

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

DATE: 29 April 2020

TIME: 08:00-08:50 a.m. USA EDT

HOG Member	Present	Council Member	Present
Greg Miller (chair)	x	Gary Myers (chair, AACC)	x
Eunice Lee (Vice-Chair)	x	Gye Chol Kwon (KSLM)	
Joseph Passarelli	x	Akira Seki (JCCLS)	x
Steve Master	x	Sverre Sandberg (IFCC)	
Ian Young	x	Tony Killeen (CAP)	
Masato Maekawa			
Philippe Gillery (IFCC SD)	x		
Anja Kessler	x		
Melissa Snyder	x	Observer	
Yeo-Min Yun		Loretta Doan (AACC)	
Andy Hoofnagle	x	Katsuyuki Nakajima (JCCLS)	
Amrom Obstfeld	x		
Ross Molanaro			

Minutes:

Council activity:

1. The financial position of ICHCLR is good. Council agreed to suspend dues for 2020 for Council and Stakeholder members. Dues notifications for 2021 will be issued in the next months to provide lead time for members' budgeting.
2. Two nominations for HOG members are under review by the Council.

HOG activity:

1. A draft summary of the meeting of Greg Miller and Gary Myers with the US FDA on Jan 31, 2020 will be sent to the FDA for review before posting to the web site.
2. A guidance document on experimental design for a standardization/harmonization project that can ensure that data from the validation experiments will be suitable for

submission to regulatory bodies is planned. This guidance was suggested during the above meeting with the US FDA. Greg will prepare a draft description of goals that other HOG and Council members can use to identify appropriate specialists with technical and regulatory expertise to form a task force to develop such guidance.

3. Gary Myers will contact the IMDRF for information on contacts with regulatory bodies in different countries. ICHCLR intends to develop a process to inform regulatory bodies of work in progress to facilitate the regulatory process that is important for final implementation.
4. The workshop on challenges to harmonization originally planned in conjunction with IFCC WorldLab in Seoul May 2020 has been cancelled. The workshop will be rescheduled in 2021.
5. ICHCLR and EQALM signed a memorandum of understanding in 2019 to develop a program to aggregate EQA data from different countries as feedback on harmonization status. A manuscript on the pilot study is ready to submit. The next step will be to create a joint task force to continue the work. HOG members interested to participate should let Greg know.
6. A structured checklist for review of information relevant to our measurand prioritization process was developed and added as page 2 of the HOG measurand evaluation form sent to HOG and Council members with these minutes.
7. A structured assignment of measurands to HOG members was agreed. Each member will produce a draft recommendation for discussion at specified HOG meetings.
8. HOG members self-declared their expertise to assist to identify where additional HOG expertise should be recruited.
9. The next ICHCLR web meetings are: May 28; June 22.