

SCIENTIFIC DIVISION

65th MEETING

Conference Calls: July 1st (2pm - 5pm CET)
July 10th (2pm – 4pm CET)
Sept. 10th (2pm – 5 pm CET)
Sept. 15th (2pm – 5 pm CET)

MINUTES (FINAL)

Members:	Abbr.	Term and Time of Office	
Philippe GILLERY (FR) (Chair)	PG	2 nd	2020 01 - 2022 12
Christa COBBAERT (NL) (Vice-Chair)	CC	2 nd	2020 01 - 2022 12
Joseph PASSARELLI (US) (Secretary)	JP	2 nd	2018 01 - 2020 12
Barnali Das (IN)	BD	1 st	2018 06 - 2020 12
Konstantinos MAKRIS (GR)	KM	2 nd	2020 01 - 2022 12
Mario PLEBANI (IT)	MP	2 nd	2020 01 - 2022 12
Michael ROTTMANN (DE) (Corporate Rep.)	MR	1 st	2020 03 - 2022 12
Karen PHINNEY (NIST Representative)	KP	Consultant	
Heinz SCHIMMEL (JRC Observer)	HS	Observer	
Ian YOUNG (UK) (Chair JCTLM)	IY	Consultant	
Chris BURNS (UK) (NIBSC Representative)	CB	Consultant	
Greg MILLER (US) (ICHCLR Representative)	GM	Observer	
Yang Zhen (CN) (NIFDC Representative)	YZ	Observer	

EXECUTIVE SUMMARY - SCIENTIFIC DIVISION 65th MEETING

Conference Call – July 1st (2pm - 5pm CET)

Present: Philippe Gillery (Chair), Christa Cobbaert (Vice-Chair), Joe Passarelli (Secretary), Barnali Das, Konstantinos Makris (Members), Michael Rottmann (Corporate Representative), Karen Phinney (NIST Representative), Chris Burns (NIBSC Representative), Ian Young (SD Consultant/Chair JCTLM), and Greg Miller (ICHCLR Representative) were in attendance. Apologies received from Mario Plebani (Member), Heinz Schimmel (JRC Observer) and Yang Zhen (NIFDC Representative). Chris Burns could not attend the meeting on July 10.

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

The EFLM Science Committee and SD leadership once again agreed there should be close liaison and communication between the two groups. Professor Eric Kilpatrick is the EFLM SC chair. His third term is scheduled to conclude at the end of 2021. The Science

Committee is responsible for scientific matters within EFLM and projects which further the scientific development of EFLM (except those specifically related to quality management, which are the responsibility of the Quality Management Committee). Activities of the Committee particularly focus on promotion of research that translates the scientific results of clinical chemistry and laboratory medicine to clinical applications and improves patient outcomes through the appropriate use and interpretation of laboratory data in clinical practice. Within the EFLM SC, there are working groups on cardiac biomarkers, biological variation, test evaluation, personalized laboratory medicine and a number of others but the consensus of the SD is that these activities do not overlap with ours. The Working Group on Test Evaluation is chaired by CC who does not believe there is much overlap as the focus is more on how to generate clinical evidence rather than on analytical standardization. PG has been in contact with the chair of the EFLM SC. Approaches to avoid overlap and work collaboratively continue to be discussed and explored. A new Task and Finish Group was established to address the measurement uncertainty for Medical Labs ISO document with Prof. Graham White as the main author (ISO/TS 20914:2019: Medical laboratories — Practical guidance for the estimation of measurement uncertainty).

6.1 WORLD HEALTH ORGANIZATION (WHO):

The WHO meeting occurs each autumn. PG attends and participates as the liaison from the SD. CB is also a full member of the WHO Expert Committee on Biological Standardization (ECBS) and provides a complete update from the WHO to the SD. There was a call for public comment with respect to the WHO Model List of in Vitro Diagnostics - https://www.who.int/medical_devices/diagnostics/selection_in-vitro/selection_in-vitro-meetings/sage-ivd-2nd-meeting/en/.

CB commented that there have been some changes in the Secretariat for ECBS. The meeting in Geneva in October will not happen but will be split into two virtual meetings. The first will be in August but focused specifically on COVID-19 reference materials. CB also mentioned that the WHO is almost completely focused on COVID-19 for the time being until the pandemic situation subsides.

6.2 CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI):

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/).

The proposal to update the CLSI EP28 guidance document on reference ranges to reflect recent advances from IFCC C-RIDL and other content was not accepted due to the very large estimated size of the revised document. Instead, CLSI made a counterproposal to split the intended revision content into two separate documents:

- Establishment/verification of reference ranges for a single population
- Multicenter studies for expanded reference ranges across regions, nations, etc.

Dr. Ozarda, Chair of the IFCC C-RIDL, will update the proposal to focus on the first topic and submit it back to CLSI. She will serve as the Vice-Chair of the revision project once it is approved to begin. She also will work on a proposal for the second topic to be submitted later.

The following new publications are planned for release through 2020:

- Revision to Collection of Capillary Blood Specimens (GP42)
- Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods (MM13)
- Revision to the Reagent Stability Guidance Document (EP25)
- Revision to Point-of-Care Coagulation Testing and Anticoagulation Monitoring (POCT14)
- Revision to the Linearity Assessment Guidance Document (EP06)

- Revision to Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays (H21)
- Revision to the Qualitative Assay Performance Evaluation Guidance Document (EP12)

6.22.1 Joint Committee on Traceability in Laboratory Medicine (JCTLM):

JCTLM Membership:

JCTLM Executive Committee Organizations:

Having met all the requirements for membership, ICSH is now the newest organizational member of the JCTLM Executive Committee.

JCTLM Newsletter:

This seventh issue of the Newsletter was released in June 2020 and can be downloaded from the following link:

<https://www.bipm.org/utis/common/pdf/JCTLM/JCTLM-Newsletter-2020.pdf>

Meetings/presentations under the auspices of the JCTLM:

- 2-3 December, 2019: JCTLM Members and Stakeholders Meeting, BIPM, Sévres.
- 4 December, 2019: JCTLM Database WG Meeting and JCTLM WG TEP, BIPM, Sévres
- 5-6 December, 2019 JCTLM Executive Committee Meeting, BIPM, Sévres.

