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SCIENTIFIC DIVISION
EXECUTIVE COMMITTEE (SD-EC)

Chair:
Prof. Philippe GILLERY (FR)

Vice Chair:
Prof. Christa M COBBAERT (NL)

Secretary:
Mr. Joseph PASSARELLI (US)

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

Corporate Representative:
Mr. James F. PIERSON-PERRY (US)

European Commission – JRC Observer:
Dr. Heinz SCHIMMEL (BE)

JCTLM Chair – SD Consultant
Dr. Gary L. MYERS (US)

NIBSC Consultant:
Dr. Chris BURNS (UK)

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) in collaboration with International Union of Pure and Applied Chemistry (IUPAC)	K. Toska (NO)
8.2.11. Molecular Diagnostics (C-MD)	D. Payne (US)
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)

8.3. Working Groups

8.3.35. Standardisation of Hemoglobin A2 (WG-HbA2)	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) in collaboration with National Kidney Disease Education Program (NKDEP)	L.M. Bachmann (US)
8.3.40. Standardisation of Pregnancy-Associated Plasma Protein A (WG-PAPP A)	S. Wittfooth (FI)
8.3.41 Growth Hormone (WG-GH)	E. Lentjes (NL)
8.3.42. Standardisation of Insulin Assays (WG-SIA) in collaboration with American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD)	A. Saenger (US)
8.3.43. Standardisation of Troponin I (WG-TNI)	R. Christenson (US)
8.3.48. Parathyroid Hormone (WG- PTH)	C. Sturgeon (UK)
8.3.49. CSF-Proteins (WG-CSF)	J. Gobom (SE)
8.3.50. Standardisation of Bone Marker Assays (WG-BMA) in collaboration with IOF	E. Cavalier (BE)
8.3.51 Commutability (WG-C)	G. Miller (US)
8.3.53 Immunosuppressive Drugs (WG-ID)	C. Seger (CH)
8.3.54 Apolipoproteins by Mass Spectrometry (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 (WG-cfDNA)	R. van Schaik (NL)
8.3.58 Standardisation of Procalcitonin Assays (WG-PCT)	V. Delatour (FR)
8.3.59 Vitamin D Standardization Program (WG-Vit D)	C. Sempos (US)

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	1st	2017 01 - 2019 12
C. Cobbaert	Vice-Chair	NL	1st	2017 01 - 2019 12
J. Passarelli	Secretary	US	2nd	2018 01 - 2020 12
K. Makris	Member	GR	1st	2017 01 - 2019 12
B. Das	Member	IN	1st	2018 06 - 2020 12
M. Plebani	Member	IT	1st	2017 01 - 2019 12
J.F. Pierson-Perry	Corporate Member	US	2nd	2018 01 - 2020 12
H. Schimmel	European Commission JRC Observer	BE		
G. Myers	JCTLM Chair / Consultant	US		
C. Burns	NIBSC Consultant	UK		
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 Laboratory Medicine and to further their application in the provision of health services and the practice of medicine. The strategic and tactical 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 six 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
K. Toska	Chair	NO	1st	2018 01 - 2020 12
Y.B.L. Hansen	Member	DK	1st	2017 03 - 2019 12
A. Jabor	Member	CZ	2nd	2016 03 - 2018 12
F. Scherrer	Member	FR	2nd	2018 01 - 2020 12
E. van der Hagen	Member	NL	1st	2018 03 - 2020 12
R. Dybkaer	Consultant	DK		

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 utilization 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

- Transfer of the NPU generic database to IFCC site: help and advice on training the future IFCC NPU database manager(s) in relation to the installation, updating and management of the database, and on its relationship relations with other national versions.
- Mapping of the IFCC-IUPAC laboratory coding system to SNOMED CT.
- Securing and structural updating of information in the NPU coding system and its environment.
- Development of an international vocabulary for nominal examinations in scientific communication.

