

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

DATE: 22 January 2019

TIME: 8:00-9:00 a.m. USA EST

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

Minutes:

Council activity:

1. Dr Ross Molinaro (Siemens Healthineers) is a new HOG member.
2. Dr. Gye Chol Kwon, new president of KSLM, replaces Dr Junghan Song as Council representative from KSLM.

HOG activity:

3. ICHCLR and IFCC SD are developing a conference proposal for a satellite meeting following the IFCC WorldLab 2020 Seoul (WorldLab is 24-28 May, satellite meeting planned for 29-30 May 2020). The planning group consists of Greg Miller, Gary Myers, Jim Pierson Perry, Christa Cobbaert, Philippe Gillery. The draft agenda will be reviewed when available.
4. Greg will attend the BIPM Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology (CCQM) meeting in Paris France 10-12 April

2019 to discuss harmonization approaches, prioritization and synergies between ICHCLR/IFCC SD and metrology institutes. A special session has been organized to address these items. Philippe and Howard will also attend.

5. A task force was established to develop a process to aggregate EQA data from commutable programs for feedback to the IVD industry to provide assessment of harmonization status. The task force members are: Greg Miller, Cas Weykamp, Sverre Sandberg, Finlay MacKenzie. EQALM is interested to collaborate on this activity.
6. Text was agreed to be added to the measurands table first paragraph as follows: “The harmonization status shown in the table reflects the situation in economically well developed countries and other geographic areas when measurement procedures supplied by global IVD manufactures are used. The harmonization status may be different when reagents, calibrators and instruments from other suppliers are used.”
7. The term “Adequate” for harmonization status on the web site was discussed. The term “Adequate/Maintain” will be substituted with an expanded footnote explanation that reference systems in place must be maintained to ensure the status remains adequate. In addition, the footnote definitions will be moved to a paragraph in the introduction to the table to ensure the terms in the measurand table are understood properly.
8. Our practice has been not to include on the web site an entry for medical impact (priority) of harmonization when the status is “Adequate.” This omission could have an impression that sustained harmonization and standardization reference systems are not needed which is not correct. The group agreed to add back a medical impact for all measurands. Measurands with blank priority will be reviewed on the next call.
9. Greg will request having the default measurand table sorted by “Harmonization Status” with measurands with “Needed” status on the first page.
10. A measurand summary for Anti-myeloperoxidase (MPO) antibody, IgG was reviewed and minor edits suggested. Melissa will make the edits and contact the chair of the IFCC Committee on Harmonization of Autoimmune Tests for current activity. The updated information will be posted to the web site.
11. The Table below shows measurand assignments for prioritization recommendations for review by HOG.

Next conference call meetings: all 8 AM USA Eastern time: 2019; Feb 25, Mar 25, Apr 29

Measurand	Assigned to
Hemoglobin and CBC parameters, blood – POCT to do	Amrom
Hematocrit	Amrom
Iron saturation	Amrom and Greg
Iron binding total	Amrom and Greg
Apolipoprotein A1 and B	Amy
Pseudocholinesterase	Amy
Calcium urine	Amy
Chloride urine	Amy
Compliment CH-50	Amy & Melissa
Glucose, urine	Anja
Calcium, ionized	Anja will provide additional EQA data to support the recommendation draft from Greg
Chlamydia	Eunice
HBV Ag and anti-HBs AB	Eunice
Vitamin B12	Greg
Iron	Greg
Protein urine	Greg
Creatinine, urine	Greg
Hemoglobin, plasma free	Greg was not able to find suitable information of harmonization status

Measurand	Assigned to
Methemoglobin	Greg was not able to find suitable information on harmonization status
Lactate dehydrogenase	Ian
Lipoprotein(a)	Ian
Anti SS-A	Melissa
cytokeratin fragment 19 (CK19F)	Melissa
Elastase 1	Melissa
Elastase 2	Melissa
IgA	Melissa
IgG	Melissa
IgM	Melissa
HIV-1 genotype	Steve
Beta-2 microalbumin	Steve; difficult to find information
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

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