Future JCTLM meetings:

- 2 December 2020: JCTLM Database Working Group meeting, BIPM, Sévres
- 3-4 December 2020: 22nd Meeting of the JCTLM Executive Committee, BIPM, Sévres
- 6-10 January 2021: JCTLM Symposium on traceability at IFCC World lab, Seoul, Republic of Korea

Given the situation with COVID-19, the above meetings may need to be converted to virtual formats in part or in total.

Professor Elvar Theodorsson has been appointed the successor to Professor Graham Beastall and will organize the next stakeholders meeting in early December 2021. It will be combined with the ICHCLR Workshop on overcoming challenges to global standardization of clinical laboratory testing: reference materials and regulations.

6.22.2 Joint Committee for Guide in Metrology (JCGM):

Dr. Martin J.T. Milton is the Chairman of the JCGM.

Report from Working Group 1 (GUM - Expression of Uncertainty in Measurement)

Dr. Graham White is acting as IFCC representative.

Correspondence was received requesting approval and / or comments to the Final Draft of GUM-6: (formerly numbered JCGM 103): Guide to the expression of uncertainty in measurement - Developing and using measurement models. Previously the SD provided comments to an earlier version and these responses can be found along with the Final Draft of GUM-6 at the following location on the JCGM webpages: <https://www.bipm.org/cc/AllowedDocuments.jsp?cc=JCGM>. The deadline for submission is November 10, 2020.

Comments received from all Member Organizations will be discussed at the next meeting of the JCGM Plenary which is planned for 7th December 2020 (visioconference) with the hope to find a consensus as to whether this Final Draft of GUM-6 can be published.

In principal, the SD approves the publication of the Final Draft of GUM-6.

Report from Working Group 2 (VIM)

Professor Gunnar Nordin is acting as IFCC representative. On June 2nd – 5th the JCGM WG2 met on the web with the ambition to, if possible, produce a draft of VIM4 for circulation among the stakeholders. Much work was done but some remaining issues were left for specific focus groups for further discussions, mostly focused on terminology. Some examples include:

“Selectivity”: the current VIM definition seems not to cover what is normally meant by “specificity”, but instead a broader concept close to “robustness” and may be modified. However, a concept like “robustness” should be defined further and retained because of its usefulness.

Other terminologies that are being further discussed are “selectivity”, “calibrator”, “standard”, “reference materials” and “certified reference material”. For example, there may be too many uses of the term “standard” in VIM3 clauses 5.1 to 5.11 to be useful and only increases confusion regarding the concepts being explained. The group will consider simplification and consolidation to fundamental concepts for the term “standard.”

The terminology around “Nominal properties” still creates confusion. Some prefer to define “qualitative analysis” as any type of binary classification, regardless if it is a classification of an underlying quantity (an ordinal property) or a categorization of nominal properties.

Remaining issues, like these above, were referred to specific focus groups (basically sub groups of the JCGM WG2) to further elaborate on during the coming weeks.

6.22.3 BUREAU INTERNATIONAL DES POIDS ET MESURES (BIPM) Consultative Committees

6.22.3.1 Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology (CCQM):

The CCQM covers measurement standards and standardization in all branches of chemical and biological measurement science, and provides a forum where NMIs can be addressed collectively. A number of the CCQM WGs have programs in which a substantial portion of their activities is related to Laboratory Medicine, and notably for the Organic Analysis (OAWG) and Protein Analysis (PAWG) working groups. The OAWG has completed a comparison of metrology institutes with Vitamin D (D3 and D2) reference measurement procedure capabilities; this covered 7 institutes and will be published soon. The PAWG has mapped out a model system to look at the different types of pure peptide/protein with respect to different challenges for purity assessment, with the aim of running comparisons to demonstrate NMI measurement capabilities for values assigning primary reference materials for peptides/small proteins.

6.22.3.2 CC for Units (CCU): The IFCC is also a Member of the BIPM's CCU and was invited to attend the 24th meeting of the Consultative Committee for Units which took place at the BIPM from Tuesday 8 to Wednesday 9 October 2019 under the chairmanship of Prof. Joachim Ullrich. Professor Philippe Gillery as representative of the IFCC participated. Some of the decisions taken:

- Improve liaison between ISO TC 12, IEC TC 25, IUPAC C2, the CIPM, and its CCs for future revision of relevant standards for units. (CCU WG on units, to make a proposal)
- Add a question on implementation of revised SI within national legal metrological framework to the questionnaire for stakeholders.
- CCU WG on units to make a proposal to CCU on the definition of “unit”, “quantity”, “value of quantity” by end Sept. 2020, possible extension of scope to be discussed by CIPM.
- NMI members and liaison organizations to bring official opinion on definition of “unit” and units for angles and frequencies to next CCU meeting (2021).

6.31 JOINT RESEARCH CENTER (JRC)

The status of JRC reference materials activities are mostly covered under the respective Cs and WGs. The JRC continues to collaborate with numerous SD Cs/WGs on a variety of projects. These include:

Enzyme CRMs:

1. CRM for alpha-amylase: ERM-AD456/IFCC:

This project was finalized and the CRM was released on 2 October 2019.

CRMs for autoimmune disorders:

1. CRM for IgG anti-B2GP (antiphospholipid syndrome (APS)): ERM-DA477/IFCC
2. CRM for IgG anti-GBM (vasculitis): ERM-DA484/IFCC
3. CRM for IgG and IgA anti tissue transglutaminase (Celiac disease)

CRMs for CSF proteins:

1. CRM for A β 1-42 in CSF: ERM-DA480/IFCC, ERM-DA481/IFCC, ERM-DA482/IFCC
The CRMs were released at the end of 2017. Re-calibration of commercial assays using the CRMs has been completed. A round-robin study is currently organized to see the effect of re-calibration on the measurement results for patient samples.
2. CRM for A β 1-40 in CSF: ERM-DA480/IFCC, ERM-DA481/IFCC, ERM-DA482/IFCC
Certification project on the existing CRMs: ERM-DA480/IFCC, ERM-DA481/IFCC and ERM-DA482/IFCC.
3. CRM for Tau project: Development of a reference system for Tau
4. Neurofilament light (Nfl): Project for the standardization of Nfl in blood (possibly in CSF).

CRM for Thalassemia:

1. CRM for HbA2: ERM-DA485/IFCC and ERM-DA486/IFCC

The calibrant materials have been processed and they will be value-assigned in the coming months. The processing of the CRMs is planned for autumn 2019.

CRM for apolipoproteins:

1. CRM for Apolipoprotein(a) apo(a): and the apolipoproteins A-I, B100, C-I, C-II, C-III and E. All is under development.

