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

DATE: 21 October 2014
TIME: 7:00 a.m. to 8:00 a.m. ET

HOG Members:

Dr. Greg Miller (Chair)
Joseph Passarelli, MS
Dr. Stephen Master
Dr. Ian Young
Dr. Linda Thienpont

ICHCLR Council Liaisons:

Dr. Gary Myers - AACC
Dr. Tony Killeen - CAP

AACC Staff:
Ms. Ashlie Doran (Scientific and Practice Affairs Coordinator)

Minutes:

1. **Welcome**
   Dr. Miller thanked everyone for joining the conference call. Unfortunately there were technical issues that prevented Dr. Eunice Lee and the JCCLS group from connecting. Following the call, Drs. Myers and Miller decided to investigate alternate systems for future international conference calls.

2. **Status of HIGs**
   Dr. Master shared via email prior to the call that he spoke with Dr. Andy Hoofnagle several weeks ago about ongoing efforts to harmonize thyroglobulin. Dr. Hoofnagle indicated that the Mayo Clinic, University of Washington, Quest, ARUP and others, including Carol Spencer (with her own RIA), are participating in a baseline study to assess the agreement among a group of common immunoassays using 80 to 200 human samples. Dr. Master said it appears that this is a well-organized and significant effort involving the major technologies based on both LC-MS/MS and commercial immunoassay methods. It was suggested that the ICHCLR website measurand table should identify this effort. We can consider approaching this group for interest in forming a HIG to formalize the initiative if it is decided to pursue a harmonization activity based on the assessment results.

   Mr. Passarelli indicated that Dr. Eef Lentjes, hGH HIG chair, had contacted one of his Roche colleagues. Dr. Miller said that he would follow-up with Dr. Lentjes for an update.

3. **Future Direction**
   Dr. Myers shared that the ICHCLR budget for 2015 is complete under the secretariat of the AACC. He emphasized that AACC is committed to its role as secretariat and as a member of

the ICHCLR Council. However, AACC leadership is concerned about the potential risk of becoming financially obligated to a HIG project that might be unable to reach completion due to insufficient fundraising to sustain the project after it had been initiated. AACC leadership suggested that ICHCLR obtain the necessary funding to complete a HIG project in advance of beginning the work.

Dr. Young highlighted that the IFCC has a lot of experience in harmonization/standardization. They commit to a working group and raise funds, as ICHCLR projected to do. IFCC accepts the risk that a project may not go to completion for technical or financial reasons; however, nearly all IFCC standardization projects do go to completion. If a project does not complete, it can be restarted again when the circumstances change. He also commented that it is difficult to predict the total cost or timeline for harmonization projects because some technical challenges are identified as a project progresses. He stated that IFCC would be prepared to take up the task of harmonizing human growth hormone, if it is considered a priority.

Mr. Passarelli added that funds committed by Roche, and similarly by other IVD manufacturers, to support such external projects are budgeted on an annual basis. He stated that it would be highly unlikely for a company to cover in advance the entire projected costs over several years associated with a harmonization effort. He also indicated that a manufacturer recognizes that such projects usually require several years to come to completion and they expect to renew the funding on an annual basis accordingly. Dr. Myers indicated he had conveyed these budgeting considerations to the AACC leadership during budget discussions.

Mr. Passarelli suggested that collaboration to streamline the FDA review process could be very valuable to the IVD industry and to promoting harmonization efforts in general. Dr. Myers commented that we had initiated discussion with the FDA and IVD industry (see www.harmonization.net resource tab) and that he, Dr. Miller and other members of staff are scheduled to continue the follow up at a meeting with the FDA on Thursday, October 23. Mr. Passarelli also suggested that education regarding and promotion of the medical value to patients of harmonization of high priority analytes would benefit patients, providers, regulatory agencies and the IVD industry.

The group concluded that even without HIGs, the ICHCLR can bring substantial value to the harmonization/standardization process by continuing to develop a prioritized list of analytes in need of harmonization and a list of standardization/harmonization activities being conducted by different organizations and research groups around the world. Such information is currently not available. In addition, working to streamline regulatory requirements for implementing harmonization, developing tools and processes for harmonization and advocating for the clinical and financial benefit of harmonization are important and valuable activities to contribute to advancing laboratory medicine.

The group agreed that in the year ahead, the HOG and Council would focus on developing and implementing a systematic approach to prioritization of measurands for harmonization/standardization, and continue to expand the list of activities being conducted by different groups globally. Suggestions to pursue for a systematic approach included contacting EQA providers to identify analytes that are poorly harmonized among different laboratories and methods, and reviewing clinical practice guidelines for laboratory tests that are critical for implementation but may not be adequately harmonized. Following the call, an email was received from Eunice Lee that recommended these same suggestions for focusing the work of the HOG.

4. **Next conference call meeting: Nov. 18 at 7-8 AM US Eastern Time (Note: daylight saving time ends November 2 in the US)**
    - HIGs Status
    - Develop new system to prioritize measurands
    - Discuss EQA providers
    - Update from AACC staff discussions with FDA