

## **Chapter 8**

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- 8.3.58. Standardisation of Procalcitonin assays (WG-PCT)
- 8.3.60. Continuous Glucose Monitoring (WG-CGM)
- 8.3.61. Development of a Reference Measurement System for sustainable PT/INR Standardisation (WG-PT/INR)

**SCIENTIFIC DIVISION  
EXECUTIVE COMMITTEE (SD-EC)**

**Chair**

Prof. Philippe GILLERY (FR)

**Vice Chair**

Prof. Christa M. COBBAERT (NL)

**Secretary**

Prof. Garry JOHN (UK)

**Members**

Dr. Barnali DAS (IN)  
Dr. Konstantinos MAKRIS (GR)  
Prof. Mario PLEBANI (IT)

**Corporate Representative**

Dr. Michael ROTTMANN (DE)

**European Commission – JRC Observer**

Dr. Liesbet DEPREZ (BE)

**ICHCLR Observer**

Prof. Ian S. YOUNG (UK)

**JCTLM Chair – SD Consultant**

Dr. Greg MILLER (US)

**NIBSC Consultant**

Dr. Chris BURNS (UK)

**NIFDC Observer**

Dr. Yang ZHEN (CN)

**NIST Consultant**

Dr. Karen W. PHINNEY (US)

## CHAIRS OF SCIENTIFIC DIVISION COMMITTEES AND WORKING GROUPS

### 8.1. Executive

P. Gillery (FR)

### 8.2. Committees

- |   |                     |
|---|---------------------|
| 8.2.6. Nomenclature, Properties and Units (C-NPU)<br>in collaboration with International Union of Pure<br>and Applied Chemistry (IUPAC) | Y.B.L. Hansen (DK)  |
| 8.2.11. Molecular Diagnostics (C-MD)  | P. Ahmad-Nejad (DE) |
| 8.2.23. Traceability in Laboratory Medicine (C-TLM)   | A. Kessler (DE)     |
| 8.2.24. Reference Intervals and Decision Limits (C-RIDL)  | Y. Ozarda (TR)      |
| 8.2.25. Standardisation of Thyroid Function Tests (C-STFT)  | H. Vesper (US)      |
| 8.2.26. Harmonization of Autoimmune Tests (C-HAT)   | J. Sheldon (UK)     |
| 8.2.27. Bone Metabolism (C-BM)  | E. Cavalier (BE)    |

### 8.3. Working Groups

- |   |                                       |
|---|---------------------------------------|
| 8.3.35. Standardisation of Hemoglobin A2 (WG-HbA2)<br>Joint Working Group with ICSH (International<br>Council for Standardization in Haematology)                               | A. Mosca (IT)                         |
| 8.3.36. Carbohydrate-Deficient Transferrin (WG-CDT)   | J. Deenmamode (UK)                    |
| 8.3.39. Standardisation of Albumin Assay in Urine (WG-SAU)<br>in collaboration with National Institute of Diabetes<br>and Digestive and Kidney Diseases (NIDDK)                 | J. Seegmiller (US)                    |
| 8.3.40. Standardisation of Pregnancy-Associated Plasma<br>Protein A (WG-PAPP A)   | S. Wittfooth (FI)                     |
| 8.3.41. Growth Hormone (WG-hGH)   | M. Vos (NL)                           |
| 8.3.42. Standardisation of Insulin Assays (WG-SIA)<br>in collaboration with American Diabetes<br>Association (ADA) and European Association for<br>the Study of Diabetes (EASD) | M. Steffes (US)<br>J. Seegmiller (US) |
| 8.3.43. Standardisation of Troponin I (WG-TNI)  | R. Christenson (US)                   |
| 8.3.49. CSF-Proteins (WG-CSF)   | J. Gobom (SE)                         |
| 8.3.51. Commutability in Metrological Traceability (WG-CMT)   | G. Miller (US)                        |
| 8.3.53. Immunosuppressive Drugs (WG-ID)   | C. Seger (CH)                         |
| 8.3.54. Apolipoproteins by Mass Spectrometry<br>(WG-APO MS)   | C. Cobbaert (NL)                      |
| 8.3.55. Pancreatic Enzymes (WG-PE)  | D. Grote-Koska (DE)                   |
| 8.3.56. Fecal Immunochemical Testing (WG-FIT)   | S. Benton (UK)                        |
| 8.3.57. Cell free DNA and related circulating biomarkers<br>(WG-cfDNA)  | R. van Schaik (NL)                    |
| 8.3.58. Standardisation of Procalcitonin assays (WG-PCT)  | V. Delatour (FR)                      |
| 8.3.60. Continuous Glucose Monitoring (WG-CGM)  | G. Freckmann (DE)                     |
| 8.3.61. Development of a Reference Measurement<br>System for sustainable PT/INR Standardisation<br>(WG-PT/INR)  | C. Cobbaert (NL)                      |

## 8. Scientific Division (SD)

A Committee on Standards was established in 1966 “to instigate and promote theoretical and practical developments in the field of standards and standardisation in clinical chemistry - in its broadest sense.” During its first decade, the main efforts of the Committee were directed toward (1) analytical nomenclature, (2) reference materials and methods, and (3) quality control. Its achievements during this period are illustrated by the list of publications on these topics. Following a Council decision in 1978, efforts have been made to extend its work to include more subjects of interest both to clinicians and clinical chemists and laboratorians. Accordingly, the name of the Committee was changed to the Scientific Committee and later to the Scientific Division.

The Division and its activities are managed by an Executive Committee. This Committee is responsible for (1) developing a mission statement, (2) developing strategy and tactics, (3) initiating and managing projects, and (4) generating and adhering to its Terms of Reference.

### 8.1. SD-Executive Committee (SD-EC)

#### Membership

| Name        | Position                            | Country | Term            | Time in Office    |
|-------------|-------------------------------------|---------|-----------------|-------------------|
| P. Gillery  | Chair                               | FR      | 2 <sup>nd</sup> | 2020 01 - 2022 12 |
| C. Cobbaert | Vice-Chair                          | NL      | 2 <sup>nd</sup> | 2020 01 - 2022 12 |
| G. John     | Secretary                           | UK      | 1 <sup>st</sup> | 2021 03 - 2023 12 |
| B. Das      | Member                              | IN      | 2 <sup>nd</sup> | 2021 01 - 2023 12 |
| K. Makris   | Member                              | GR      | 2 <sup>nd</sup> | 2020 01 - 2022 12 |
| M. Plebani  | Member                              | IT      | 2 <sup>nd</sup> | 2020 01 - 2022 12 |
| M. Rottmann | Corporate Member                    | DE      | 1 <sup>st</sup> | 2020 03 - 2022 12 |
| L. Deprez   | European Commission<br>JRC Observer | BE      |                 |                   |
| I. Young    | ICHCLR Observer                     | UK      |                 |                   |
| G. Miller   | JCTLM Chair / Consultant            | US      |                 |                   |
| C. Burns    | NIBSC Consultant                    | UK      |                 |                   |
| Y. Zhen     | NIFDC Observer                      | CN      |                 |                   |
| K. Phinney  | NIST Consultant                     | US      |                 |                   |

#### 8.1.1. Mission Statement

The mission of the SD is to advance the science of Clinical Chemistry and Laboratory Medicine and to apply it to the practice of Clinical Laboratory Science.