6.33 NATIONAL INSTITUTE OF BIOLOGICAL STANDARDS AND CONTROL (NIBSC)

NIBSC has been heavily involved in the UK and global response to Covid19 since February/March 2020. Many work programmes are on hold until further notice, but medicines-testing activities and standardization activity continues. NIBSC and WHO held their annual review of Standardization projects on the 24th June and reviewed progress in all projects that will be presented to the WHO Expert committee for biological standardization for establishment later in the year.

Completed projects for establishment in 2020:

- Insulin-like growth factor-1
- 6th WHO IS for human chorionic gonadotrophin (hCG)
- 3rd WHO IS for Thrombin
- 3rd IS for interferon-alpha 2b
- 1st minimum potency reference reagent for anti-human platelet antigen-15b antibody:
- 1st WHO IS for Bevacizumab
- 1st WHO IS for Trastuzumab
- 1st WHO IS for Herpes Simplex Virus (HSV) Nucleic Acid Amplification Techniques (NAT):

- 1st WHO IS for West Nile Virus (WNV) RNA for Nucleic Acid Amplification Techniques (NAT):
- 1st WHO IS for anti-MERS-CoV antibody
- 1st WHO IS for *Plasmodium vivax* antigens
- 1st WHO Reference Reagent for Anti-Malaria (*Plasmodium vivax*) human plasma:

Proposed new projects:

- Proposed 6th IS for human urinary FSH/LH
- Proposed 4th IS for human pituitary TSH
- Proposed 2nd WHO IS for FXIII plasma
- Proposed 9th IS for FVIII concentrate
- Proposed 2nd IS for meningococcal group C polysaccharide
- Proposed 1st WHO IS for Anti- β 2GPI IgG Autoantibody
- Proposed 1st international viral reference panel for adventitious virus detection by deep sequencing
- Proposed 1st WHO Reference Reagent for Mesenchymal Stromal Cells
- Proposed 1st WHO IS for Mesenchymal Stromal Cells
- Proposed WHO 1st International Standards for EGFR genomic variants (C797S)
- Proposed WHO 1st International Standards for FLT3 genomic variants (ITD)
- Proposed 1st WHO RRs for DNA Extractions for Microbiome Analysis. WHO International Standards for COVID-19 (for rapid submission – Dec 2020):
 - SARS-CoV-2 RNA standards
 - SARS-CoV-2 antibody standards

6.37 NATIONAL INSTITUTE FOR STANDARDS AND TECHNOLOGY (NIST):

The status of NIST reference materials activity is mostly covered under the respective C's and WGs.

In addition, the NIST website (www.nist.gov) can provide information on materials and services available today.

The most relevant projects to the IFCC and SD are:

- urine albumin
- cardiac troponin I
- human insulin-like Growth Factor 1
- potential standards for COVID

8.2 MAIN ACTIVITIES OF COMMITTEES:

8.2.6 C-NOMENCLATURE, PROPERTIES AND UNITS (C-NPU):

As a reminder, in 2014 a formal agreement between IFCC and IUPAC was put in place. Wikipedia presence for the NPU was created 2015 (edited by the chair with input from many NPU members). The Wikipedia entry is a useful introduction: (https://en.wikipedia.org/wiki/NPU_terminology) and the NPU Website is performing well. The NPU Steering Committee continues to provide governance for the NPU terminology through representation from key stakeholders consisting of IFCC, IUPAC and National Release Centre representative, while the C-NPU functions as the technical and scientific expert committee.

A proposal of the start of a Laboratory Information Model was made. In the presentation, it was suggested that the outcome of a Laboratory Information Model should be a laboratory result overview, in which quantity results from different labs can be highlighted to show which results can be compared. The model should also be committed to other purposes

such as billings and AI. Before commencing this work, the Steering Committee has suggested that a survey of a laboratory information model in use in any countries be made. The chair sent a survey to the attendees after the last C meeting. It was suggested that a publication should be commenced in which 5 most essential issues are highlighted. The C-NPU will discuss how to approach this with help of volunteers. It was scheduled to be discussed in detail at the WorldLab in Seoul next January.

8.2.11 C-MOLECULAR DIAGNOSTICS (C-MD):

Due to the Corona pandemic and the numerous tests and procedural changes and innovations that had to be made by many members, only a few points for the C-MD have been implemented in the last weeks. This includes the successful publication of the C-MD in CCLM:

IFCC Paper Deborah A. Payne, Graciela Russomando, Mark W. Linder, Katarina Baluchova, Tester Ashavaid, Werner Steimer and Parviz Ahmad-Nejad*, the IFCC Committee for Molecular Diagnostics (C-MD) External quality assessment (EQA) and alternative assessment procedures (AAPs) in molecular diagnostics: findings of an international survey: Clin Chem Lab Med 2020; aop

In addition, the list of molecular diagnostics centers and the application form for these has to be revised.

Furthermore, the C is considering to initiate a survey (SurveyMonkey) on Corona PCR testing to identify the diagnostic differences and challenges.

The question arises whether to implement this issue alone or in combination with the Covid Task Force. The chair of C-MD will contact the chair of the IFCC COVID Task Force to determine if collaboration would be valuable.

8.2.23 C-TRACEABILITY IN LABORATORY MEDICINE (C-TLM):

RELA 2020 has been announced and the samples were shipped in November 2019. Due to the pandemic, participants asked to postpone the deadline of the survey. Thus, the survey period did not end in April 2020, but on June 30, 2020. In this way, approximately 88% of the results could be delivered. This feedback is comparable to previous years – this is a great success with respect to the present situation. From 610 expected measurement results for 36 different measurands in total 536 results were entered up to deadline. This is an increase of participation by 16% compared to the previous year. The results will be evaluated and the preliminary reports will be sent to all participants. After their feedback the results of RELA2020 will be published at the website (<http://www.dgkl-rfb.de:81>) and discussed among the members of the advisory board C-TLM.

It is planned to conduct RELA surveys in parallel with CCQM comparison studies of NMIs for HbA1c and enzymes, respectively. The coordinators of NMIs contacted the chair of C-TLM to discuss the design and organization of both projects. These projects will be pending, however, the effects of the pandemic on progress cannot yet be estimated.

It is standard for the IFCC HbA1c Network to organize two intercomparison studies a year. Due to the pandemic the first study has been postponed to a later date. The HbA1c network will continue its activities in 2021.