8.2.11. Molecular Diagnostics (C-MD)

Membership

Name	Position	Country	Term	Time in Office
D. Payne	Co-Chair	US	2nd	2016 01 - 2018 12
M Linder	Co-Chair	US	1st	2017 03 - 2018 12
P. Ahmad-Nejad	Member	DE	2nd	2016 01 - 2018 12
T. Framroze Ashavaid	Member	IN	1st	2017 05 - 2018 12
G. Russomando	Member	PY	2nd	2016 01 - 2018 12
O. Slanař	Member	CZ	1st	2017 05 - 2018 12
W. Steimer	Member	DE	1st	2018 05 - 2020 12
M. Relling	Consultant	US		
H. Parkes	Consultant	UK		

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	1st	2018 01 - 2020 12
J. Anetor	Member	NG	2nd	2018 01 - 2020 12
F. Canalias	Member	ES	1st	2016 06 - 2018 12
R.H. Girardi	Member	AR	1st	2018 03 - 2020 12
J. Infusino	Member	IT	1st	2017 03 - 2019 12
L. Mackay	Member	AU	2nd	2016 01 - 2018 12
C. Weykamp	Consultant	NL		
G. Schumann	Consultant	DE		

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).

Current Projects

- Organisation of IFCC Ring Trials for reference laboratories

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

Membership

Name	Position	Country	Term	Time in Office
Y. Özarda	Chair	TR	1st	2016 01 - 2018 12
D. Kang	Member	JP	1st	2016 06 - 2018 12
J. Macri	Member	CA	2nd	2017 01 - 2019 12
K. Sikaris	Member	AU	1st	2017 03 - 2019 12
T. Streichert	Member	DE	1st	2017 03 - 2019 12
B. Yadav	Member	NP	2nd	2017 01 - 2019 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 transferabilty 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 organisations 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
- Creation of a website to provide the reference intervals obtained from the global study for practice of Evidence Based Laboratory Medicine
- Preparation of a publication on the distinction of Reference Intervals and Clinical Decision Limits

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

Membership

Name	Position	Country	Term	Time in Office
H. Vesper	Chair	US	1st	2018 01 - 2020 12
A. Hishinuma	Member	JP	1st	2018 03 - 2020 12
J. Kratzsch	Member	DE	1st	2018 03 - 2020 12
K. Van Uytfanghe	Member	BE	1st	2018 03 - 2020 12
M.M. Patru	Member/OCD	US	2nd	2018 01 - 2020 12
M. Rottmann	Consultant	DE		
L. Thienpont	Consultant	BE		

In the previous terms, the committee developed the basis needed to implement standardization 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 organizations to ensure that free thyroid hormones and TSH are standardised 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

Name	Position	Country	Term	Time in Office
J. Sheldon	Chair	UK	1st	2017 03 - 2019 12
X. Bossuyt	Member	BE	1st	2017 03 - 2019 12
M.J. Fritzler	Member	CA	1st	2017 03 - 2019 12
L. Wienholt	Member	AU	1st	2017 03 - 2019 12
M. Rottmann	Member/Roche	DE	1st	2017 03 - 2019 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.

8.3. SD Working Groups

8.3.35. Standardisation of Haemoglobin A2 (WG-HbA2)

Membership

Name	Position	Country	Term	Time in Office
A. Mosca	Chair	IT		1st
2017 01 - 2019 12				
C. Arsene	Member	DE		
P. Kaiser	Member	DE		
Q. Liu	Member	SG		
R. Paleari	Member	IT		

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	1st	2018 01 - 2020 12
R.F. Anton	Member	US		
V. Bianchi	Member	IT		
A. Helander	Member	SE		
F. Schellenberg	Member	FR		
J.P.M. Wielders	Member	NL		
C.W. Weykamp	Member	NL		

Terms of Reference

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

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

Membership

Name	Position	Country	Term	Time in Office
L.M. Bachmann	Chair	US	2nd	2016 01 - 2018 12
A. Beasley Green	Member	US		
D. Bruns	Member	US		
D. Bunk	Member	US		
G. Curhan	Member	US		
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. Lieski	Member	US
M. McQueen	Member	CA
G. Miller	Member	US
G. Myers	Member	US
A. Narva	Member	US
M. Panteghini	Member	IT
K.W. Phinney	Member	US
S. Sandberg	Member	NO
H. Schimmel	Member	BE
D. Seccombe	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	2nd	2018 01- 2020 12
C. Sturgeon	Member	UK		
A. Katrukha	Member	RU		
K. Pettersson	Member	FI		
K. Spencer	Member	UK		
S. Jones	Member	UK		

