

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

**DATE:** 11 December 2019

**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		Sverre Sandberg (IFCC)	
Ian Young	x	Tony Killeen (CAP)	x
Masato Maekawa			
Philippe Gillery (IFCC SD)	x		
Anja Kessler			
Melissa Snyder		<b>Observer</b>	
Yeo-Min Yun		Loretta Doan (AACC)	
Andy Hoofnagle	x	Katsuyuki Nakajima (JCCLS)	
Amrom Obstfeld	x		
Ross Molanaro			

**Minutes:**

Council activity:

1. Biobase Biodustry in China has joined as a new Stakeholder member. ICSH has indicated they will join as either a Council or Stakeholder member.
2. The Council has approved revising the Operating Procedures to allow extension of Council Chair, HOG Chair and HOG Vice-chair for 1 additional year in exceptional circumstances. The Council approved extending Greg Miller as HOG chair for 2020.
3. The current Operating Procedures allows the Council to extend the terms of HOG members on request from the HOG chair to ensure continuity of HOG expertise. Greg Miller requested that terms be extended for Joe Passarelli, Ian Young and Steve Master.

HOG activity:

1. Several ICHCLR members attended the JCTLM Members and Stakeholders meeting in Paris December 2-3. ICHCLR is a Stakeholder member of JCTLM. Key points from the meeting included:
  - a. Over 100 countries have regulations for selling IVD devices. IVD manufacturers have to comply with regulations in different countries. The complexity of compliance with different regulations in different countries was recognized as an important challenge to implementing harmonization or standardization initiatives. The workshop on barriers to harmonization organized by the ICHCLR and IFCC in May 2020 is intended to discuss and make recommendations on regulatory challenges. However, the organizers are having difficulty to identify regulatory experts able to attend the workshop. Gary and Greg plan to visit the US FDA in January 2020 to discuss how to engage regulators to harmonize regulations associated with harmonization of IVD test results. We will propose a joint conference with FDA and possibly other organizations such as the International Medical Device Regulators Forum (IMDRF) to address harmonization of regulations.
  - b. There was discussion of the importance of prioritizing measurands in need of harmonization and having a portal to share information on harmonization/standardization activities by different organizations. Since these are two key goals for ICHCLR, we need to continue our work and expand the recognition of ICHCLR.
  - c. We were asked how we evaluate priority of measurands and if we used an algorithm. Our response was expert opinion of HOG members. However, the inquiry emphasized that we need to develop a structured checklist or approach to our 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.
2. Email solicitation will be sent in early January to current ICHCLR members to ask persons interested to join the HOG to send us a letter and CV for consideration. Expanding the HOG expertise will occur in 2020.
3. Measurand recommendations were reviewed for: ionized calcium to be posted to the web site; Chlamydia trachomatis PCR to which Eunice will add EQA data; Theophylline with added EQA data to be reviewed by Yeo-Min; and BCR-ABL that Tony will further enhance regarding coordination among groups currently addressing harmonization.

**Follow-up pending from our previous calls.**

4. A resources page to recognize and promote EQA with validated commutable samples is planned for the web site.
5. A letter requesting nominations for new HOG members will be sent to Council and Stakeholder members.
6. The Table below shows measurand assignments for prioritization recommendations for review by HOG and posting to the measurands table.

**Next conference call meeting:** to be arranged

<b>Measurand</b>	<b>Assigned to</b>
Hemoglobin and CBC parameters, blood – POCT to do	Amrom
Iron saturation	Amrom and Greg
Iron binding total	Amrom and Greg
Apolipoprotein A1 and B	IFCC WG
Pseudocholinesterase	
Calcium urine	Anja
Chloride urine	Anja
Glucose, urine	Anja
Pregnancy associated plasma protein A (taken down)	Eunice?
Chlamydia; for STD	Eunice
Folate (taken down)	Greg
Vitamin B12	Greg
Iron	Greg
Protein urine	Greg

<b>Measurand</b>	<b>Assigned to</b>
Creatinine, urine	Greg
Lactate dehydrogenase	Ian
Lipoprotein(a)	Ian
Compliment CH-50	Melissa
anti-nuclear antibody (taken down)	Melissa
Anti SS-A	Melissa
cytokeratin fragment 19 (CK19F)	Melissa
Elastase 1	Melissa
Elastase 2	Melissa
HIV-1 genotype	Steve
Albumin, CSF	Steve; Likely dependent on urine and serum albumin harmonization
BCR/ABL	Tony
Hepatitis A Ab IgM	Tony and Melissa
Hepatitis A Ab IgG	Tony and Melissa
Hepatitis A Ab (Total)	Tony and Melissa
Hepatitis B core IgG and IgM	Tony and Melissa
Hepatitis B core Ab	Tony and Melissa
Hepatitis B DNA quant	Tony and Melissa
Hepatitis C Ab	Tony and Melissa

<b>Measurand</b>	<b>Assigned to</b>
Drugs: acetaminophen, salicylate, tobramycin, gentamycin, benzodiazepine, amphetamines, tacrolimus, serolimus, lidocaine, methotrexate, N-acetylprocainamide, procainamide, primidone, quinidine, valproic acid, amikacin, barbiturates, cyclosporine, cocaine urine, methadone	Yeo-Min