SD allowed C-TLM to establish the position of a Consultant of the European Metrology Network “TraceLabMed” on the committee. The goal is to provide information about the activities and - where possible – set up joint projects. Dr. Milena Quaglia from the British NMI, LGC had been nominated and the committee is pleased to welcome her as new consultant of C-TLM.

8.2.24 C-REFERENCE INTERVALS AND DECISION LIMITS (C-RIDL):

Last year, the C published a manuscript in CCLM describing that there are many statistical techniques for indirect methods in establishing reference intervals but that there is no consensus on the best model.

A second paper will be submitted in CCA with respect to a global study. Six indirect methods was compared with the direct method. The C investigated the following:

Direct methods:

- 1) Nonparametric method by CLSI: D-NP-CLSI
- 2) Parametric method without LAVE: D-P-LAVE(-)
- 3) Parametric method with LAVE: D-P-LAVE(+)
- 4) Parametric Tukey method: D-P-Tukey

Indirect methods:

- 1) Parametric Tukey method: ID-P-Tukey
- 2) "Computerized" Hoffman method: ID-C-Hoffman
- 3) "Original" Hoffman method: ID-O-Hoffman
- 4) Bhattacharia method: ID-Bhatt
- 5) Wosniok method: ID-RLE
- 6) Arzideh method: ID-TML

A third paper is in preparation, involving a joint study with the "Number Group" in the Netherlands. It will address the criteria for establishing indirect reference intervals studies including a systematic review:

Regarding the proposal to revise the CLSI document EP28 (guidance to establish reference intervals), the CLSI Consensus Council in April again rejected the revised project plan. The major concern was the eventual length of the guidance document, which was deemed too long. According to the feedback received, the project has to be split into two parts; 1) verification of the reference intervals and 2) multicenter trials to establish reference intervals. Professor Ozarda (chair of C-RIDL) will consider this in the coming months.

8.2.25 C-STANDARDIZATION OF THYROID FUNCTION TESTS (C-STFT):

Establishing a system to maintain traceability of free thyroid hormone and TSH measurements has been completed and now the focus is on implementation:

Laboratory Network for ft4 RMP:

The Network is necessary to ensure consistency in measurements over time performed by the conventional RMP for ft4. Furthermore, the network will provide measurement capacity as high need for reference measurements is anticipated, and will ensure consistency of national or regional standardization efforts. Currently there are four laboratories in the network and activities are underway to expand.

TSH Harmonization:

The IFCC C-STFT is the only organization providing an ISO 17511 compliant traceability chain for TSH by maintaining a harmonization sample panel generated using a generally recognized harmonization protocol. The current harmonization panel is kept at NIBSC.

- It is anticipated that the current harmonization sample panel (single donor) will be exhausted within 2 years. C-STFT is ensuring consistency in assay harmonization over time by developing a follow harmonization sample panel.

Development of reference intervals, clinical and research data linked to the IFCC C-STFT reference system:

Reference intervals and research data generated with assays that are harmonized or standardized to the C-STFT reference system are critical to effectively transition to standardized assays in patient care. Discussions with stakeholders found that there is a

need to adjust (normalize) existing data, assist researchers with their ongoing studies, and ensure future studies are performed with standardized assays. The C-STFT is working with research institutions on developing such approaches.

Education of stakeholders about the new reference system and its impact on patient data:

The implementation of harmonization of TSH occurred without any notable problems in Japan. Therefore, it is assumed that similar efforts in other regions will occur in the same manner. Concerns have been raised about the impact of fT4 standardization. These concerns were raised mainly by IVD manufacturers. C-STFT is addressing these concerns by helping national or regional groups with educational activities.

Other Activities:

- collaborating with UK NIBSC on the development of a new TSH reference material
- collaborating with US NIST on characterizing potential materials for fT4
- collaborating with US CDC to ensure the CDC standardization program for fT4 is aligned to the IFCC C-STFT

8.2.26 C-HARMONIZATION OF AUTOIMMUNE TESTS (C-HAT):

IgG anti Glomerular basement membrane antibodies:

- candidate material has been prepared and aliquoted
- samples for the commutability studies have been analyzed by 6 methods
- result analysis showed good method correlation
- commutability will be repeated with selected methods by end July 2020

IgA (and IgG) anti tissue transglutaminase antibodies:

- candidate material with high titres/concentrations of IgA and IgG anti TTG antibodies have been sourced
- these have also been confirmed as having high titres of anti endomysial antibodies
- tTG IgA commutability will be done during July 2020

IgG anti β 2 glycoprotein 1 antibodies:

- the prepared reference material is aliquoted and all analysis have been completed
- the reference material is commutable
- However, the purified antibody that should have been used for value assignment is not commutable. Therefore value assignment in mass units cannot be achieved.
- Dr. Evi Monogioudi (JRC) and Dr. Joanna Sheldon (C-HAT) have discussed with NIBSC to see whether this material could be assigned a value in arbitrary units so the commutable material could be available.
- If this is accepted by NIBSC it will then be presented to the WHO ECBS in October 2020 for likely "release" in 2021.

8.2.27 C-BONE METABOLISM (C-BM):

PTH standardization:

A pilot study has been performed. The assays used were Roche and Abbott (2nd generation) and DiaSorin and Fujirebio (3rd generation). Results will be presented during The sample pools prepared are mostly commutable, but the limits used to make them

commutable are quite broad (+/-25%) which “consumes” the capital of total error available based on biological variation of PTH. Nevertheless, this is the state of the art and it will be proposed to move on with other methods.

- **RMP for PTH:** Dr. Candice Ulmer presented the results of the RMP LCMS/MS method on which she's currently working at the CDC facilities. She is working on improving the LOQ of the method and expanding the number of fragments recognized by the method.

PINP:

The chair has written a paper on biological variation of bone markers. The paper has been accepted by IFCC, IOF and EFLM boards. The paper has been submitted to Osteoporosis International.

The C is working to find a commutable standard for PINP. One matrix has been found to be commutable with the 3 methods when enriched with the IDS topdose.

CTX:

A paper on the multicenter study has been written, but it has been put on hold due to inconsistencies of the results.. Manufacturers will need to work to improve the issues observed during the multicentre study. This is mandatory for the future of the marker.

