

International Consortium for Harmonization of Clinical Laboratory Results
Harmonization Oversight Group - Organizational Conference Call
Monday, August 12 8:00AM-9:00AM EDT (USA)
Call Minutes

Members Present:

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

AACC Staff:

Gary Myers – Chair, ICHCLR Council, staff liaison to HOG

AGENDA ITEMS:

1. Greg and Gary welcomed everyone as members of the initial Harmonization Oversight Group (HOG)
2. Gary provided a brief program overview and history of the establishment of the ICHCLR. The information is substantially contained in the ICHCLR proposal for participation dated August 2012 that was distributed for the call and is available on the www.harmonization.net web site.
 - a. ICHCLR Council members include: AACC; Korean Society of Clinical Chemistry; College of American Pathologists; and Chinese Association for Clinical Laboratory Management
3. Greg reviewed the following responsibilities of the HOG:
 - a. Communication with the Strategic Partners Group (stakeholders) for submission of measurands for consideration and to report the status of harmonization for measurands.
 - b. Decisions on the priority of a measurand for harmonization based typically on input from a Special Working Group (SWG). Priority is based on clinical need for harmonization.
 - c. Decisions on the technical feasibility of harmonization based typically on input from a SWG.
 - d. Creation and oversight of SWGs to provide recommendations on prioritization and technical feasibility for harmonization of a specific measurand.
 - e. Obtaining and providing information on the status of harmonization activities for measurands already being addressed, and a link to the organizations addressing such measurands.
 - f. Typically referring standardization to another organization for a new high priority measurand for which a reference measurement procedure (RMP) can be developed,

- and providing information on the status and a link to the organization addressing such a measurand.
- g. Typically, soliciting funding for and creating a Harmonization Implementation Group (HIG) to develop and execute a harmonization plan for a new high priority measurand for which a RMP is not likely to be developed.
 - h. Submission of approved work products of HIGs to the Joint Committee for Traceability in Laboratory Medicine (JCTLM) for review and listing. There was discussion of the most appropriate mechanisms for approving work products and agreement that this topic needed further development.
 - i. Communication of harmonization issues and technical advances to regulatory bodies.
 - j. Dissemination of information on the status of harmonization activities being conducted by this or any other organizations to avoid duplication of effort.
4. A screen shot of the measurand table from the website was provided and a review of the current and planned features of the website was presented. It was suggested that the term “Active” be replaced with “In Progress” or “Ongoing” in the measurand status table. There was discussion regarding plans to enhance the coverage of the measurands in the table. Members were asked to submit comments/recommendations regarding the website in writing to Gary.
 5. Greg led a discussion of the following initial tasks the HOG will need to undertake.
 - a. Four HOG members will need to volunteer for initial 2 year terms to allow for staggered terms for HOG membership going forward.
 - b. Solicit stakeholders to join the Strategic Partners Group.
 - c. Solicit stakeholders to submit measurands for consideration.
 - d. Provide information on current activities by organizations to be added to the web site Summary of Measurands table.
 - e. Review the ICHCLR proposal document and provide suggestions for transitioning it to a standard operating procedure for the program.
 6. The dates of October 9-10 for an initial face to face meeting of the Council and HOG will not work so other potential dates will need to be considered.

ACTION ITEMS FROM CALL

1. Review responsibilities of Strategic Partners Group (SPG) and develop specific criteria to qualify as a SPG member.
2. Review JCTLM requirements for the approval process by a submitting body for harmonization work products to be submitted, and revise the operating procedures accordingly.
3. Establish procedure for HOG review of measurand status table entries before posting to the web site.
4. 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.
5. Submit written comments on improvements to the web site.
6. Submit comments and proposed edits to convert the ICHCLR proposal to an operating procedure document (Word version).

7. Send unavailable dates through the end of the year so that a poll for a face to face meeting can be prepared.
8. Four volunteers are needed to serve initial 2 year terms (Greg and Bill have volunteered).
9. The next HOG conference call will be, **Monday, August 26, 2013 at 8:00AM EDT, (GMT-5)**; primary agenda items to discuss are #1 and #2 above.