

SCIENTIFIC DIVISION

53rd MEETING Istanbul, Turkey (2014 06 20-21)

MINUTES (*Final Draft*)

Members:	Abbr.	Term and Time of Office
Ian YOUNG (UK) (Chair)	IY	2 nd 2014 01 - 2016 12
Philippe GILLERY (FR) (Vice-Chair)	PG	2 nd 2014 01 - 2016 12
Gary MYERS (US) (Secretary)	GLM	2 nd 2012 01 - 2014 12
Christa COBBAERT (NL)	CC	1 st 2012 01 - 2014 12
Naotaka HAMASAKI (JP)	NH	2 nd 2012 01 - 2014 12
Giampaolo MERLINI (IT)	GMI	2 nd 2014 01 - 2016 12
Joseph PASSARELLI (US) (Corporate Rep.)	JP	2 nd 2013 01 - 2015 12
David BUNK (NIST Representative)	DB	Consultant
Heinz SCHIMMEL (IRMM Representative)	HS	Consultant
Mathias MÜLLER (JCTLM Representative)	MM	Consultant

EXECUTIVE SUMMARY - SCIENTIFIC DIVISION 53rd MEETING, ISTANBUL, TURKEY, JUNE 20-21, 2014.

Present: Ian Young (Chair), Philippe Gillery (Vice-Chair), Gary Myers (Secretary), Christa Cobbaert, Giampaolo Merlini, Joseph Passarelli (Corporate Representative), Mathias Müller (JCTLM Representative), Heinz Schimmel (IRMM Representative) and Ms Paola Bramati (IFCC Office) were in attendance. Apologies received from Naotaka Hamasaki.

5.4 EUROPEAN FEDERATION of CLINICAL CHEMISTRY and LABORATORY MEDICINE (EFLM):

The EFLM Scientific Committee and SD leadership agreed there should be close liaison and communication between the two groups. Minutes of the SD meeting in Bali were provided to the EFLM. Elvar Theodorsson, Linköping University, Sweden, is the new Chair of the EFLM Science Committee. The SD was advised EFLM is planning a meeting November 24-25, 2014 in Milano, Italy titled, "Defining analytical performance goals 15 years after the Stockholm Conference". This conference will be dealing with analytical performance goals and quality requirements.

6.1 WORLD HEALTH ORGANIZATION (WHO): There has been no contact from WHO concerning a meeting in 2014.

6.2 CLSI: The complete list of cooperative IFCC/CLSI joint projects is available on the IFCC website. The link to these projects is under CPD: [http://www.ifcc.org/ifcc-communications-publications-division-\(cpd\)/ifcc-publications/clsi-ifcc-joint-projects/](http://www.ifcc.org/ifcc-communications-publications-division-(cpd)/ifcc-publications/clsi-ifcc-joint-projects/)

6.22.1 JCTLM: The JCTLM Executive (6 December, 2013), established an ad-hoc WG on JCTLM Structure. The ad-hoc WG was established to consider the future development of the JCTLM and prepare proposals for: a) Increasing the impact of JCTLM activities; b) Considering the need for a wider scope and opening up for the participation of other international bodies charged with professional activities in laboratory medicine; c) Improving the efficiency of JCTLM activities; and d) Extended or alternative funding models for JCTLM activities.

6.22.2 JCGM: WG2 (on the VIM) has prepared a Plan of Work describing the development of a 4th edition of the VIM (VIM4), with an extended scope to encompass a limited number of concepts related to nominal properties and the creation of “the Annotated VIM3”, an html web tool based on the content of the VIM3, complemented by annotations.

6.22.3 BIPM Consultative Committees

SD received no correspondence from CCQM or CCU.

6.31 INSTITUTE FOR REFERENCE MATERIALS AND MEASUREMENTS (IRMM):

IRMM will play a role in implementation of the new EU IVD legislation. The changes in the IVD Directive regulations are held up between the European Council and the European Parliament.