Vitamin D metabolites assay standardization

Moving forward, the C will propose an “external” validation of IVD certified assays for VDSP and work on current VDSP performance guidelines for 25(OH)D (measurement uncertainty)

PUBLICATIONS:

European Biological Variation Study (EuBIVAS): within- and between-subject biological variation estimates of β -isomerized C-terminal telopeptide of type I collagen (β -CTX), N-terminal propeptide of type I collagen (PINP), osteocalcin, intact fibroblast growth factor 23 and uncarboxylated-unphosphorylated matrix-Gla protein-a cooperation between the EFLM Working Group on Biological Variation and the International Osteoporosis Foundation-International Federation of Clinical Chemistry Committee on Bone Metabolism. Cavalier E, Lukas P, Bottani M, Aarsand AK, Ceriotti F, Coşkun A, Díaz-Garzón J, Fernández-Calle P, Guerra E, Locatelli M, Sandberg S, Carobene A; European Federation of Clinical Chemistry and Laboratory Medicine Working Group on Biological Variation and IOF-IFCC Committee on Bone Metabolism Osteoporos Int. 2020 Apr 8. doi: 10.1007/s00198-020-05362-8.

Harmonization of commercial assays for PINP; the way forward.

Vasikaran SD, Bhattoa HP, Eastell R, Heijboer AC, Jørgensen NR, Makris K, Ulmer C, Kanis JA, Cooper C, Silverman S, Cavalier E. Osteoporos Int. 2020 Mar;31(3):409-412. doi: 10.1007/s00198-020-05310-6.

8.3 MAIN ACTIVITIES OF WORKING GROUPS:

8.3.35 WG - STANDARDISATION OF HEMOGLOBIN A2 (WG-HbA2):

A joint committee with ICSH (The International Council for Standardization in Hematology) is being formed. The following is a short update of the current status of activities:

Candidate reference measurement procedure for HbA2:

The recombinant hemoglobins to be used for calibration and produced by Trenzyme GmbH in summer 2019 have to be characterized for purity and content. The rHbA2 was further purified at the PTB. The amino acid analysis will be done in duplicate at the PTB and at the JRC. In the meantime, another lab has expressed the intention to participate in the exercise in which the HbA2 titer will be given to the CRMs, and has started implementing the method. This laboratory belongs to the National Institute of Metrology in Beijing (CN). Afterwards, the lacking experiments will be performed in order to prepare the final version to be submitted to the SD board for approval and for the ballot before publication.

Certified reference material (CRMs) for HbA2:

The supply of fresh blood to prepare the large batches has been completed. In total, 8 blood donations (4 from healthy donors and 4 from healthy donors, beta-thal carriers) have been collected and shipped to the JRC. The stabilized hemolysates have been prepared before the Covid-19 lockdown and will be processed for lyophilization, probably after the summer. Approximately 3000 vials per level are expected.

A roadmap for the standardization of hemoglobin A2:

The chair has prepared a roadmap to be submitted to Clinical Chimica Acta for the special issue dedicated to the activities of the IFCC activities.

8.3.36 WG - STAND. OF CARBOHYDRATE-DEF. TRANSFERRIN (WG-CDT):

The following is a summary and a description of the current focus of this WG:

The WG has postponed the annual CDT September meeting in Schiphol due to the COVID-19 situation. A tentatively schedule sometime in November is planned instead and social media options being explored.

The IFCC CDT 2020 study cycle has gone as planned with both network labs and manufacturers. Closing date 31/5. The primary WG communication would be to discuss the findings and to relay the info to the manufacturers in particular. Preliminary results of the 2020 study indicated that overall, performance by the participating network sites is positive. However, most curious and intriguing are failures by 4 devices relating to 2 manufacturers. Therefore, EQA concerns appear to be justified.

EQA scheme organizers for CDT-IFCC, such as Equalis (Sweden) and the Dutch scheme would like to attend and participate in future (WG) CDT annual open meetings.

Implementation and adoption of the IFCC method still continues to be a challenge. There is still reluctance from many sites and authorities to switch from classic CDT and worse yet, many are dual reporting. Manufacturers seem reluctant to specify solely CDT-IFCC. Yet another frustration is the fear of legal challenges rather than embrace a test that is so clinically significant compared to the less reliable traditional markers.

The WG continues its efforts to promote the IFCC method via multiple approaches.

8.3.39 WG – STAND. OF ALBUMIN ASSAYS IN URINE (WG-SAU):

All activities of the WG-SAU are a joint effort with the Laboratory Working Group (LWG) of the National Kidney Disease Education Program (NKDEP), USA.

Reference measurement procedure for UA (funded by NKDEP and NIST):

NIST and Mayo continued the development of their candidate reference measurement procedures and conducted planning sessions for validation and JCTLM submission. In previous discussions with the NKDEP-LWG, it was agreed upon between Mayo Clinic and the University of Minnesota that a synthetic urine matrix would be utilized for calibrator preparation to ensure lot-to-lot calibrator consistency and long-term availability. The matrix would not consist of a proprietary commercial synthetic material or materials; rather it will be a matrix that can be prepared in the laboratory from commercially available chemicals.

NIST is using SRM 2925 for calibration of their candidate reference measurement procedure and has provided some guidance on linking the concentrations of calibrators at Mayo Clinic and the University of Minnesota to SRM 2925. Next steps involve consensus on alignment of calibration between laboratories with the use of the NIST reference material, performing sample comparison studies and proceeding with the validation of the reference measurement procedure.

The group has reviewed the JCTLM submission requirements and is designing validation and round robin sample exchanges to fulfil the submission requirements.

NIST and Mayo will continue to develop and validate their reference measurement procedures and will work identifying sources of disagreement among the methods, and pursue validation of the candidate reference measurement procedures in accordance with ISO 15193 and other relevant standards for JCTLM listing.

Reference materials for UA and urine creatinine:

SRM 2925 Human Serum Albumin from NIST is a primary certified reference material for use with higher order reference measurement procedures for albumin. Documentation is currently in review in the NIST Office of Reference Materials. To facilitate standardization of routine methods, NIST SRM 3666 is currently being developed based on the specifications recommended by the WG-SAU and the LWG of the NKDEP. Value-assignment of SRM 3666 for urine albumin and creatinine will be conducted by NIST. The WG-SAU will continue to facilitate development of NIST SRM 3666.

