

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

**DATE:** 03 March 2020

**TIME:** 08:00-08:55 a.m. USA EST

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

**Minutes:**

Council activity:

1. Email solicitation was sent in early January to current ICHLCR members to ask persons interested to join the HOG to send us a letter and CV for consideration. Seungman Park, MD, Specialist of Laboratory Medicine, Laboratory director, department of molecular microbiology, GreenCross Laboratories, Korea, was approved as a new member of the HOG.
2. Two other nominations for HOG members are under review by the Council
3. An additional 3 year term was approved for HOG members Joe Passarelli, Ian Young and Steve Master.
4. Greg Miller's term as HOG chair was extended 1 year.
5. Gary Myers term as Council chair was extended 1 year.

HOG activity:

1. A draft summary of a meeting of Greg Miller and Gary Myers with the US FDA on Jan 31, 2020 was reviewed. The draft will be sent to the FDA for review before posting to the web site. The focus of the meeting was on simplification of the review process for implementing calibration adjustments based on international standardization/harmonization projects. ICHCLR and FDA agreed that standardization and measures to expedite implementation were important. The following were discussed on the call as next steps that ICHCLR could facilitate.
  - a. A guidance 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 will be useful. We agreed to set up a task force to develop such guidance in collaboration with stakeholders. 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 develop such guidance. The guidance could take the form of an ISO TC212 new work item proposal.
  - b. The FDA indicated they would like to be informed about standardization/harmonization projects in development. One approach within the IFCC SD process is to become corresponding members of committees and working groups. ICHCLR will develop a process to inform regulatory bodies of work in progress to facilitate the regulatory process that is important for final implementation. We will contact the IMDRF for information on contacts with regulatory bodies in different countries.
  - c. We discussed that a coordinated implementation plan with education of labs and practitioners was important when implementing standardization/harmonization projects. This activity can be challenging for all involved. We agreed that a task force to address this challenge would be set up following the work to develop guidance for experimental designs mentioned in item (a).
2. The intention to provide information on the web site identifying EQA programs that use commutable samples was discussed. Some challenges include: minimum experimental evidence and criteria to conclude samples are commutable, what assumptions are acceptable when preparing samples, for what concentrations of EQA samples must commutability data be available, what time interval is appropriate to carry forward a commutability assessment conclusion for new batches, what evidence is needed for stability of commutability during the use period of EQA samples in participant labs. We

decided to defer pursuing this information service until more information is available on these challenges. We will suggest that some of these points be considered by the IFCC WG on Commutability.

3. Deferred from the previous call. We agreed to develop a structured checklist or approach to our measurand prioritization process. Brainstorming regarding components of our measurand review process developed a list to be evolved into a structured measurand review template over the next few calls.
4. We discussed that review of measurands for harmonization status and priority needs to receive additional focus from HOG members. Each member will review previous measurand assignments with a goal for each member to prepare one review for each call.
5. Greg will poll to set up the next ICHCLR calls.