International Consortium for Harmonization of Clinical Laboratory Results
Harmonization Oversight Group - Organizational Conference Call
Monday, August 26 8:00AM-8:50AM EDT (USA)
Call Minutes

Members Present:
Greg Miller – Chair, HOG
Eun-Hee Lee
Stephen Master
William Rosner
Joseph Passarelli
Thomas Scholl
Linda Thienpont
Ian Young

AACC Staff:
Gary Myers – Chair, ICHCLR Council, staff liaison to HOG

Members Excused:
Sverre Sandberg

AGENDA DISCUSSION:

1. Greg led a discussion regarding the role, responsibilities and make-up of the Strategic Partners Group (SPG). There was concern expressed by the group as to how the process would work to obtain approval of harmonization work products by members of the SPG. Would there be problems if the decision was simply a yes or no vote? What would the implications be if one or a small minority of SPG members voted to reject a work product at the end of a multi-year work effort? Greg indicated he had carefully reviewed the JCTLM website and found no requirements stating that organizations submitting reference materials for consideration by JCTLM must be from an organization that maintains a process for international voting by members to approve work products. Ian confirmed that JCTLM has no such requirements. The only criteria for acceptance by JCTLM are conformance to ISO standards such as ISO 15194. In light of this determination, the HOG decided that voting by the SPG members to approve a harmonization work product was not needed. The SPG key responsibilities will be to submit measurands for harmonization, submit names for HOG membership, and to provide comments on initial harmonization project plans and on project milestone updates from HIGs. In this manner, the SPG would have a substantive role and provide input to projects as they progress. . The HOG will assume full responsibility to approve, modify or cancel a HIG project and for final approval of harmonization work products.

2. The discussion turned next to qualifications for membership in the SPG. It is important that we demonstrate global interest and support of the ICHCLR harmonization effort through enrollment of members in the SPG. In light of the change in role of the SPG, it was decided to allow interested individuals and organizations join the SPG. Membership dues for 2013-2014 will be $500.00. It was felt that until we see what interest there was

in joining the SPG, we should not establish a limit on the number of potential members. Greg will develop and circulate for comment edits to the SPG description on the website.

3. The group next addressed the requirements for JCTLM approval of reference material submissions. Greg reviewed his communications with Linda concerning the submission and review process for JCTLM, and how to broaden the requirements of JCTLM to apply to the approaches developed around harmonization. JCTLM maintains a List I for SI-traceable reference materials (with assigned values by a RMP), and List II for reference materials for which values of the measurands are not SI-traceable but are assigned by or traceable to an internationally agreed upon protocol. Linda suggested that a 3rd list be established that would list measurands with a harmonization process supported by a panel of patient sera with a scheme for value assignment that is not SI-traceable. The HOG expressed interest in proposing a modification to the JCTLM WG1 Quality Manual to add a List III. Changes may be proposed to the WG1 Quality Manual at any time.

4. Discussion then turned to the ISO process to revise a standard and to propose a new standard. Options include revising ISO 15194:2008 to include criteria for the use of patient samples or proposing the development of a new ISO standard to address harmonization by procedures other than certified reference materials and SI traceable reference measurement procedures, such as a process that uses patient panels for harmonization. The group felt developing a new work project was the preferred approach. Following the call, Greg learned that the ISO process is to submit a Preliminary Work Item (PWI) to the plenary session of TC212. If approved by the member countries, a PWI permits a draft document to be developed and then submitted to the TC when ready as a New Work Item Proposal (NWIP). If a NWIP is accepted, the clock starts on the ISO timeline for review by member countries and advancing through the draft and approval process. A PWI can be submitted by the end of September and be placed on the agenda for the TC212 meeting in November 2013 in Singapore. The PWI would need to come from a member country. Greg is a member of the US delegation who could be asked to submit the PWI.

5. It appears no dates remaining in 2013 will work for a face to face meeting of the HOG. Members on the call indicated the week of January 20, 2014 looked possible. Everyone was asked to hold this week open as a possible time to schedule the HOG and Council meeting. More information to follow.

6. The next conference call is scheduled for September 23, 2013 at 8:00AM EDT (US).

ACTION ITEMS REMAINING FROM AUGUST 12th CALL

7. Revise the document “Proposal for Participation 2Aug2012” currently on the web site to become an operating procedure.

8. Establish procedure for HOG review of measurand status table entries before posting to the web site.

9. Submit contacts for organizations working on standardization/harmonization activities in different countries to expand the information in the measurand status table on the web site.

10. Submit written comments on improvements to the web site.

11. Four members have agreed to serve initial 2 year terms (Greg, Bill, Sverre and Steve have volunteered).