#### 8.1.2. Strategy

According to the Statutes of IFCC, the Federation exists to advance the science and practice of Clinical Chemistry and to further its application in the provision of health services and the practice of medicine. The goals to which the Scientific Division is committed are to:

- Identify research areas of relevance to Clinical Chemistry and Laboratory Medicine and assist the transfer of research results to the profession.
- Identify scientific and technological problems in current practice and provide solutions and guidelines on how to resolve them.
- Facilitate the development and transfer of technical innovations to clinical laboratory professionals and clinicians.
- Facilitate the development and implementation of diagnostic strategies.

- Establish standards for scientific and technical aspects of good laboratory practice.
- Facilitate the development of reference measurement processes and the production of reference materials
- Establish networks of reference laboratories
- Respond to scientific and technical needs of IFCC Member Societies, IFCC Corporate Members and external agencies.
- Participate actively in the scientific programmes of IFCC congresses and other scientific meetings.
- Ensure the quality of IFCC scientific documents.
- Organise Master discussions

### 8.1.3. Projects

The SD initiates and manages projects with its own resources or through its Committees and Working Groups. Work is conducted in cooperation with other IFCC units and with relevant National and International Organisations. The SD ensures that each of its Committees and Working Groups are functioning under clear terms of reference together with an agreed schedule of activity. The SD will assist in the development of the project proposals and will undertake an annual review of progress and review and approve any documents that result from the work.

### 8.1.4. Terms of Reference

The SD consists of up to seven IFCC sponsored individuals, which include the Chair and the Vice-Chair, and additionally one individual is nominated by the Corporate Members of IFCC. The Division may co-opt additional member(s) to address specific issues. The Chair, the Vice-Chair and all Full Members are appointed by EB after consultation between the EB, SD and Member Societies.

The SD working units are Committees, that are theme-oriented, and Working Groups, that are task-oriented. Committees (C) are usually funded by IFCC for one full meeting per year. Only the Chair of Working Groups (WG) is normally funded by IFCC; however, a WG may be partially or totally supported by IFCC, Member Societies, Corporate Members, or other Organisations.

## 8.2. SD Committees

Over the years, the SD has initiated and managed a number of applicable committees. These have been numbered sequentially with the Mueller numbering system beginning with 8.2.1. Current committees and their activities are listed below. Earlier Committees and those with missing numbers are found in prior editions of the IFCC Handbook.

### 8.2.6. Nomenclature, Properties and Units (C-NPU) in collaboration with IUPAC

#### Membership

| Name             | Position   | Country | Term            | Time in Office    |
|------------------|------------|---------|-----------------|-------------------|
| Y.B.L. Hansen    | Chair      | DK      | 1 <sup>st</sup> | 2021 01 - 2023 12 |
| S. Deveraj       | Member     | US      | 1 <sup>st</sup> | 2020 03 - 2022 12 |
| K. Furuta        | Member     | JP      | 1 <sup>st</sup> | 2019 02 - 2021 12 |
| F. Meric Yilmaz  | Member     | TR      | 1 <sup>st</sup> | 2021 03 - 2023 12 |
| E. van der Hagen | Member     | NL      | 2 <sup>nd</sup> | 2021 01 - 2023 12 |
| G. Nordin        | Consultant | SE      |                 |                   |

### Terms of Reference

- To continuously provide advice in relation to the management, updating and publishing of NPU terminology.
- To make recommendations on NPU for reporting clinical laboratory data that conform to or adapt current standards of authoritative organisations, and that will improve their utilisation for health care.
- To provide a connection with other organisations concerned with NPU, such as the Bureau International des Poids et Mesures (BIPM), the European Committee for Standardization (CEN) and the International Organization for Standardization (ISO), and, by extension, clinical laboratory sciences societies, such as the International Union of Pure and Applied Chemistry (IUPAC), and the in vitro diagnostics industry, to ensure that problems encountered by health care professionals in the area of NPU are considered by those organisations.
- To act as a consultant group on NPU in clinical chemistry and, by extension, in the rest of clinical laboratory sciences to international scientific panels, regional and national clinical laboratory sciences organisations, editors of scientific journals, manufacturers of clinical laboratory instrumentation and products, and to individual clinical laboratory professionals and other health care professionals.
- To report and offer advice to the SD Chair and the SD Executive Committee on matters concerning NPU in all its aspects (all items above).

### Current Projects

- Revision of Terms of reference
- To establish a Laboratory Information Data Model and a coherent concept system that will support comparisons of laboratory results.
- To provide an online platform that presents the principles and rules of the NPU terminology, including recommendations of measurement units to clinical laboratorians. The platform has been established on <https://labterminology.com/>, and is under development.

#### 8.2.11. Molecular Diagnostics (C-MD)

##### Membership

| Name                  | Position   | Country | Term            | Time in Office    |
|-----------------------|------------|---------|-----------------|-------------------|
| P. Ahmad-Nejad        | Chair      | DE      | 2 <sup>nd</sup> | 2021 01 - 2023 12 |
| K. Baluchova          | Member     | SK      | 1 <sup>st</sup> | 2019 02 - 2021 12 |
| M. Linder             | Member     | US      | 2 <sup>nd</sup> | 2021 01 - 2023 12 |
| A. Vacaflares Salinas | Member     | BO      | 1 <sup>st</sup> | 2020 03 - 2022 12 |
| S. Pan                | Member     | CN      | 1 <sup>st</sup> | 2021 05 - 2023 12 |
| J. Huggett            | Consultant | UK      |                 |                   |
| D. Payne              | Consultant | US      |                 |                   |
| M. Relling            | Consultant | US      |                 |                   |
| C. Zhang              | Observer   | CN      |                 |                   |

##### Terms of Reference

- To foster dynamic exchanges between IFCC and molecular diagnostic laboratories and industry
- To produce guidelines on clinical validation of tests, conduct and reporting of molecular diagnostic tests
- To create a network of locus specific IFCC Molecular Diagnostics Centres