8.3.40 WG – STAND. OF PREGNANCY-ASS. P-PROTEIN A (WG-PAPPA):

The WG main goal is to harmonize the PAPP-A measurements of the various methods commercially available:

- a) To establish well-characterized reference materials
- b) To characterize different antibody combinations (reference assays and company assays) with these materials in different matrices
- c) Assays detect different forms of PAPP-A similarly to test reference materials in different matrices with commercial assays
 - Recombinant PAPP-A - **not suitable**
 - Endogenous PAPP-A purified from retroplacental blood - **not suitable**
 - Pooled 2nd trimester or 3rd trimester serum – **suitable**
- d) to select, manufacture and validate reference material NIST SRM 1949

Companies actively participating:

- Beckman Coulter
- Perkin-Elmer Wallac
- Roche Diagnostics
- Siemens Healthineers
- Thermo Fisher (B.R.A.H.M.S.)

Plans:

- Confirmation of commutability of SRM 1949
- Value assignment (average of commercial assays using mIU/L)

Part A – University of Turku

- Initial concentration for the 4 pools/products of SRM 1949 determined at the University of Turku
- The suitable pool(s) identified, dilution scheme designed, aliquots prepared

Part B - Companies

- Each company will be given
 - 2 vials of chosen SRM 1949 products -> 4 dilutions prepared of each vial according to instructions
 - 5 pools of 1st trimester serum (to secure commutability)
 - 2 samples of premade SRM 1949 dilutions
 - 15 samples in total
- 15 samples in total analysed 5 times as duplicates (one method / company)
- Results sent to the University of Turku for analysis

8.3.41 WG – GROWTH HORMONE (WG-GH)

The overall goal of the WG-GH is to achieve standardization of growth hormone through secondary reference materials and a reference measurement procedure.

A long recognized problem in the reliable measurement of GH is the lack of standardization of different assays that are currently used. Standardization of the GH assays has been hampered by the unavailability of a commutable certified reference material and of an acknowledged reference method. The WHO standard IS 98/574, against which all current assays are calibrated, was found not to be commutable when tested in different matrices.

To address these issues, the WG is currently organizing a commutability study at two reference laboratories using LCMS/MS. The difference in bias will be compared with a pre-determined criterion based on medically relevant differences. The goal is to determine how close the bias of a RM (reference material) and the CS (clinical representative samples) are to each other. A RM is commutable if the systematic difference, or bias, for the RM and the average bias for the CS between two measurement procedures (dRM), at the RM level, is within an agreed criterion. A maximum of dRM, named the commutability criterion (C), is already decided.

Once the reference material and reference measurement procedure is finalized the following commercial assay will be studied:

Siemens	Immulite 2000/XP
DiaSorin	Liaison
BeckmanCoulter	Access/DXi
IDS	Isys
Roche	Cobas/Elecsys

8.3.42 WG – STANDARDIZATION OF INSULIN ASSAYS (WG-SIA)

This is a joint project between ADA/EASD and IFCC. The overall goal of the WG is to establish a reference system for serum/plasma insulin measurement to achieve standardization of all commercial methods to assay insulin.

Current status:

1. Ongoing development and validation of MS/MS method for intact insulin at University of Minnesota. Significant progress has been made following prioritization and financial support for development of the LC-MS/MS insulin assay at the University of Minnesota.
2. Continued collaboration with other laboratories (Quest Diagnostics, Mayo Clinic) developing insulin methods by mass spectrometry and sustained efforts to evolve reference method procedures in these laboratories.
3. In collaboration with the College of American Pathologists (CAP), established criteria for ongoing accuracy based evaluation of serum pools for testing of insulin, C-peptide, and glucose.
4. Continued collaboration with NIBSC to evaluate the insulin candidate reference material which will ultimately be utilize to calibrate the mass spec method and establish it as a higher order reference method.

Future Plans and activities:

1. Implement accuracy based proficiency testing survey using serum pools for insulin (and c-peptide) via the College of American Pathologists; results will allow for assessment of comparability of results across assays, using a commutable matrix, as the WG moves towards standardization or harmonization.
2. Working group report or peer-reviewed publication regarding either insulin/c-peptide serum pool data across hundreds of laboratories/assays and/or lack of harmonized conversion factor across insulin assays.

8.3.43 WG – STANDARDIZATION OF TROPONIN I (WG-TNI)

Unfortunately, the WG-TNI activities have been significantly delayed due to COVID-19, especially given the severity in the United States.

The WG collected all of the cardiac troponin I (cTnI) samples from Myocardial Infarction patients that are needed to produce the commutable reference material (RM) 8121 (SRM 2922). Development of this material has been in close collaboration with NIST. High cTnI samples will be blended with heparinized plasma from healthy individuals. The WG was just about to initiate blood collection from the healthy individuals when the COVID-19 crisis forced the university to bring a hard stop to activities. Thus, the WG-TNI project to develop RM 8121 in collaboration with NIST has been unavoidably delayed.

Ongoing activities:

- NIST is actively evaluating commercial vendors that will blend RM 8121 (SRM 2922) at the specified series of concentrations.
- The chair worked with NIST to develop a submission for funding that will help cover the costs of screening and recruiting the healthy individuals who will donate units of heparinized blood for production of the plasma that will be used for blending with high cTnI samples.
- The abstract for the pilot study was submitted to the AACC and has been selected for oral presentation at the Annual Meeting to be conducted in Chicago, IL in December.

8.3.49 WG – CSF Proteins (WG-CSF):

The WG is in contact with NMIs for the standardization of the Tau proteins. There seems to be some coordinated activities. So far, the following have been accomplished:

- Two RMPs for CSF amyloid β 1-42 have been published and approved by the JCTLM (C12RMP1 and C11RMP9).
- A method for measurement of CSF amyloid β 1-40 by SRM has been published and validation of a RMP is ongoing.
- Mass spectrometric methods for measurement of CSF tau have been developed by several work group members.
- Three CRMs for CSF amyloid β 1-42 have been developed (ERM®-DA480/IFCC, ERM®-DA481/IFCC and ERM®-DA482/IFCC).
- Collection of CSF for development of CRMs for tau is ongoing.
- Round-Robin study of CSF-amyloid beta 1-42/1-40 ratio RMPs by mass spectrometry is in the planning stage.
- Round-Robin study of CSF tau RMPs by mass spectrometry is being planned.
- There has been reluctance by industry to adopt the new reference system and the WG has prepared training materials and trying to move this forward.

