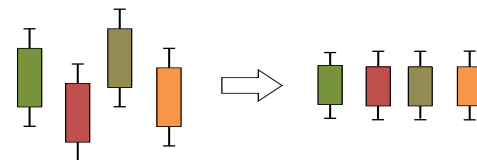
- International Forum organized by AACC in October, 2010
- 90 participants from 12 countries
- Representing 62 organizations & manufacturers



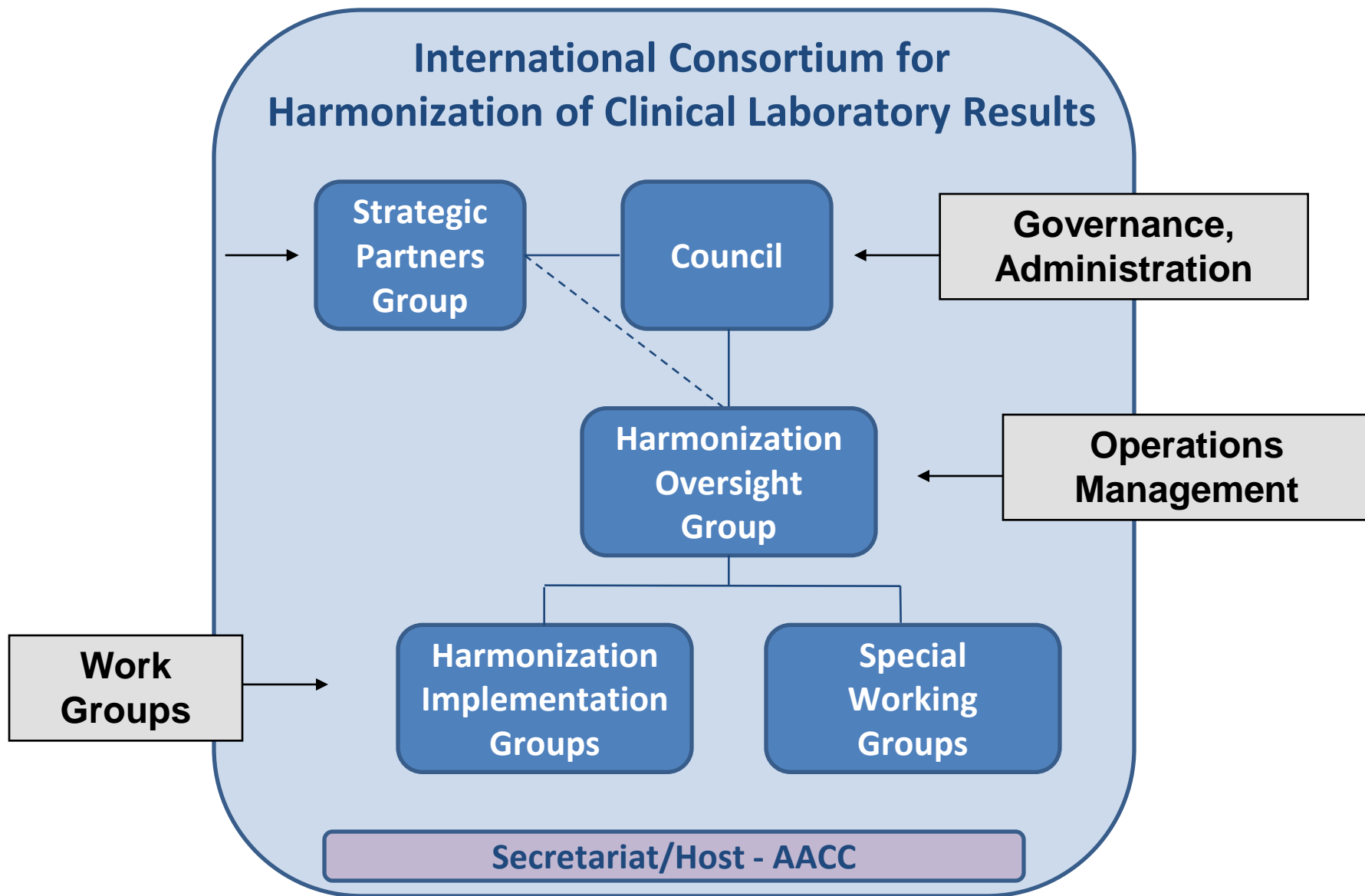
The Roadmap

Develop an infrastructure to coordinate harmonization activities world wide:

1. Prioritize measurands by medical importance
2. Coordinate the work of different organizations
3. Develop technical processes to achieve harmonization when there is no reference measurement procedure or reference material
4. Promote surveillance of the success of harmonization



AN INFRASTRUCTURE FOR HARMONIZATION

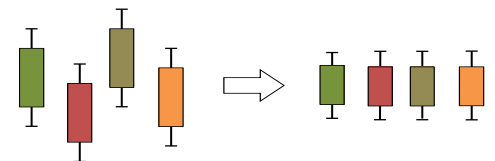


ICHCLR Council Members:

❖ Council Member Organizations in 2015

- AACCC (Secretariat)
- Japanese Committee for Clinical Laboratory Standards
- Korean Society for Clinical Chemistry

❖ Anticipate same members in 2016



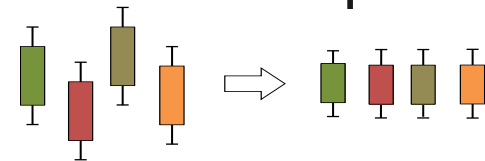
Collaborative Activities:

❖ JCCLS Harmonization Project

- Consulted with JCCLS to review study results and draft manuscript
- Manuscript accepted by Clin Chem

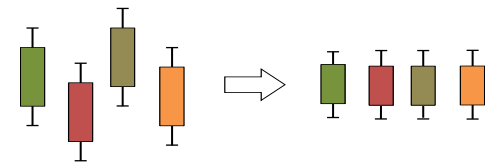
❖ Sustainable Predictive Oncology Therapeutics and Diagnostics (SPOT/Dx) Project

- Presented invited talk on the harmonization consortium at SPOT/Dx meeting
- Met with SPOT/Dx project organizers to advise on establishing a Harmonization Implementation Group for the SPOT/Dx project.



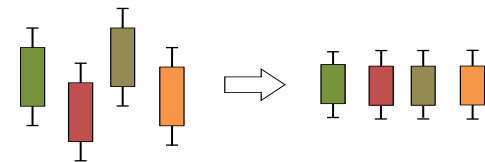
Collaborative Activities:

- ❖ NIH Epstein-Barr Virus (EBV) Harmonization
 - Consulted with National Cancer Institute, NIH concerning harmonization of EBV testing for nasopharyngeal cancer
 - Presented invited talk on harmonization and commutability at NIH Workshop
- ❖ Co-editing special issue on harmonization for IFCC eJournal



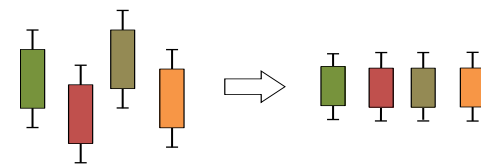
Collaborative Activities:

- ❖ ISO TC 212 Preliminary Work Item “Requirements for international harmonization protocols intended to establish metrological traceability of values assigned to product (end user) calibrators and patient samples”
 - Developed by ICHCLR Harmonization Oversight Group and submitted to ISO through ANSI
 - Now out for vote to advance to a New Work Item Proposal



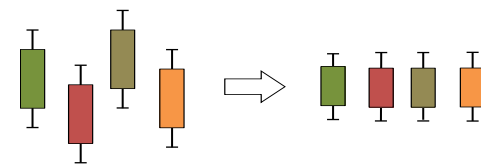
Prioritization and Selection of Measurands:

- ❖ Human Growth Hormone
 - First measurand identified by the Consortium
 - Identified Dr. Eef Lentjes, University Medical Center Utrecht to Chair hGH HIG
 - Facilitated IFCC taking hGH on as new WG activity
- ❖ Harmonization Oversight Group is assessing new model for prioritizing measurands



Prioritization and Selection of Measurands:

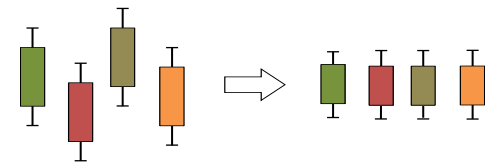
- ❖ Update information on harmonization.net
 - Collected harmonization activity from the following organizations:
 - ✓ LGC, UK
 - ✓ NIBSC, UK
 - ✓ Korean CDC
 - ✓ Reference Material Institute for Clinical Chemistry Standards, Japan
 - ✓ National Measurement Institute, Australia



New ICHCLR Member Category:

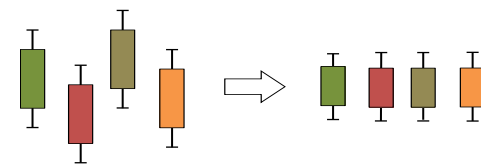
❖ Organizational Member Category

- Provides an opportunity for organizations (e.g., IVD manufacturers, professional societies, standard-setting organizations, etc.) to become a member of the ICHCLR at an intermediate level of financial support (\$10K).
- Organizational Member can appoint a representative to be a member of the HOG.
- IFCC, CAP and some IVD manufacturers have indicated interest in joining at this level
- Approved by full ICHCLR Council



ICHCLR Planned Activities for 2016:

- ❖ Continue to update and refine harmonization.net webpage
- ❖ Promote new Organizational Member category
- ❖ Develop prioritized list of measurands
- ❖ Co-host meetings with JCCLS and KSCC for IVD companies and regulators in Japan and Korea to raise awareness of harmonization (requested by JCCLS and KSCC)



Thank You