### Current Projects

- Establish an International Network of IFCC Reference Centres in Molecular Diagnostics
- Standardise formats for reporting of molecular diagnostic results
- Facilitate integration of pharmacogenetic testing into routine diagnostics at the appropriate quality standards

### 8.2.23. Traceability in Laboratory Medicine (C-TLM)

#### Membership

| Name             | Position   | Country | Term            | Time in Office    |
|------------------|------------|---------|-----------------|-------------------|
| A. Kessler       | Chair      | DE      | 2 <sup>nd</sup> | 2021 01 - 2023 12 |
| T. Badrick       | Member     | AU      | 1 <sup>st</sup> | 2019 03 - 2021 12 |
| R.H. Girardi     | Member     | AR      | 2 <sup>nd</sup> | 2021 01 - 2023 12 |
| J. Infusino      | Member     | IT      | 2 <sup>nd</sup> | 2020 01 - 2022 12 |
| M. Pérez-Urquiza | Member     | MX      | 1 <sup>st</sup> | 2019 03 - 2021 12 |
| T. Zhang         | Member     | CN      | 1 <sup>st</sup> | 2021 05 - 2023 12 |
| M. Quaglia       | Consultant | UK      |                 |                   |
| C. Siebelder     | Consultant | NL      |                 |                   |
| S. Qu            | Observer   | CN      |                 |                   |

#### Terms of Reference

- To support activities regarding Traceability in Laboratory Medicine, permitting IFCC to continue its international role in this area and providing an operating link between the SD and the WGs of the Joint Committee on Traceability in Laboratory Medicine (JCTLM), concerning identification of reference measurement procedures, reference materials and reference laboratories.
- To support reference laboratories in the context of complete reference systems (accepted reference measurement procedures of higher order, reference materials, and reference laboratories) by establishing an External Quality Assessment Scheme (EQAS) for reference laboratories in order to monitor their competence.
- To promote establishment and maintenance of IFCC reference laboratory networks for clinically relevant measurands (e.g., the IFCC HbA1c network - <https://www.ifcchba1c.org/>).

### Current Projects

- Organisation of IFCC RELA surveys for calibration laboratories and candidate calibration laboratories (<http://www.dgkl-rfb.de:81/index.shtml>)

### 8.2.24. Reference Intervals and Decision Limits (C-RIDL)

#### Membership

| Name          | Position | Country | Term            | Time in Office    |
|---------------|----------|---------|-----------------|-------------------|
| Y. Özarda     | Chair    | TR      | 2 <sup>nd</sup> | 2019 01 - 2021 12 |
| D. Kang       | Member   | JP      | 2 <sup>nd</sup> | 2019 01 - 2021 12 |
| K. Kataria    | Member   | US      | 1 <sup>st</sup> | 2020 03 - 2022 12 |
| K. Sikaris    | Member   | AU      | 2 <sup>nd</sup> | 2020 01 - 2022 12 |
| T. Streichert | Member   | DE      | 2 <sup>nd</sup> | 2020 01 - 2022 12 |

#### Terms of Reference

- To review current concepts of establishing reference intervals and decision limits and to prepare state-of-the-art position statements regarding new avenues



- To make available reference intervals and decision limits that respect the requirements of international directives such as the European IVD Directive 98/79, and relevant ISO standards
- To determine priority list of measurands (analytes) for which reference intervals and/or decision limits have to be developed, considering various factors, such as age, gender, ethnicity, and for which the greatest improvements in medical decision making are anticipated
- To monitor and evaluate currently proposed reference intervals for selected measurands (analytes) in the light of the concept of traceability and of the identification of the uncertainty
- To establish transferability protocols of reference intervals and decision limits, which take into consideration inter-routine laboratory method variations and achieve better applicability in clinical practice
- To collaborate with other organizations and/or to undertake establishment of reference intervals or decision limits for measurands (analytes) identified as a priority
- To work in close collaboration with other Cs and WGs of SD and other IFCC Divisions for the development and appropriate clinical utilization of reference intervals and decision limits

### Current Projects

- Conduction of a new study to compare alternative approaches (conventional and big data) for the determination of reference intervals
- Creating a website to provide the reference intervals obtained from the global study for practice of Evidence Based Laboratory Medicine
- Preparation of a publication on comparison direct and indirect approaches for the determination of reference intervals.

### 8.2.25. Standardisation of Thyroid Function Tests (C-STFT)

#### Membership

| Name             | Position   | Country | Term            | Time in Office    |
|------------------|------------|---------|-----------------|-------------------|
| H. Vesper        | Chair      | US      | 2 <sup>nd</sup> | 2021 01 - 2023 12 |
| A. Hishinuma     | Member     | JP      | 2 <sup>nd</sup> | 2021 02 - 2023 12 |
| V. Raverot       | Member     | FR      | 1 <sup>st</sup> | 2020 03 - 2022 12 |
| K. Van Uytfanghe | Member     | BE      | 2 <sup>nd</sup> | 2021 01 - 2023 12 |
| S.L. Andersen    | Member     | DK      | 1 <sup>st</sup> | 2021 05 - 2023 12 |
| I. Erlund        | Consultant | FI      |                 |                   |
| M. Rottmann      | Consultant | DE      |                 |                   |
| L. Thienpont     | Consultant | BE      |                 |                   |
| H. Völzke        | Consultant | DE      |                 |                   |

In the previous terms, the committee developed the basis needed to implement standardisation of thyroid function tests. Specifically, the committee:

- developed reference measurement systems (reference materials/reference methods) to establish traceability of free thyroid hormone and TSH assays,
- provided an infrastructure for procurement of serum panels,
- demonstrated that the traceable assays can use a common reference interval,
- informed the clinical and research community about the importance of standardised tests.

Building on these accomplishments, the current committee set the following terms of reference:

**Terms of Reference:**

- Establish a system to maintain traceability of free thyroid hormone and TSH measurements.
- Coordinate programs to evaluate free thyroid and TSH assays with regards to their analytical performance.
- Develop reference intervals for free thyroid hormones and TSH.
- Liaise with key stakeholders to promote the use of the standardised assays in routine clinical practice and public health, to ensure analytical performance requirements meet clinical needs, and to help with developing and establishing reference intervals.