8.3.51 WG – COMMUTABILITY IN METROLOGICAL TRACEABILITY (WG-CMT)

WG-C is retired; replaced with WG-Commutability in Metrological Traceability (WG-CMT). Paper published: Miller WG, Budd J, Greenberg N, Weykamp C, Althaus H, Schimmel H, Panteghini M, Delatour V, Ceriotti F, Keller T, Hawkins D, Burns C, Rej R, Camara JE, MacKenzie F, van der Hagen E, Vesper H, for the IFCC Working Group on Commutability. IFCC Working Group Recommendations for Correction of Bias Caused by Noncommutability of a Certified Reference Material Used in the Calibration Hierarchy of an End-User Measurement Procedure. Clin Chem 2020;66:769-78.

WG-CMT is now working on recommendations for criteria for commutability assessment of certified reference materials, trueness controls, and EQA materials.

In the terms of reference going forward, focus is to develop recommendations for commutability assessment of replacement batches of certified reference materials and EQA materials; and recommendations for using certified reference materials for

metrological traceability when the matrix is not compatible with the sample type, e.g. serum-matrix CRM with whole blood analyzers.

The group is working very well and meeting frequently but the issue of commutability is complicated.

8.3.53 WG – IMMUNOSUPPRESSIVE DRUGS (WG-ID):

The WG is devoted to the establishment of candidate reference procedures and reference materials for immunosuppressive drugs (ISDs) such as cyclosporine, sirolimus, tacrolimus, everolimus, and mycophenolic acid (MPA).

The WG came to several agreements, which will serve as basis of future undertakings:

- There is a definitive need to bridge the traceability gap between primary and secondary reference materials and the industrial master calibrators.

- At least two quality levels of procedures must be provided to allow on the one hand the characterization of highest order reference materials and on the other hand, to support industry and other stakeholders with measurement platforms allowing to characterize sample cohorts of different study settings (e.g. instrument comparison studies ...).

- JCTLM listing of reference methods and materials is a must for the WG outcome to be successful.

- qNMR is most likely the key technology to provide reference materials of unmet quality and that any reference measurement procedure must be published such, that a sufficiently qualified laboratory is in the position to participate in a reference measurement network to be defined as ultimate goal of our initiative.

Dr. Loralie Langman as Past President of the IATDMCT and member of WG-ID took up the task to establish a link between IFCC and IATDMCT. Consequently a "memorandum of understanding" to extend the WG-ID to an IFCC-IATDMCT joint WG was prepared. This memorandum is already signed by the IFCC and has been recently forwarded to the IATDMCT.

Next meetings of the WG-ID are planned at the Worldlab 2020 in Seoul and the EuroMedlab 2021 in Munich. It is envisioned to organize joint presentations with the C-TLM, since JCTLM registration of established materials and methods is a central milestone of the WG-ID work. Furthermore, the WG plans to make a presentation at the IATDMCT conference 2021 in Banff – hopefully this will be the inauguration meeting of the IFCC-IATDMCT joint WG.

8.3.54 WG – APOLIPOPROTEINS BY MASS SPECTROMETRY (WG-APO MS):

Reference Measurement Procedure:

The WG set two major goals for 2020: the optimization of the LC-MS measurement method, including further evaluation of harmonization and proof of equimolar digestion of apo(a).

Work has been initiated on both topics, but efforts have been hampered by the COVID-19 crisis.

To optimize the method, new stable isotope labelled standards (SIL) were procured, which are heavy labelled on their arginine or lysine residues. This ensures uniform labelling and allows better specificity as the typically formed γ - type peptide fragments carry the label and can thus to be further differentiated based on their fragments. Using these peptides, a novel SIL mixture representing a typical serum sample was produced, which can be used for further method optimization and evaluation.

Besides the SIL mixture, a novel system suitability sample (SSS) was also produced. This sample contains all of the newly labelled SIL, as well as their endogenous synthetic analogues. Both the SIL mixture as well as the SSS have been distributed early June 2020 among the three candidate reference laboratories for further evaluation.

A plan of work was made to prove equimolar digestion of apo(a), which is essential for the envisioned peptide based calibration. The aim is to first assess whether the peptide based calibrators behave the same in native material and in artificial matrix. This will ensure that the appropriate matrix for the calibrators is selected. Subsequently, the digestion behaviour of purified proteins will be assessed, and finally protein and peptide-based calibration strategies will be compared to assess complete and thus equimolar digestion. The first experiments, pertaining to the peptide behaviour are currently being executed for four of the five peptides

Reference materials:

The first batch of primary calibrators for apo(a) has been prepared. All apo(a) peptides have sufficient purity to do first experiments. However, the most crucial peptide, LFLEPTQADIALLK dissolves poorly, thus hampering the stability study, amino acid analysis and distribution to the reference laboratories. Strategies to improve solubility are currently evaluated.

Peptide calibrators were procured for apoA1 and B, and for apo's CI, CII, CIII and E. They will be distributed for stability and purity assessment once the JRC/LNE laboratories are open again after COVID-19.

An alternative source of secondary reference material has been identified in recombinant apo(a). This material is currently being procured and awaits shipment from France to JRC/Belgium.

A first commutability study for the secondary reference materials has been drafted, and participating laboratories and IVD-manufacturers have been contacted and have confirmed their participation in the commutability study. However, due to COVID-19, the samples are not yet all on-site in Belgium, and should from there be shipped in similar conditions to the different laboratories. This has delayed progress of the commutability study.

A first manuscript by the group has been prepared and has been send to IFCC SD for review. This manuscript is a conceptual paper explaining the approach the WG took for standardization of multiple clinically relevant apolipoproteins based on Next Generation protein Diagnostics with a harmonized, bottom-up LC-MS approach.

8.3.55 WG – PANCREATIC ENZYMES (WG-PE):

The focus of the WG is developing a reference system for pancreas amylase in serum. Considering intra laboratory investigations at three sites in 2019, the RMP may be fit for purpose. In 2020 a final draft SOP for the RMP of pancreatic amylase was generated by the working group. An interlaboratory comparison will begin in late summer until end of 2020. Four reference laboratories are part of the comparison study. Samples to investigate will consist of native human pools and of proficiency testing material. Two pools have been collected, portioned and stored in the calibration laboratory in Hannover (Dr. Grote-Koska). Two proficiency testing materials are now under production and will be provided by SKML (Dr. Weykamp) soon. Roche will provide the desired reagents before distribution of the materials, which is planned for August 2020 by Dr. Grote-Koska. Based on the results of this evaluation, the WG will determine if further optimization of the RMP with subsequent investigation is necessary. Otherwise a completion of verification of the procedure is planned prior to publication.

