

Harmonization Oversight Group (HOG) Conference Call**DATE:** July 2, 2014**LOCATION:** Conference Call**TIME:** 7:00 – 8:00 AM EDT**HOG Members:**

Dr. Greg Miller (Chair)
Dr. Eun-Hee Lee (Vice-Chair)
Mr. Joseph Passarelli, MS
Dr. Thomas Scholl
Dr. Stephen Master
Dr. William Rosner
Dr. Ian Young
Dr. Linda Thienpont

ICHCLR Council Liaisons:

Dr. Gary Myers
Dr. Naotaka Hamasaki

AACC Staff:

Ms. Ashlie Doran (Scientific and Practice Affairs Coordinator)

Minutes:**1. Welcome**

Dr. Miller thanked everyone for joining the call.

2. Status of HIG for hGH

Dr. Miller circulated information in advance of the meeting on prior work and status of growth hormone harmonization efforts, largely provided by Dr. Linda Thienpont, including correspondence with Drs. Christa Cobbaert, Heinz Schimmel and Linda Thienpont. Dr. Miller met with Drs. Cobbaert and Thienpont in Istanbul during IFCC WorldLab meeting to discuss the project and a possible chair from the Netherlands, Dr. Eef Lentjes, who has been responsible for harmonization of hGH in the Netherlands. There was discussion if standardization by developing a reference measurement procedure or harmonization using reference sera was preferred for hGH. It was agreed to have the HIG consider the feasibility and time line for each approach and make a recommendation. The HOG approved the creation of a hGH Harmonization Implementation Group (HIG). Dr. Miller will contact Dr. Lentjes to invite him to chair the HIG. Subsequent to the meeting, Dr. Lentjes accepted the chair of this HIG to harmonize hGH.

Dr. Miller requested names of suggested experts to provide to the hGH HIG Chair to help in the formation of the HIG. The HOG suggested that people to consider for membership in this HIG should include those with experience in the Netherlands project, those with experience developing candidate LC/MS/MS reference measurement procedures for hGH, those who were formerly involved with the IFCC WG, those who have published recently on the subject and IVD industry scientists. People

mentioned for consideration included: LC/MS specialists: Andy Hoofnagle, Univ of Washington, USA; Cristian G Arsene and Andre Henrion, Physikalisch-Technische Bundesanstalt (PTB), Germany; Mario Thevis, Center for Preventive Doping Research – Institute of Biochemistry, German Sport University Cologne, Germany; authors of recent publications recommending harmonization: David R. Clemmons, Univ. of North Carolina, Chapel Hill, USA; Cathy Sturgeon, UK NEQAS, Gilbert Wieringa, Bolton NHS Trust, UK; Michael Rottmann, Roche Diagnostics; former member of IFCC WG: Akira Shimatsu, Japan. Dr. Miller will work with Dr. Lentjes to develop a list of candidates for membership in the HIG. The final list of proposed members for HOG approval will include CVs of the candidates.

3. Draft report on status of ICHCLR to be sent to SPG

Dr. Miller circulated a first draft report that was reviewed. It was agreed to be a good summary of progress to date. Dr. Young suggested to include planned future activities in the report to include monthly calls and the intention to create 2-3 HIGs in 2014, and 3 HIGs in each of 2015 and 2016. Dr. Miller will update the draft report and asked for any other edits to be sent in the next two days. Dr. Myers will follow up with AACC IT to determine how quickly prior HOG/ICHCLR Council conference calls' minutes can be posted to the harmonization.net website. The intention is to have quarterly status updates to send to SPG members and to post to the web site.

4. Status of identifying harmonization/standardization activities of other organizations to add to the web site measurand table

Dr. Myers and staff have contacted representatives from various relevant organizations for updates on their harmonization efforts and are awaiting information. Efforts will continue. As soon as information is received, they will update the harmonization.net measurand table. Dr. Miller noted that many of our contacts have busy schedules and persistence to gather information was needed. He suggested this topic be a standing agenda item. HOG members should continue to provide contacts at organizations to develop the web portal as an information resource.

5. Prioritization of measurands to form a second HIG

IGF-1 and rheumatoid factor were proposed for formation of a second HIG. Dr. Young said he would ask the relevant IFCC working group to comment on harmonizing rheumatoid factor. Dr. Rosner suggested that the hGH HIG could provide an initial recommendation on combining IGF-1 and hGH harmonization or having two HIGs. The HOG noted that it was important not to overburden one HIG to ensure good progress on a given harmonization project. Dr. Master agreed to do a preliminary literature review on IGF-1 after the AACC 2014 Annual Meeting at the end of July.

6. Agenda items for Chicago meeting (July 28; 12:00-14:30)

- Status of initial HIG for hGH
- Identification of additional high priority measurands for harmonization
- Continue to evolve the web portal measurand list and information on standardization/harmonization activities in other organizations

- Review of the Japanese multi-analyte project to harmonize routine tests; Dr. Hamasaki will invite guests involved with the project
- Discuss plans for funding HIG project for hGH

It was agreed that a conference call line would not be needed for this meeting; minutes would suffice.