**Current Projects:**

- Establishment of a reference laboratory network
- Develop and establish follow-up panel for TSH
- Collaborate with relevant organisations to ensure that free thyroid hormones and TSH are standardized consistently
- Collaborate with stakeholders to define reference populations and plan study to establish reference intervals
- Provide information and training to stakeholders about the importance of standardised thyroid function assays, and support organisations working on promoting high quality of thyroid function tests

**8.2.26. Harmonisation of Autoimmune Tests (C-HAT)****Membership**

| <b>Name</b>   | <b>Position</b> | <b>Country</b> | <b>Term</b>     | <b>Time in Office</b> |
|---------------|-----------------|----------------|-----------------|-----------------------|
| J. Sheldon    | Chair           | UK             | 2 <sup>nd</sup> | 2020 01 - 2022 12     |
| X. Bossuyt    | Member          | BE             | 2 <sup>nd</sup> | 2020 01 - 2022 12     |
| M.J. Fritzler | Member          | CA             | 2 <sup>nd</sup> | 2020 01 - 2022 12     |
| L. Wienholt   | Member          | AU             | 2 <sup>nd</sup> | 2020 01 - 2022 12     |
| M. Rottmann   | Member/Roche    | DE             | 2 <sup>nd</sup> | 2020 01 - 2022 12     |

**Terms of Reference**

- To evaluate what are the main causes of variability for a number of diagnostically critical autoantibodies.
- To identify autoantibodies where a common calibrator could reduce the inter-assay variability
- To identify or produce commutable materials that could be used as interim calibration material for autoantibody assays.
- To produce well-characterised pure antibody preparations with known concentration and identity and use these to transfer values to a matrix preparation.
- To evaluate the impact of new reference material on the variability of autoantibody tests and identify areas where further harmonisation would improve diagnostic accuracy.

**8.2.27. Bone Metabolism (C-BM)****Membership**

| <b>Name</b>  | <b>Position</b> | <b>Country</b> | <b>Term</b>     | <b>Time in Office</b> |
|--------------|-----------------|----------------|-----------------|-----------------------|
| E. Cavalier  | Chair           | BE             | 1 <sup>st</sup> | 2019 01 - 2021 12     |
| H.P. Bhattoa | Member          | HU             | 1 <sup>st</sup> | 2019 02 - 2021 12     |
| A. Heijboer  | Member          | NL             | 1 <sup>st</sup> | 2019 02 - 2021 12     |
| C. Ulmer     | Member          | US             | 1 <sup>st</sup> | 2019 01 - 2021 12     |
| S. Vasikaran | Member          | AU             | 1 <sup>st</sup> | 2019 02 - 2021 12     |

|             |            |    |
|-------------|------------|----|
| V. Delatour | Consultant | FR |
| K. Phinney  | Consultant | US |
| C. Sempos   | Consultant | US |
| C. Sturgeon | Consultant | UK |
| H. Vesper   | Consultant | US |

As of January 2019, the IFCC has created this Committee on “**Bone Metabolism (C-BM)**”, formed by the joining of the already existing Working Groups:

- *Standardisation of Bone Markers Assays (WG-BMA) in collaboration with IOF*
- *Parathyroid Hormone (WG-PTH)*
- *Vitamin D Standardisation Program (WG-Vit D)*

### Terms of Reference

- Standardise PTH assays
- Standardise or harmonise bone markers assays
- Standardise vitamin D metabolites assays

### Current Projects

#### 1. PTH assays

- Create liaison with International Endocrinological, Rheumatological and Nephrological organisations
- Define the measurand (what we need to measure for all clinical situations)
- Develop a reference measurement procedure (RMP) for PTH(1-84) and moieties of clinical interest
- Evaluate the commutability of PTH International standard PTH 95/646 and the need to create primary reference material
- Replicate the RMP in a second lab and create a network of 3-4 reference labs
- Create an accuracy-based external quality assessment scheme
- Constitute an appropriate and international panel of sera and plasma to establish PTH reference intervals
- Specify performance criteria for RMP and routine methods
- Provide services to manufacturers, notably by providing a reliable source for primary reference materials
- Post-survey of the standardisation effects

#### 2. Bone markers assays

- Continue the liaison with IOF and extend to other relevant international societies

#### Current CTX and PINP project:

- Complete the multicentre study and harmonise CTX and PINP assays
- Collaborate with EQAS provider(s) to improve the surveys
- Constitute an appropriate and international panel of sera and plasma to establish CTX and PINP reference intervals
- Post-survey of the standardisation/harmonisation effects.

#### Future projects:

- Select biomarkers to be standardized/harmonized (g.: bone alkaline phosphatase, FGF-23, sclerostin).

#### 3. Vitamin D metabolites

- Re-evaluate current VDSP performance guidelines for 25(OH)D
- Establish VDSP performance guidelines for 24,25(OH)2D, C3-epimer and vitamin D

- binding protein
- Post-survey of the standardisation effects
- Propose services to reassess the true value of 25OHD obtained in former epidemiological or interventional studies that had used non-standardised methods

### 8.3. SD Working Groups

#### 8.3.35. Standardisation of Hemoglobin A2 (WG-HbA2)

##### Joint Working Group with ICSH (International Council for Standardization in Haematology)

###### Membership

| Name       | Position | Country | Term            | Time in Office    |
|------------|----------|---------|-----------------|-------------------|
| A. Mosca   | Chair    | IT      | 2 <sup>nd</sup> | 2020 01 - 2022 12 |
| C. Arsene  | Member   | DE      |                 |                   |
| P. Kaiser  | Member   | DE      |                 |                   |
| R. Paleari | Member   | IT      |                 |                   |
| L. Wu      | Member   | CN      |                 |                   |
| T. Zhang   | Member   | CN      |                 |                   |

###### Terms of Reference

- To promote the standardisation of hemoglobin A2 measurement through the definition of an international reference system, including a reference measurement procedure and primary and secondary reference materials.

###### Current Projects

- Definition of a reference measurement procedure using mass spectrometry associated with proteolytic degradation.
- Preparation of a secondary reference material for hemoglobin A2 (in cooperation with JRC).