6.33 NATIONAL INSTITUTE OF BIOLOGICAL STANDARD AND CONTROL (NIBSC)

NIBSC, previously part of the Health Protection Agency (HPA), is now a new center of the Medicines and Healthcare Products Regulatory Agency (MHRA) alongside the Clinical Practice Research Datalink (CPRD). The MHRA is an executive agency of the Department of Health, UK.

6.37 NATIONAL INSTITUTE FOR STANDARDS AND TECHNOLOGY (NIST):

NIST reported that 927e Bovine Serum Albumin (7% solution) was now available.

8.2 MAIN ACTIVITIES OF COMMITTEES:

8.2.6 C-NPU: The C-NPU developed a one-page document promoting NPU terminology and its use, titled: “Communicate lab results everywhere using the NPU Terminology”.

IUPAC and IFCC signed an agreement with regards to the database management. The terminology database is now on the IFCC server and searchable via the web.

8.2.11 C-MD: The C-MD is updating its website to improve links to AIMS and Molecular Centers' websites. The C-MD is developing content to add educational opportunities via the website. The Committee proposes developing a process for case studies illustrating key aspects in quality assurance for molecular testing which will include a survey of guidance documents used by members.

8.2.21 C-RSE: The C-RSE continues to work on two activities: 1) evaluation of the commutability of IRMM CRMs for ALT, LDH, and CK and 2) refinement of the pancreatic lipase reference method.

8.2.23 C-TLM: The annual Ring Trial for Reference Laboratories – conducted on behalf of the IFCC by the German RfB -was started in October 2013. Results will be published on the RELA website (<http://www.dgkl-rfb.de:81/>). C-TLM is collaborating with the IFCC Committee on Reference Intervals (C-RIDL) for the assignment of values to panels of sera from different ethnic population groups using reference measurement procedures. The C-TLM also continues to provide an interface between IFCC and the JCTLM Working Groups.

8.2.24 C-RIDL: The C-RIDL continues to work to establish regional reference intervals. These regional reference intervals should be traceable to reference measurement procedures where possible.

8.2.25 C-STFT: The C-STFT Chair organized a meeting of the C-STFT and interested IVD company representatives with the US Food and Drug Administration on March 6, 2014 to present an overview of the concepts/approaches for standardization and harmonization of FT4 and TSH assays, and report on the past activities. Minutes of the meeting were distributed.

8.3 MAIN ACTIVITIES OF WORKING GROUPS:

8.3.35 WG-HbA2: The recent activities of the WG-HbA2 have mainly concerned the development of the reference measurement procedure based on isotope dilution-mass spectrometry (ID-MS). Recombinant hemoglobins (HbA0 and HbA2) have been obtained and the purity and content of peptide was assessed in collaboration with the Physikalisch-Technische Bundesanstalt (PTB), the National Metrology Institute in Germany. Internal calibration was assured by the use of ¹⁵N labelled recombinant hemoglobins (HbA0 and HbA2).

8.3.36 WG-CDT: A meeting of the WG-CDT was convened at Schiphol Airport, Sheraton Hotel, October 31, 2013. Minutes of the meeting were distributed. Results of Study 6 were reviewed where the main goals were to test the sustainability of the network laboratories and test the success of harmonization for the CDT methods on the market. All methods delivered satisfactory results. It was concluded that harmonization (inter-method CV went down to 3.8%) and commutability was proven successfully.

8.3.39 WG-SAU: All activities of the WG-SAU are a joint effort with the NKDEP Laboratory Working Group. A manuscript on the results of the albumin adsorption study has been published. Robinson MK, Caudill SP, Koch DD, Ritchie J, Horton G, Eckfeldt JH, Sandberg S, Williams D, Myers G, Miller WG. Albumin adsorption onto surfaces of urine collection and analysis containers. Clin Chim Acta 2014;431:40–45. In addition a manuscript on the status of harmonization among commercial immunoassays for urinary albumin has been published, Bachmann LM, Nilsson G, Bruns DE, McQueen MJ, Lieske JC, Zakowski JJ, Miller WG. State of the Art for Measurement of Urine Albumin: Comparison of Routine Measurement Procedures to Isotope Dilution Tandem Mass Spectrometry. Clin Chem 2014; 60:471-480.