Certification of reference materials for enzymes being performed at the JRC:

In 2019 characterization studies of the new ERM reference material ERM AD456/IFCC of pancreatic amylase were performed by well-respected sites of WG-PE and others. Stability studies were performed in the calibration laboratory in Hannover for EC-JRC. The material is now released and available.

In 2020 investigations to monitor stability are being performed in the RfB-calibration laboratory in Hannover (Dr. Grote-Koska). Future activities are depending on the needs of the JRC. So far no plans are decided.

8.3.56 WG – FECAL IMMUNOCHEMICAL TESTING (WG-FIT):

Given the COVID-19 pandemic, work is mostly through emails and also via WG sub-groups. Each meeting is highly attended by approximately 20 members including four manufacturers and work continues in spite of the current situation. A virtual conference is planned at the end of October which will focus on discussing the harmonization studies of FIT methods. It was previously confirmed that standardization will not be possible and a sub-group of the FIT-WG has drawn up a harmonization protocol. The final protocol is now with the manufacturers for approval and the hope is to start the harmonization work in October with it being completed (all going well) by December 2020. A great deal of work has been done to develop the RM (reference material) with the JRC in the lead and in the end material from Japan has been chosen. Four manufactures will perform the study and first run their methods and then recalibrate with the chosen RM.

Two papers were recently published which relate to the activities of the FIT-WG concerning independent IQC and suitable EQA material;

- One relates to the lack of availability of third party IQC. During one of the FIT-WG meetings all manufacturers agreed that the WG could test each manufacturer IQC on the other analysers. Once the IQC work on all analysers is complete is to then see if the manufacturers are willing to market their IQC independent of the FIT method until there is the possibility of 3rd party IQC:
 - Letter to the Editor Carolyn Piggott*, Zinab Shugaa and Sally C. Benton Independent internal quality control (IQC) for faecal immunochemical tests (FIT) for haemoglobin: use of FIT manufacturers' IQC for other FIT systems (Clin Chem Lab Med 2020; aop)
- EQA is challenging for FIT because of the pre-analytical variability and the WG members had a lot of discussion as to what an ideal EQA should be for FIT. A paper recently published that looks at different type of EQA material:
 - Shane O'Driscoll, Carolyn Piggott, Helen Bruce and Sally C. Benton* An evaluation of ten external quality assurance scheme (EQAS) materials for the faecal immunochemical test (FIT) for haemoglobin (Clin Chem Lab Med 2020; aop; published online August 7, 2020)

8.3.57 WG – CELL FREE DNA and RELATED CIRCULATING BIOMARKERS (WG-cfDNA):

The WG has reached out for corporate member sponsorships to enable face-to-face meetings.

Terms of Reference:

- To identify and provide guidance on preanalytical and analytical aspects for obtaining good and reproducible results for cfDNA and related circulating biomarkers for clinical use, and to guide the correct clinical implementation of these biomarkers.

Current projects:

- Defining pre-analytical aspects / drafting guideline
- Defining minimal analytical performance
- Setting up proficiency testing for cfDNA
- Organizing international workshops
- Defining grant proposals to address unmet needs

The chair and WG have prepared a paper about the pre-analytical aspects and the paper is currently being reviewed by the WG. The chair believes the WG members will provide expertise in lung cancer, organ rejection, and other broad areas (such as exosomes). The WG also plans to be involved early on with NMIs.

8.3.58 WG – PROCALCITONIN (WG-PCT):

The following is the status of WG-PCT to date:

- Development of candidate reference method for PCT by mass spectrometry: RMP optimization was pursued with the objective to improve the limit of quantification. For now, the LOQ is between 0.5 and 1ng/mL. Method validation will be conducted in July.
- Commutability study: due to the coronavirus crisis, collection of large single donation was stopped between March and May and then resumed in June. So far, 23 large single donations were collected but only 10 of these have a volume sufficient to be measured by all immunoassays.
- EQA Survey: ten external quality assessment scheme (EQAS) providers from eight different countries were approached and asked to provide results of their PCT EQAS : ANSM in France, CSCQ in Switzerland, Equalis in Sweden, Instand and RfB in Germany, Labquality in Finland, Probioqual in France, RCPA in Australia, SKML in The Netherlands and WEQAS in the UK. Between 2014 to 2020, 2229 routine laboratories conducted 26758 PCT measurements using 100 EQA materials which PCT concentration ranged from 0.15 ng/mL to 43.66 ng/mL (median 3.02 ng/mL). Different types of serum-based EQA materials were used. The need to improve comparability of PCT measurements was evaluated according to between-lab CV%. The mean global CV% was 19.3% but a considerable dispersion of between lab CVs was observed. In the best case, a global CV of 6-8% was observed, suggesting that comparability of PCT results is quite satisfactory but in a number of surveys, global CVs of 20-25% were observed, suggesting that comparability of PCT results is poor and should be improved. It can be speculated that differences in estimates of between lab agreements is (at least partially) due to variable commutability levels of the EQA materials. This confirms the need to evaluate commutability of EQA materials before a conclusion can be made regarding the need to improve comparability of PCT assays.
- EQA providers will be invited providing their materials so as to include these in the commutability study that will be organized early-mid 2021.
- Next steps:
 - Validation of the candidate RMP by IDMS
 - Pursue samples collection and preparation of the commutability study

8.3.59 WG – CONTINUOUS GLUCOSE MONITORING (WG-CGM):

This is a relatively new WG and activities have been significantly affected by the COVID-19 pandemic. The WG is preparing work packages and publications:

Terms of Reference:

- Establish traceability of glucose values obtained by continuous glucose monitoring (CGM) to materials and methods of higher metrological order
- Establish metrics for the evaluation of the analytical performance of CGM
- Work with ISO on a new CGM guideline (analogous to ISO 15197) to establish standardized procedures and acceptance criteria for CGM

Current projects:

- Propose means suitable for establishing the traceability of glucose values obtained by CGM to materials and methods of higher metrological order according to ISO

- 17511, including definition of adequate compartment(s) for reference samples (capillary, venous)
- Find procedures suitable for assessment of analytical performance of CGM systems
 - Define metrics and corresponding minimum acceptance criteria for the analytical performance of CGM systems

8.19 MEETINGS

- 8.16.65 65th SD Meeting – July 2nd and 10th, 2020 via extended web conference calls
- 8.16.66 66th SD Meeting – December 7, 2020 via extended web conference call
- 8.16.67 67th SD Meeting – TBD