#### 8.3.36. Carbohydrate-Deficient Transferrin (WG-CDT)

###### Membership

| Name            | Position | Country | Term            | Time in Office    |
|-----------------|----------|---------|-----------------|-------------------|
| J. Deenmamode   | Chair    | UK      | 2 <sup>nd</sup> | 2021 01 - 2023 12 |
| R.F. Anton      | Member   | US      |                 |                   |
| J. Delanghe     | Member   | NL      |                 |                   |
| F. Schellenberg | Member   | FR      |                 |                   |
| C.W. Weykamp    | Member   | NL      |                 |                   |
| J.P.M. Wielders | Member   | NL      |                 |                   |

###### Terms of Reference

- Promoting the use of the HPLC reference measurement procedure (RMP) as the accuracy base for CDT test standardisation
- Maintaining sustainability of an international network of reference laboratories
- Supporting the worldwide standardisation of commercial methods against the RMP
- Offering consultation concerning use of biomarkers of alcoholism towards national or international agencies
- Providing scientific support for the production and delivery of authorised CRM
- Supporting the development of guidelines for clinical use of CDT assays

### Current Projects

- Promoting the use of the HPLC reference measurement procedure (RMP) as the accuracy base for CDT test standardisation
- Maintaining an international network of reference laboratories
- Supporting the worldwide standardisation of commercial methods against the RMP

### 8.3.39. Standardisation of Albumin Assay in Urine (WG-SAU) - in collaboration with NIDDK

In cooperation with "National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) - <https://www.niddk.nih.gov/>"

#### Membership

| Name             | Position | Country | Term            | Time in Office    |
|------------------|----------|---------|-----------------|-------------------|
| J. Seegmiller    | Chair    | US      | 1 <sup>st</sup> | 2020 01 - 2022 12 |
| A. Beasley Green | Member   | US      |                 |                   |
| J. Delanghe      | Member   | BE      |                 |                   |
| J. Eckfeldt      | Member   | US      |                 |                   |
| J. Fleming       | Member   | US      |                 |                   |
| N. Greenberg     | Member   | US      |                 |                   |
| G. Hortin        | Member   | US      |                 |                   |
| Y. Itoh          | Member   | JP      |                 |                   |
| G. Jones         | Member   | AU      |                 |                   |
| J. Kaufmann      | Member   | US      |                 |                   |
| T. Killeen       | Member   | US      |                 |                   |
| J. Lieski        | Member   | US      |                 |                   |
| G. Miller        | Member   | US      |                 |                   |
| G. Myers         | Member   | US      |                 |                   |
| M. Panteghini    | Member   | IT      |                 |                   |
| A. Parsa         | Member   | US      |                 |                   |
| K.W. Phinney     | Member   | US      |                 |                   |
| S. Sandberg      | Member   | NO      |                 |                   |
| H. Schimmel      | Member   | BE      |                 |                   |
| D. Secombe       | Member   | CA      |                 |                   |
| J. Zakowski      | Member   | US      |                 |                   |

#### Terms of Reference

- To establish a reference procedure and reference materials for the measurement of albumin in urine

### Current Projects

- Development of reference materials for urine creatinine and urine albumin
- Development of urine albumin IDMS candidate reference measurement procedures

### 8.3.40. Standardisation of Pregnancy-Associated Plasma Protein A (WG-PAPP A)

#### Membership

| Name          | Position | Country | Term           | Time in Office    |
|---------------|----------|---------|----------------|-------------------|
| S. Wittfooth  | Chair    | FI      | 1yr extra term | 2021 01 – 2021 12 |
| S. Jones      | Member   | UK      |                |                   |
| A. Katrukha   | Member   | RU      |                |                   |
| K. Pettersson | Member   | FI      |                |                   |

|             |        |    |
|-------------|--------|----|
| K. Spencer  | Member | UK |
| C. Sturgeon | Member | UK |

### Terms of Reference

- To establish a reference material for PAPP-A measurement employed as a marker for prenatal screening

### Current Projects

- Evaluation of candidate reference materials in relation to the major assay constructs presently being used in routine prenatal testing

## 8.3.41. Growth Hormone (WG-hGH)

### Membership

| Name          | Position               | Country | Term            | Time in Office    |
|---------------|------------------------|---------|-----------------|-------------------|
| M. Vos        | Chair                  | NL      | 1 <sup>st</sup> | 2021 01 - 2023 12 |
| C. Arsene     | Member                 | DE      |                 |                   |
| E. Lentjes    | Member                 | NL      |                 |                   |
| M. Quaglia    | Member                 | UK      |                 |                   |
| C. Sturgeon   | Member                 | UK      |                 |                   |
| J.S. Blanchet | Member/Beckman Coulter | FR      |                 |                   |
| M. Rottmann   | Member/Roche           | DE      |                 |                   |
| C. Weykamp    | Consultant             | NL      |                 |                   |
| C. Cobbaert   | Consultant             | NL      |                 |                   |

### Terms of Reference

- To establish a higher order Reference Measurement System for enabling hGH standardisation of commercial IVDs, encompassing both the development of Reference Materials and a harmonised Reference Measurement Procedure. The RMP should be set-up in at least two calibration labs, and preferentially in a network of calibration labs.

### Current projects

- Defining the accuracy base for hGH standardisation in order to establish a complete and sustainable Reference Measurement System.
- Developing an MS-based Reference Measurement Procedure for the measurement of hGH which allows an operational definition of the relevant measurand, according to the matching calibration hierarchy described in ISO 17511:2020. The reference method should meet relevant ISO standards (i.e., ISO 15195) and its performance should be validated. In the end, it should be IFCC endorsed and also listed in the JCTLM database.
- Establish the suitability of recombinant human growth hormone preparations as primary reference material with appropriate properties.
- Establish the performance of commercially available hGH assays compared to the MS-based RMP using single donation samples (from sporters) and the effect of using a common primary reference material or serum pools on between method agreement.
- Determination of the effect of freeze/thawing on measured hGH (a requirement to establish the validity of materials for 4. above).

### 8.3.42. Standardisation of Insulin Assays (WG-SIA) in collaboration with ADA/EASD

#### Membership

| Name             | Position             | Country | Term | Time in Office |
|------------------|----------------------|---------|------|----------------|
| M. Steffes       | Co-Chair             | US      |      |                |
| J. Seegmiller    | Co-Chair             | US      |      |                |
| D. Holmes        | Member               | CA      |      |                |
| R. Little        | Member               | US      |      |                |
| M. McPhaul       | Member               | US      |      |                |
| G. Miller        | Member               | US      |      |                |
| H. Ritzén        | Member               | SE      |      |                |
| D. Sacks         | Member               | US      |      |                |
| G. Wark          | Member               | UK      |      |                |
| B. Akolkar       | Consultant/NIH NIDDK | US      |      |                |
| K. Van Uytvanghe | Consultant           | BE      |      |                |

#### Terms of Reference

- To improve the standardisation of assays for insulin by the development of a candidate reference method and materials.

#### Current Projects

- The development of a reference method for the measurement of insulin by electrospray ionisation-isotope dilution-liquid chromatography-tandem mass spectrometry (ID-LC/tandem MS).
- Establishment of the suitability or otherwise of a lyophilised recombinant human insulin preparation as a primary reference material with appropriate properties
- Establishment of the performance of commercially available insulin assays compared to the ID-LC/tandem MS method using single donation samples and the effect of using a common primary reference material or serum pools on between method agreement.
- Determination of the effect of freeze/thawing on measured insulin (a requirement to establish the validity of materials for 3 above).