8.3.40 WG-PAPPA: Activity to develop a reference system for standardisation of PAPP-A measurement employed as a marker for prenatal screening have been very slow. SD is considering closing the WG-PAPPA.

8.3.42 WG-SIA: Establishment of a reference measurement procedure for serum insulin is on-going.

8.3.43 WG-TNI: Results from the cTnl pilot study will be presented in two papers side by side, paper 1 – harmonization status of cTnl assays; status post mathematical recalibration and paper 2 – commutability of cTnl candidate serum reference materials. The Troponin and Natriuretic Peptide tables on the IFCC website will continue to be updated by the WG-TNI.

8.3.45 WG-HAT: A meeting of the WG-HAT was held in Nice, France 27-28th March 2014. Minutes of the meeting were distributed.

Update on MPO material

- The reference material is made and bottled
- Value assignment is progressing
- WG needs to review the data for the 2nd anti MPO commutability study

Update on cardiolipin antibodies and beta-2 glycoprotein

- The polyclonal reference material is made and bottled
- 20-30mg of monoclonal protein is needed for value assignment (by mass spectrometry)

8.3.47 WG–cMSP: The current projects of the WG–cMSP include:

- Evaluate different procedures to collect, fractionate/enzymatically digest biological samples prior to quantitative mass spectrometry analysis.
- Evaluate the multi-site implementation of different quantitative mass spectrometry analysis including: the detection of hepcidin and the multiplex detection of proteins in blood, with a specific focus on apolipoproteins.
- Coordination with other proteomics initiatives (HUPO/EuPA, FP7) in particular regarding mass spectrometry based quantitative assays.

8.3.48 WG-PTH: The WG-PTH continues to work on developing a reference system for PTH. Activities include:

- Confirmation of commutability of WHO standard must be completed before IVD companies can use the material for traceability purposes.
- WG to prepare a publication on commutability of the WHO standard.
- The Mayo Clinic method for measurement of 1-84 PTH by immunocapture coupled with LC-MS/MS has been validated for clinical use, but is not being used routinely at Mayo. Sensitivity is 10 X less than most immunoassays. WG has decided to move on to another type of MS and get a second lab to set up the method.

8.3.49 WG–CSFP: The WG has completed a full validation, according to ICH guidelines, of the mass spec assays for CSF A β 1-42, on a Q Exactive instrument. This project was summarized in a manuscript published in Clinical Chemistry. Andreas Leinenbach, Josef Pannee, Thomas Dülffer, Andreas Huber, Tobias Bittner, Ulf Andreasson, Johan Gobom, Henrik Zetterberg, Uwe Kobold, Erik Portelius, and Kaj Blennow , on behalf of the IFCC Scientific Division Working Group on CSF proteins. Mass Spectrometry–Based Candidate Reference Measurement Procedure for Quantification of Amyloid- β in Cerebrospinal Fluid. Clin Chem 2014;60:987-94

8.3.50 WG–SBMA: This is a joint activity with the International Osteoporosis Foundation.. The National Bone Health Alliance (NBHA) also has a WG focused on bone marker standardization. All three organizations will be working collaboratively on this project. The American Society of Bone and Mineral Research (ASBMR) also have a WG, but not sure if ASBMR will join with other groups.

8.3.51 WG-COMM: The WG-COMM has established four Task Forces.

(TF1) Selecting patient specimens for inclusion in a commutability study

(TF2) Qualification of measurement procedures for inclusion in a commutability study

(TF3) Criteria to make a determination that a RM is commutable (or non-commutable). It was agreed that this TF should begin to develop recommendations although, to some extent, the application of criteria depends on the statistical approach used.

(TF4) Statistical designs to assess commutability

8.19 MEETINGS

8.19.53 53rd SD Meeting – Istanbul, Turkey, June 20-21, 2014

8.19.54 54th SD Meeting – Milano, Italy, November 7-8, 2014