Terms of Reference

- To develop a reference system for standardisation of PAPP-A measurement employed as marker for prenatal screening

Current Projects

- Evaluation of different PAPP-A preparations in relation to the major assay constructs presently being used in routine prenatal testing

8.3.41 Growth Hormone (WG-GH)

Membership

Name	Position	Country	Term	Time in Office
E. Lentjes	Chair	NL	1st	2017 01 - 2019 12
C. Arsene	Member	DE		
C. Sturgeon	Member	UK		
M. Rottmann	Member/Roche	DE		
J.S. Blanchet	Member/Beckman Coulter	FR		
C. Weykamp	Consultant	NL		

Terms of Reference

- To achieve standardisation of growth hormone through secondary reference materials and a reference measurement procedure

Current projects

- Define the analyte/measurand to be measured
- Test the feasibility of serum pools as secondary, commutable reference preparations
- Preparation of secondary reference preparation for GH (3 serum pools)
- Development of an LCMSMS based reference method for GH

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

Membership

Name	Position	Country	Term	Time in Office
A. Saenger	Chair - ADA/EASD	US		
M. Steffes	Co-Chair ADA/EASD	US		
J. Dekker	Member	NL		
D. Holmes	Member	CA		
R. Little	Member	US		
M. McPhaul	Member	US		
G. Miller	Member	US		
D. Sacks	Member	US		
K. Van Uytfanghe	Member	BE		
G. Wark	Member - IFCC	UK		
B. Akolkar	Consultant - NIDDK	US		

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	1st	2017 07 - 2019 12
J. Barth	Member	UK		
A. Katrukha	Member	FI		
J. Noble	Member	UK		
M. Panteghini	Member	IT		

H. Schimmel	Member	BE
J. Tate	Member	AU
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)

8.3.48 Parathyroid Hormone (WG- PTH)

Membership

Name	Position	Country	Term	Time in Office
C. Sturgeon	Chair	UK	extra term	2018 01 - 2018 12
C. Burns	Member	UK		
W. Fraser	Member	UK		
R. Singh	Member	US		
J-C. Souberbielle	Member	FR		
S. Sprague	Member	US		
H. Vesper	Member	US		
A. Algeciras	Consultant	US		
L. Demers	Consultant	US		
D. Fogarty	Consultant	UK		

Terms of Reference

- Collaborative educational effort to encourage worldwide implementation of PTH IS 95/646 and to assess the effect of this on between-method agreement.
- Definition of inclusion / exclusion requirements for an appropriate panel of sera and plasma with which to establish reference intervals and establishment of such a panel with support from the clinical community and diagnostics manufacturers
- Development of a reference measurement procedure for PTH(1-84) to a standard that would enable its adoption by the IFCC reference laboratory network.
-

Current Projects

- Raise awareness of shortcomings of current PTH assays with renal physicians and clinical biochemists.
- Prepare good practice recommendations for the optimal pre-analytical handling of patients and samples.
- Confirm results of a harmonisation study that derived assay-specific targets
- Encourage adoption of assay-specific PTH action limits for managing renal patients as an interim measure pending standardisation of PTH methods in terms of a common standard.