### 8.3.43. Standardisation of Troponin I (WG-TNI)

#### Membership

| Name           | Position | Country | Term            | Time in Office    |
|----------------|----------|---------|-----------------|-------------------|
| R. Christenson | Chair    | US      | 2 <sup>nd</sup> | 2020 01 - 2022 12 |
| D. Armbruster  | Member   | US      |                 |                   |
| J. Barth       | Member   | UK      |                 |                   |
| A. Katrukha    | Member   | FI      |                 |                   |
| J. Noble       | Member   | UK      |                 |                   |
| M. Panteghini  | Member   | IT      |                 |                   |
| A. Saenger     | Member   | US      |                 |                   |
| H. Schimmel    | Member   | BE      |                 |                   |
| L. Wang        | Member   | US      |                 |                   |

#### Terms of Reference

- Development of a candidate secondary reference measurement procedure and candidate secondary reference material for cardiac troponin I (cTnI)
- Testing for cTnI standardisation and clinical validation by comparison with validated commercial assays in a round robin study

### Current Projects

- Preparation of a secondary reference material for cTnI consisting of three cTnI positive serum pools (Phase 2)
- Validation of cTnI standardisation through a round robin after a value transfer using the secondary reference material as common calibrator (Phase 3)

### 8.3.49. Working Group CSF-Proteins (WG-CSF)

#### Membership

| Name              | Position | Country | Term            | Time in Office    |
|-------------------|----------|---------|-----------------|-------------------|
| J. Gobom          | Chair    | SE      | 2 <sup>nd</sup> | 2021 01 - 2023 12 |
| U. Andreasson     | Member   | SE      |                 |                   |
| K. Blennow        | Member   | SE      |                 |                   |
| R. Bateman        | Member   | US      |                 |                   |
| V. Delatour       | Member   | FR      |                 |                   |
| R. Jenkins        | Member   | US      |                 |                   |
| M. Korecka        | Member   | US      |                 |                   |
| S. Lehmann        | Member   | FR      |                 |                   |
| P. Lewczuk        | Member   | DE      |                 |                   |
| M. Lowenthal      | Member   | US      |                 |                   |
| E. Portelius      | Member   | SE      |                 |                   |
| L.M. Shaw         | Member   | US      |                 |                   |
| E. Stoops         | Member   | BE      |                 |                   |
| H. Vanderstichele | Member   | BE      |                 |                   |
| E. Vanmechelen    | Member   | BE      |                 |                   |
| I. Zegers         | Member   | BE      |                 |                   |
| H. Zetterberg     | Member   | SE      |                 |                   |

#### Terms of Reference

- To develop a RMP for CSF amyloid  $\beta$  1-42
- To develop a RMP for CSF amyloid  $\beta$  1-40
- To develop a RMP for CSF total tau
- To develop CRMs for CSF amyloid  $\beta$  1-42
- To develop CRMs for CSF amyloid  $\beta$  1-40
- To develop CRMs for CSF total tau

#### Current Projects

- Two RMPs for CSF amyloid  $\beta$  1-42 have been published and approved by the JCTLM (C12RMP1 and C11RMP9)
- A method for measurement of CSF amyloid  $\beta$  1-40 by SRM has been published and validation of a RMP is ongoing
- Development of a method for measurement of tau by SRM is ongoing
- Three CRMs for CSF amyloid  $\beta$  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

### 8.3.51. Commutability in Metrological Traceability (WG-CMT)

#### Membership

| Name       | Position | Country | Term            | Time in Office    |
|------------|----------|---------|-----------------|-------------------|
| G. Miller  | Chair    | US      | 1 <sup>st</sup> | 2020 03 - 2022 12 |
| H. Althaus | Member   | DE      |                 |                   |



|                  |        |    |
|------------------|--------|----|
| J. Budd          | Member | US |
| C. Burns         | Member | UK |
| J. Camara        | Member | US |
| F. Ceriotti      | Member | IT |
| V. Delatour      | Member | FR |
| N. Greenberg     | Member | US |
| J. Johansen      | Member | DK |
| P. Kaiser        | Member | DE |
| T. Keller        | Member | DE |
| A. Lyle          | Member | US |
| F. MacKenzie     | Member | UK |
| M. Panteghini    | Member | IT |
| R. Rej           | Member | US |
| S. Sandberg      | Member | NO |
| H. Schimmel      | Member | BE |
| M. Spannagl      | Member | DE |
| E. van der Hagen | Member | NL |
| H. Vesper        | Member | US |

### Terms of Reference

- Advise IFCC Committees and Working Groups on how to assess the commutability of materials on which they are working.
- Establish procedures to use commutable reference materials, and to correct for non-commutability bias, in a metrological traceability hierarchy.
- Establish how to define the criterion for acceptable commutability that is required for a given reference material, taking into account its intended use in a metrological traceability hierarchy or for surveillance of harmonisation/standardization status of results from different measurement procedures.
- Provide recommendations on verifying commutability for replacement batches of a reference material.

### Current Projects

- How to specify acceptance criteria for commutability assessment.
- How to verify commutability for a new batch of a reference material.
- How to use a CRM in the calibration hierarchy for a measurement procedure for which the sample matrix is not intended.

### 8.3.53. Immunosuppressive Drugs (WG-ID)

#### Membership

| Name           | Position | Country | Term            | Time in Office    |
|----------------|----------|---------|-----------------|-------------------|
| C. Seger       | Chair    | CH      | 2 <sup>nd</sup> | 2021 01 - 2023 12 |
| M.J. Barten    | Member   | DE      |                 |                   |
| S. Bergan      | Member   | NO      |                 |                   |
| M. Brunet      | Member   | ES      |                 |                   |
| U. Christians  | Member   | US      |                 |                   |
| B. de Winter   | Member   | NL      |                 |                   |
| L. Elens       | Member   | BE      |                 |                   |
| D. Grote-Koska | Member   | DE      |                 |                   |
| V. Haufroid    | Member   | BE      |                 |                   |
| A. Henrion     | Member   | DE      |                 |                   |
| D.W. Holt      | Member   | UK      |                 |                   |

|                |        |    |
|----------------|--------|----|
| A. Kessler     | Member | DE |
| P.K. Kunicki   | Member | PL |
| L. Langman     | Member | US |
| S. Masuda      | Member | JP |
| D. Moes        | Member | NL |
| T. Pawiński    | Member | PL |
| L.M. Shaw      | Member | US |
| M. Shipkova    | Member | DE |
| C. Snozek      | Member | US |
| N. Torre Vethe | Member | NO |
| T. van Gelder  | Member | NL |
| M. Vogeser     | Member | DE |
| P. Wallemacq   | Member | BE |
| E. Wieland     | Member | DE |

