International Consortium for Harmonization of Clinical Laboratory Results Harmonization Oversight Group / Council Joint Meeting

DATE: 3 August 2016

TIME: 12:30 a.m. to 2:00 p.m. EDT LOCATION: Philadelphia, PA, USA

HOG Members:

Dr. Greg Miller (Chair)

Dr. Eunice Lee (Vice-Chair)

Mr. Joseph Passarelli

Dr. Ian Young

Dr. Steve Master

ICHCLR Council Members:

Dr. Gary Myers (chair, AACC)

Mr. Hirofumi Koide (JCCLS)

Dr. Katsuyuki Nakajima (JCCLS)

Dr. Masato Maekawa (JCCLS)

Dr. Junghan Song (KSLM)

Dr. Hyosoon Park (KSLM)

HOG Members Absent:

Dr. Naotaka Hamasaki

Dr. Tony Killeen

Minutes:

- 1. A document reviewing the history and current status of the ICHCLR was provided to the AACC BOD and will be posted to the web site. The review can be shared with the BODs of the other Council and Organizational Members if desired.
- 2. A discussion of new members to invite to join the HOG recognized that the measurand prioritization would be completed in the coming year and that additional biomarkers in disciplines broader than traditional clinical chemistry and that represent emerging biomarkers would be addressed. In addition, the effort to identify global standardization and harmonization activities to post to the web site needs to consider all of laboratory medicine. Mid-career clinical laboratorians are needed to provide continuity when current HOG members rotate and a specialist in molecular testing is desirable. The Council, with HOG concurrence, agreed to invite Amy Saenger and Jason Park to join the HOG. Gary Myers will coordinate the invitations. A specialist in coagulation would be appropriate to consider in the future.
- 3. A discussion on how to solicit new Organizational Members concluded that web improvements were needed to allow potential members to review and understand the role of organizational members. Large national organizations

such as in molecular diagnostics, coagulation or WASPALM should be invited to consider becoming Organizational Members.

Joe Passarelli pointed out that in Europe new regulations in 2018 would likely limit IVD manufacturers' representatives from participation in professional organizations where they might have a role in decisions by that organization. The impact on ICHCLR is unclear but we recognize that participation by IVD manufacturers in harmonization activities is essential for success.

- 4. Gary Myers will follow up with a list of organizations with active harmonization activities that were solicited for current activities to post to the web site.
- 5. The harmonization.net web site updates have been difficult and slow to get from the AACC team. At this point it will be 2107 before some of the basic improvements will be addressed by AACC. The HOG/Council agreed to investigate a 3rd party web provider to improve the responsiveness of web site information. The web site is an essential tool to disseminate the work of the ICHCLR and must be very responsive to changes and updates.
- 6. The process for prioritizing measurands was reviewed. IN general the current process based on most frequently ordered tests is working well. The main limitation is inability to disseminate information via the web site. Going forward emerging biomarkers and measurands in other disciplines will be addressed.
- 7. A joint meeting with JCCLS is scheduled for November 4 in Tokyo. Drs. Myers and Miller will attend to promote the work of ICHCLR particularly in JCTLM, ISO and regulatory related areas.
- 8. A similar joint meeting with KSLM is planned for October 18-20, 2017 in conjunction with their national conference.
- 9. Council members reviewed the annual 50,000 USD contribution and concluded the amount was appropriate for the work of the ICHCLR.
- 10. Conference call meetings will resume in the fall to continue the prioritization and related work.