8.3.49 CSF-Proteins (WG-CSF)

Membership

Name	Position	Country	Term	Time in Office
J. Gobom	Chair	SE	1st	2018 01 - 2020 12
K. Blennow	Member	SE		
U. Andreasson	Member	SE		
R. Bateman	Member	US		
R. Jenkins	Member	US		
M. Korecka	Member	US		
S. Lehmann	Member	FR		
P. Lewczuk	Member	DE		
M. Lowenthal	Member	US		
G. Martos	Member	FR		
E. Portelius	Member	SE		
L.M. Shaw	Member	US		
E. Stoops	Member	BE		
H. Vanderstichele	Member	BE		
I. Zegers	Member	BE		
H. Zetterberg	Member	SE		

Terms of reference

- To develop a RMP for CSF amyloid β 1-42
- To develop a RMP for CSF amyloid β 1-40
- To develop a RMP for CSF total tau
- To develop CRMs for CSF amyloid β 1-42
- To develop CRMs for CSF amyloid β 1-40
- To develop CRMs for CSF total tau

Current projects and achievements

- 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
- Development of a method for measurement of tau by SRM is ongoing
- 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

8.3.50 Standardisation of Bone Marker Assays (WG-SBMA) in collaboration with IOF

Membership

Name	Position	Country	Term	Time in Office
E. Cavalier	Chair	BE	1st	2018 01 - 2020 12
C. Cooper	Co Chair - International Osteoporosis Foundation			
S. Vasikaran	Secretary	AU		
C. Biegelmayer	Member	AT		
EF. Eriksen	Member	NO		
A. Griesmacher	Member	AT		
K. Makris	Member	GR		
S. Niemi	Member			
J. Kanis	Member/IOF			

M. Munk	Corp. Rep/IDS
B. Ofenloch Haehnle	Corp. Rep./Roche
S. Silverman	National Bone Health Alliance (NBHA)

Terms of Reference

- To standardise or harmonise (as technically feasible or appropriate at this time) clinical assays available for routine and research use, for the following two bone turnover markers; the serum assay for C-telopeptide fragments of collagen type I a1 chains containing the epitope Glu-Lys-Ala-His-Asp-ß-Gly-Gly-Arg in an isomerised form (also known as serum Crosslaps (CTx)) and the serum assay for N-terminal Propeptide of Type I Procollagen (P1NP).

Current Projects

- Review literature and current status of available assays in order to develop and undertake a project to establish a reference measurement system for serum β-CTx or harmonisation of the assays for serum β-CTx as appropriate.
- Review literature and current status of available assays in order to develop and undertake a project to establish a reference measurement system for serum P1NP or harmonisation of the assays for serum P1NP as appropriate.
- Review and identify data required for the regulatory authorisation of these modified assays.
- Review literature and consider the critical decision limits and potential target levels of serum β-CTx and serum P1NP for treatment of postmenopausal osteoporosis and other causes of osteoporosis as appropriate
- IOF-IFCC study summarises fracture prediction strength of reference bone turnover markers

8.3.51 Commutability (WG-C)

Membership

Name	Position	Country	Term	Time in Office
G. Miller	Chair	US	2nd	2016 01 - 2018 12
H. Althaus	Member	DE		
J. Budd	Member	US		
C. Burns	Member	UK		
A. Caliendo	Member	US		
J. Camara	Member	US		
G. Cattozzo	Member	IT		
F. Ceriotti	Member	IT		
C. Cobbaert	Member	NL		
V. Delatour	Member	FR		
R. Durazo	Member	US		
N. Greenberg	Member	US		
G. Horowitz	Member	US		
P. Kaiser	Member	DE		
A. Kessler	Member	DE		
A. Killeen	Member	US		
P. Lindstedt	Member	SE		
F. MacKenzie	Member	UK		
G. Nilsson	Member	SE		
M. Nuebling	Member	DE		
M. Panteghini	Member	IT		
K. Phinney	Member	US		

R. Rej	Member	US
R. Romeu	Member	FR
S. Sandberg	Member	NO
H. Schimmel	Member	EU
G. Schumann	Member	DE
M. Spannagl	Member	DE
J. Vaks	Member	US
H. Vesper	Member	US
C. Weykamp	Member	NL
I. Zegers	Member	EU

Terms of Reference

- Establish operating procedures for the formal assessment of the commutability of a reference material intended for use as a calibrator, trueness control or EQA sample, taking into account different measurement procedure properties and categories of traceability described in ISO 17511.
- Establish how to define the degree of commutability which is required for a given reference material, taking into account its intended use and the intended use of the measurand. The degree of commutability becomes the criteria used in the assessment process.
- Propose standard terminology to describe the degree of commutability of a reference material, taking into account its intended use.
- Provide guidance to manufacturers and laboratories about what information should be provided by manufacturers in relation to the commutability of reference materials used to establish the calibration traceability of a measurement procedure.
- Advise IFCC Committees and Working Groups on how to assess the commutability of materials on which they are working.
- Develop educational materials regarding commutability for manufacturers, laboratories and users of laboratory results.