### Terms of Reference

- The WG is devoted to the establishment of candidate reference procedures and reference materials for immunosuppressive drugs (ISDs) as cyclosporine, sirolimus, tacrolimus, everolimus, and mycophenolic acid (MPA). Demonstration of the current state of the art in ISD – TDM by measurement comparison will define the need for harmonisation or – if feasible – standardisation of measurement services

### Current projects

- *Regulatory framework:*
  - Establish and communicate the regulatory framework which allows submitting to the JCTLM reference materials, measurement methods and measurement services established within the WG-ID.
- *Measurement comparison initiative aimed to assess the state of art in ISD TDM:*
  - Baseline assessment including method comparability.
  - Influence of secondary reference materials on method comparability.
- *Production of reference materials to be listed in the JCTLM database:*
  - Characterisation of primary reference materials.
  - Production of primary reference materials.
  - Characterisation and production of secondary reference materials.
- *Establishment of reference methods to be listed in the JCTLM database:*
  - Design and validation of a candidate reference method by at least two to three partner institutions.
- *Establishing reference procedures:*
  - Establishment of a reference laboratory network.
  - Establishment of a reference measurement service network.

### 8.3.54. Apolipoproteins by Mass Spectrometry (WG-APO MS)

#### Membership

| Name         | Position  | Country | Term            | Time in Office    |
|--------------|-----------|---------|-----------------|-------------------|
| C. Cobbaert  | Chair     | NL      | 2 <sup>nd</sup> | 2020 01 - 2022 12 |
| L.R. Ruhaak  | Secretary | NL      |                 |                   |
| I. Begcevic  | Member    | US      |                 |                   |
| U. Ceglarek  | Member    | DE      |                 |                   |
| V. Delatour  | Member    | FR      |                 |                   |
| J. Dittrich  | Member    | DE      |                 |                   |
| A. Hoofnagle | Member    | US      |                 |                   |

|                |                            |    |
|----------------|----------------------------|----|
| Z. Kuklennyik  | Member / CDC               | US |
| A. Lyle        | Member / CDC               | US |
| H.W. Vesper    | Member / CDC               | US |
| H. Althaus     | IVD Representative/Siemens | DE |
| U. Prinzing    | IVD Representative/Roche   | DE |
| E. Angles-Cano | Consultant                 | FR |
| G.M. Kostner   | Consultant                 | AT |
| F. Kronenberg  | Consultant                 | AT |
| L. Deprez      | Consultant / JRC           | BE |
| I. Dikaïos     | Consultant / JRC           | BE |

### Terms of Reference

- To achieve standardisation of a panel of clinically relevant serum apolipoproteins (apo) A-I, B, C-I, C-II, C-III, E and apo (a) (including qualitative phenotyping where needed). Standardisation is done in such a way that measurement results are traceable to SI as outlined in ISO 17511. Other traceability chains will be used in cases where traceability to SI cannot be achieved.
- To evaluate clinical performance and clinical utility of serum apolipoprotein panel(s) for CVD risk stratification and treatment, in comparison to or together with contemporary blood lipids.

### Current projects

- Define the analytes / measurands intended to be measured.
- Development of primary and secondary reference materials, including evaluation of commutability.
- Development of an LC-MS/MS-based reference method for the above-mentioned analytes that are unaffected by genetic variants, post-translational modifications and other factors. The reference method will meet relevant ISO standards (i.e., ISO 15195).
- Evaluation of the analytical performance of the LC-MS/MS reference method.
- Assessment of the performance of commercially available apolipoprotein assays compared to the reference method using commutable reference materials as well as single donation samples.
- Any reference materials and reference measurement procedures developed will be submitted to JCTLM for review and listing on the JCTLM database.

### Future Projects

- Evaluation of clinical performance and clinical utility of the multiplexed apolipoprotein test according to the Test Evaluation framework developed by the EFLM working group on Test Evaluation (Horvath AR et al., CCA, 2014).

## 8.3.55. Pancreatic Enzymes (WG-PE)

### Membership

| Name           | Position | Country | Term            | Time in Office    |
|----------------|----------|---------|-----------------|-------------------|
| D. Grote-Koska | Chair    | DE      | 2 <sup>nd</sup> | 2020 01 - 2022 12 |
| F. Canalias    | Member   | ES      |                 |                   |
| F. Ceriotti    | Member   | IT      |                 |                   |
| B. Chen        | Member   | CN      |                 |                   |
| J. Infusino    | Member   | IT      |                 |                   |
| S. Pal         | Member   | IN      |                 |                   |
| S. Ueda        | Member   | JP      |                 |                   |
| M. Veuger      | Member   | NL      |                 |                   |

### Terms of Reference

- To develop a primary reference method for pancreatic Lipase in Serum
- To develop a primary reference method for pancreatic Amylase in Serum
- To support EC-JRC (Joint Research Centre, Directorate F – Health, Consumers and Reference Materials, formerly IRMM) in case of studies and certification of reference materials for enzymes

### Current projects

- Development of a Pancreatic-Amylase method to obtain a practical version to act as reference method

### 8.3.56. Fecal Immunochemical Testing (WG-FIT)

#### Membership

| Name             | Position     | Country | Term | Time in Office    |
|------------------|--------------|---------|------|-------------------|
| S. Benton        | Chair        | UK      | 2nd  | 2020 01 - 2022 12 |
| J.M. Auge        | Member       | ES      |      |                   |
| L. Deprez        | Member       | BE      |      |                   |
| N. Djedovic      | Member       | UK      |      |                   |
| M. Frasa         | Member       | NL      |      |                   |
| S. Jones         | Member       | UK      |      |                   |
| P. Kocna         | Member       | CZ      |      |                   |
| C. Piggott       | Member       | UK      |      |                   |
| P. St. Louis     | Member       | CA      |      |                   |
| J. Strachan      | Member       | UK      |      |                   |
| E. Symonds       | Member       | AU      |      |                   |
| S. Takehara      | Member       | JP      |      |                   |
| E. van der Hagen | Member       | NL      |      |                   |
| A. Cugini        | Corp. Member | IT      |      |                   |
| Y. Doi           | Corp. Member | JP      |      |                   |
| M. Fujimura      | Corp. Member | JP      |      |                   |
| T. Fukuda        | Corp. Member | JP      |      |                   |
| H. Hayashi       | Corp. Member | JP      |      |                   |
| A. Horikawa      | Corp. Member | JP      |      |                   |
| Y. Masuda        | Corp. Member | JP      |      |                   |
| F. Rota          | Corp. Member | IT      |      |                   |
| S. Wu            | Corp. Member | JP      |      |                   |
| M. Zacherl       | Corp. Member | DE      |      |                   |

