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

DATE: 10 September 2014 TIME: 7:00 a.m. to 7:36 a.m. ET

| HOG Members: | ICHCLR Council Liaisons: |
|-------------------------|----------------------------|
| Dr. Greg Miller (Chair) | Dr. Gary Myers |
| Joseph Passarelli, MS | Dr. Naotaka Hamasaki |
| Dr. Stephen Master | |
| Dr. Ian Young | Guests: |
| Dr. Linda Thienpont | Dr. Seayun Baik for Dr. Eu |

Dr. Thomas Scholl Dr. William Rosner

Dr. Seayun Baik for Dr. Eunice Lee

AACC Staff:

Ms. Ashlie Doran (Scientific and Practice Affairs Coordinator)

Minutes:

1. Welcome

Dr. Miller thanked everyone for joining the conference call.

2. Review minutes from 28 July meeting

- a. In review of the Japanese multi-analyte project to harmonize routine tests, Dr. Hamasaki stated there were approximately 6,000, not 600 donors, as recorded in the minutes.
 - i. The minutes will be updated.

3. Status of HIGs for hGH and TG

Dr. Miller contacted Eef Lentjes, hGH HIG chair, for an update on the formation of the HIG. A few potential members have been contacted. In regards to corresponding members, Dr. Miller clarified that HIG membership does not include corresponding members. The intent is to have a small group of focused people who are able to move a project forward.

It was suggested that Dr. Miller draft an outline of HIG member responsibilities to assist chairs when contacting people to explain the responsibilities and commitment of HIG members. Dr. Miller will draw from the ICHCLR operating procedures to prepare a draft and will circulate it within the HOG for comment before external circulation.

Dr. Myers suggested providing Dr. Lentjes with the list of possible hGH HIG members developed by the HOG with the offer of AACC staff contacting the individuals to see if they are available to participate. Dr. Miller would make this offer to Dr. Lentjes and copy Dr. Myers.

Dr. Master expects to follow-up with Dr. Andy Hoofnagle within the next several days to discuss his interest in or recommendation for a chair for the thyroglobulin HIG. Dr. Master will provide an update afterwards.

4. Next analyte to form a HIG

In regards to autoimmune markers, Dr. Young spoke with Dr. Joanna Sheldon, an IFCC WG Chair of the Harmonisation of Autoantibody Tests (WG-HAT) from the UK. They are working on a range of autoimmune markers and developing reference materials. Work on reference materials for anti-beta 2 GP1 (also called anti-apoH) and anti-myeloperoxidase is in the advanced stage. Other biomarkers being considered include anti-double-stranded DNA and anti-CCP. Anti-ds DNA had a WHO reference material in the past.

Dr. Young suggested it may be helpful if there were a more formal process of prioritization of autoimmune markers. Dr. Miller indicated the ICHCLR could play this role. It would be helpful for the IFCC WG or other stakeholders to submit analytes to the ICHCLR to initiate a prioritization process. Dr. Young will speak to Dr. Sheldon again. He'll ask for what she considers top priorities as well as a complete overall list of autoimmune markers. He will also contact immunologists independent of the IFCC's WG for a list, as well.

Dr. Master asked about the status of harmonization efforts of IGF-1. The IFCC had a working group on IFG-1, Dr. Young said. Unfortunately, the level of activity was low and the working group was closed. Dr. Young said the same experts on growth hormone, after that HIG is formed, could be asked to consider IGF-1.

For additional analytes to consider, Dr. Myers suggested that perhaps AACC staff could contact other clinical societies and ask them within their area of concern what tests they would feel could benefit from harmonization and what lab tests are critical in practice guidelines. Dr. Young suggested asking EQA organizations to identify the analytes with the greatest variability in results. Both suggestions will be pursued.

Dr. Miller requested relevant contact information be shared, especially for those outside the USA.

5. Next conference call meetings: Oct. 21, Nov. 18, all at 7-8 AM US Eastern Time (Note: daylight saving time ends November 2 in the US)