

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

DATE: July 28, 2014

LOCATION: Chicago, IL

TIME: 12:00 – 2:30 PM CDT

HOG Members:

Greg Miller (Chair)
Eun-Hee Lee (Vice-Chair)
Joseph Passarelli, MS
Stephen Master
Ian Young
Linda Thienpont

ICHCLR Council Liaisons:

Gary Myers
Anthony Killeen
Naotaka Hamasaki

Guests:

Tetsuro Sugiura, Kochi Univ.
Katsuyuki Nakajima, JCCLS
Hirofumi Koide, JCCLS
Tomonori Mimura, Hitachi
Katsuhiko Mochizuki, Fujirebio

Minutes:

1. Welcome

Greg Miller thanked everyone for attending the meeting. He informed the group that the first SPG status report was sent on 11 July 2014 and also posted to the web site. In addition, a paper by Cas Weykamp et al. and an accompanying editorial by Ingrid Zegers and Heinz Schimmel were published in the July issue of *Clinical Chemistry* that used the ICHCLR toolbox in a harmonization project for carbohydrate deficient transferrin sponsored by the IFCC. The same issue included a Q&A on harmonization featuring comments from HOG members Greg Miller, Ian Young, Joseph Passarelli and William Rosner.

2. Status of HIG for hGH

Eef Lentjes, who has been responsible for harmonization of hGH in the Netherlands, accepted the chair of this HIG to harmonize hGH. The list of possible members from the last HOG call were sent to Eef. He will propose members of the HIG to the council for approval. Greg will follow up with him following this meeting. The next step after formation of the HIG will be to prepare a draft harmonization plan that can be used to solicit funding.

3. Approaches to solicit funding for a HIG

Some of the costs that were identified included: internal costs for participants to perform measurements; procurement of patient samples and pools; volunteer time to obtain samples; development of reference materials; distribution of materials. Attributes to build into projects included: reliable cost estimate; written commitment to complete the steps; hold all participants accountable to the agreed timeline. It was suggested to investigate if labs such as Mayo or ARUP could

upgrade clinical routine IDMS procedures to reference measurement procedure performance for high priority analytes identified for HIG formation.

Possible funding sources to consider for a given project included: IVD manufacturers, pharmaceutical manufacturers, SPG member organizations, metrology institutes especially if a reference material would be developed for sale, clinical societies, charities and non-governmental organizations focused on patient care issues and impact, NIH or other research funding agencies. Ian Young offered that IFCC has a list of contacts within IVD companies to approach; AdvaMedDX or other trade associations may be of assistance with contacts.

4. Identify the next measurand to form a HIG, and other high priority measurands to consider

Thyroglobulin was chosen as the next analyte to develop a HIG. **Steve Master** will contact Andy Hoofnagle regarding current status of IDMS to develop into a reference measurement procedure and for his interest in or recommendation for a chair. Possible funding sources include NIH Office of Dietary Supplements or NIST.

Other measurands to consider included: Calprotectin, **Ian Young** will follow up; CRP; autoimmune markers, **Tony Killeen and Ian Young** will follow up. **Review of analytes with method specific reference intervals was suggested as a way to identify candidate analytes for harmonization.**

5. Web portal measurand list and information on standardization/harmonization activities in other organizations

The measurand table will change measurand to analyte. Staff will continue to contact other organizations for input; suggested contacts included: metrology institutes; International Council for Standardization in Haematology (note they will meet in Chicago in May 2015); NIBSC, Chris Burns; LGC, Helen Parks. HOG and Council members were asked to provide contacts they are aware of.

6. Council and SPG financial structure

The relative annual contributions of Council and SPG were discussed. The original goal for Council members was to provide the funding for administrative overhead for operation of the ICHCLR and to be free of perceived influence from IVD industry. The HOG, whose functions are supported by the administrative overhead, is required to have IVD industry representation. The initial organizational meeting of a HIG will be funded as administrative overhead; but the harmonization work will be funded by contributions from sponsors for each project. The SPG annual fee was set relatively low to encourage participation by a large range of stakeholders with different financial resources and recognizing that some SPG members would likely fund specific HIG harmonization activities. The annual contributions consistent with ICHCLR goals will be reviewed as plans and budgets for ICHCLR operations are developed for 2015 and 2016.

7. Review the Japanese multi-analyte project to harmonize routine tests

The JCCLS has developed a harmonization scheme for approximately 30 analytes measured in primary care medicine. In summary, conventional secondary reference materials were prepared as pools of sera from approximately 6000 donors collected at a Red Cross blood donation center. The abnormal concentration pool was prepared by supplementing the base pool. Value assignment was by 45 labs that were certified by JCCLS or the Japanese Society of Medical Technology. Traceability of calibration was by recovery of target values for various international certified reference materials. Use of the conventional secondary reference materials as calibrators for a range of routine laboratory measurement procedures produced good harmonization of results for most of the analytes measured in a panel of 30 individual patient sera among 165 labs. Assessment of commutability for the conventional secondary reference materials was included in the study. The JCCLS plans to expand the program throughout Japan in the years ahead. The recommendation from the HOG to the JCCLS was to publish the results in an international journal as the basis for a submission to JCTLM to list the conventional secondary reference materials.

8. **Next conference call meetings: Sept. 10, Oct. 21, Nov. 18, all at 7-8 AM US Eastern Time (note that daylight saving time ends November 2 in the US)**