#### Terms of Reference

- To harmonise and/or standardise analysis of haemoglobin in faecal samples by immunochemistry (FIT)
- To establish EQA and 3<sup>rd</sup> party IQC programmes
- To determine the feasibility of developing reference materials and/or commutable calibrators
- The IFCC FIT-WG can provide recommendations and guidance on preanalytical and analytical aspects of FIT

#### Current projects

- Identification of a suitable reference material and assessment of commutability for all available laboratory quantitative FIT methods
- Review of all FIT EQA programmes currently available globally

### 8.3.57. Cell free DNA and related circulating biomarkers (WG-cfDNA)

#### Membership

| Name          | Position | Country | Term            | Time in Office    |
|---------------|----------|---------|-----------------|-------------------|
| R. van Schaik | Chair    | NL      | 2 <sup>nd</sup> | 2021 01 - 2023 12 |
| M. del Re     | Member   | IT      |                 |                   |
| S. Galbiati   | Member   | IT      |                 |                   |
| E. Lianidou   | Member   | GR      |                 |                   |
| D. Lo         | Member   | HK      |                 |                   |
| M. Oellerich  | Member   | DE      |                 |                   |

#### 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
- Organising international workshops
- Defining grant proposals to address unmet needs under a) and b)

### 8.3.58. Working Group Standardisation of Procalcitonin assays (WG-PCT)

#### Membership

| Name           | Position               | Country | Term            | Time in Office    |
|----------------|------------------------|---------|-----------------|-------------------|
| V. Delatour    | Chair                  | FR      | 2 <sup>nd</sup> | 2021 01 - 2023 12 |
| A. Boeuf       | Member                 | FR      |                 |                   |
| H. Briand      | Member                 | FR      |                 |                   |
| N. Corocher    | Member                 | IT      |                 |                   |
| A.M. Dupuy     | Member                 | FR      |                 |                   |
| P. Hausfater   | Member                 | FR      |                 |                   |
| P. Kaiser      | Member                 | DE      |                 |                   |
| Q. Liu         | Member                 | SG      |                 |                   |
| B. Machetanz   | Member                 | DE      |                 |                   |
| L. Pallavicini | Member                 | IT      |                 |                   |
| S. Pastori     | Member                 | IT      |                 |                   |
| J. Pfannkuche  | Member                 | DE      |                 |                   |
| K. Schneider   | Member                 | DE      |                 |                   |
| P. Schütz      | Member                 | CH      |                 |                   |
| C. Tsatsanis   | Member                 | GR      |                 |                   |
| C. Yuan        | Member                 | US      |                 |                   |
| P. Bryan       | Member/OCD             | US      |                 |                   |
| M. Grimmmler   | Member/Diasys          | DE      |                 |                   |
| P. Jauria      | Member/Radiometer      | FI      |                 |                   |
| T. Masetto     | Member/Diasys          | DE      |                 |                   |
| J. Odarjuk     | Member/Thermo Fisher   | DE      |                 |                   |
| N. Parker      | Member/Siemens         | US      |                 |                   |
| M. Patru       | Member/OCD             | US      |                 |                   |
| K. Paulsen     | Member/Beckman Coulter | DE      |                 |                   |
| M. Rottmann    | Member/Roche           | DE      |                 |                   |
| S. Ruetten     | Member/Abbott          | US      |                 |                   |

|           |                        |    |
|-----------|------------------------|----|
| A. Rybin  | Member/Siemens         | US |
| L. Seaver | Member/Abbott          | US |
| M. Solari | Member/Beckman Coulter | US |
| B. Thomas | Member/Thermo Fisher   | DE |

### Terms of Reference

- Develop and validate a reference measurement procedure for PCT absolute quantification by Stable Isotope Dilution Mass Spectrometry
- Document and understand the variability of results provided by the different commercially available PCT assays
- Evaluate the need for standardisation of PCT assays
- Evaluate the feasibility for standardisation of PCT assays
- Perform standardisation of PCT assays, if needed and feasible.

### Current projects

- Production of commutable EQA materials designed to assess comparability of commercially available PCT assays
- Production and characterisation of candidate primary calibrators
- Development of a candidate reference method for absolute quantification of PCT by IDMS

## 8.3.60. Working Group on Continuous Glucose Monitoring (WG-CGM)

### Membership

| Name              | Position     | Country | Term            | Time in Office    |
|-------------------|--------------|---------|-----------------|-------------------|
| G. Freckmann      | Chair        | DE      | 1 <sup>st</sup> | 2019 07 - 2021 12 |
| R. Slingerland    | Co-Chair     | NL      |                 |                   |
| P. Diem           | Member       | CH      |                 |                   |
| E. Eriksson Boija | Member       | SE      |                 |                   |
| J. Jendle         | Member       | SE      |                 |                   |
| Y. Ju             | Member       | CN      |                 |                   |
| D. Klonoff        | Member       | US      |                 |                   |
| J. Nichols        | Member       | US      |                 |                   |
| M. Tangirala      | Member       | IN      |                 |                   |
| A. Thomas         | Member       | DE      |                 |                   |
| N. Tran           | Member       | US      |                 |                   |
| R. Hinzmann       | Member/Roche | DE      |                 |                   |

### 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 standardised 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.

### 8.3.61 Development of a Reference Measurement System for sustainable PT/ INR Standardization (WG-PT/INR)

At the time of publication of this handbook, the definition of this SD Working Group is on-going.

Please refer to the IFCC website under the SD to view the current Membership, Terms of Reference, and Current projects.

### 8.4. Publications

A complete list of IFCC publications is available on the IFCC web site at:  
<http://www.ifcc.org/ifcc-scientific-division/sd-yearly-publications-of-interest/>

### 8.5. List of Addresses

#### SD EXECUTIVE COMMITTEE

##### Chair

###### **Prof. Philippe GILLERY**

Service de Biochimie - Pharmacologie –  
Toxicologie  
Pôle de Biologie Médicale et Pathologie  
CHU de Reims  
Pôle de Biologie Territoriale  
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##### Vice-Chair

###### **Prof. Christa M. COBBAERT**

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##### Secretary

###### **Prof. Garry JOHN**

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