Current Projects

- Recommendations for assessing commutability part 1: general experimental design
- Recommendations for assessing commutability part 2: based on the difference in bias between a reference material and clinical samples
- Recommendations for assessing commutability part 3: based on the calibration effectiveness of a reference material
- Recommendations for assessing commutability part 4: validation of a replacement batch of a reference material
- Recommendations for assessing commutability part 5: correction of an assigned value for a reference material for non-commutability with a measurement procedure
- Recommendations for assessing commutability part 6: criteria for making an assessment of commutability of a reference material

8.3.53 Immunosuppressive Drugs (WG-ID)

Membership

Name	Position	Country	Term	Time in Office
C. Seger	Chair	CH	1st	2018 01 - 2020 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
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
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 harmonization 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	1st	2017 01 - 2019 12
U. Ceglarek	Member	DE		
V. Delatour	Member	FR		

J. Dittrich	Member	DE
C. Hirtz	Member	FR
A. Hoofnagle	Member	US
Z. Kuklenyik	Member	US
L.R. Ruhaak	Member	NL
H.W. Vesper	Member	US
H. Althaus	IVD Siemens	DE
U. Prinzing	IVD Roche	DE
G.M. Kostner	Consultant	AT
H. Schimmel	Consultant	BE
I. Zegers	Consultant	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	1st	2017 01 - 2019 12
F. Ceriotti	Member	IT		
J. Gella	Member	ES		
S. Pal	Member	IN		
R. Rej	Member	US		
S. Ueda	Member	JP		

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	1st	2017 01 - 2019 12
J.M. Auge	Member	ES		
H.M. Chiu	Member	TW		
N. Djedovic	Member	UK		
M. Frasa	Member	NL		
S. Jones	Member	UK		
P. Kocna	Member	CZ		
B. Levy	Member	US		
J. Strachan	Member	UK		
E. Symonds	Member	AU		
S. Takehara	Member	JP		
I. Zegers	Member	BE		
Y. Doi	Corp. Member	JP		
M. Fujimura	Corp. Member	JP		
T. Fukuda	Corp. Member	JP		
M. Gramegna	Corp. Member	IT		
H. Hayashi	Corp. Member	JP		
T. Ichiyanagi	Corp. Member	JP		
T. Kosaka	Corp. Member	JP		
Y. Masuda	Corp. Member	JP		
M. Zackerl	Corp. Member	DE		

Terms of Reference

- To harmonise and/or standardise analysis of haemoglobin in faecal samples by immunochemistry (FIT)
- To standardise the pre-analytical phase
- To establish EQA and 3rd party IQC programmes
- To determine impact of assay interference of Hb variants and other factors
- To determine the feasibility of developing reference materials and/or commutable calibrators

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	1st	2018 01 - 2020 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

a) Defining pre-analytical aspects / drafting guideline
b) Defining minimal analytical performance
c) Setting up proficiency testing for cfDNA
e) Organizing international workshops
f) Defining grant proposals to address unmet needs under a) and b)

8.3.58 Standardisation of Procalcitonin Assays (WG-PCT)

Membership

Name	Position	Country	Term	Time in Office
V. Delatour	Chair	FR	1st	2018 01 - 2020 12
A. Boeuf	Member	FR		
P. Hausfater	Member	FR		
Q. Liu	Member	SG		
J. Pfannkuche	Member	DE		
P. Schütz	Member	CH		
C. Tourneur	Member	FR		
C. Yuan	Member	US		
J. Odarjuk	Member/Thermo Fisher	DE		
M. Rottmann	Member/Roche	DE		
S. Ruetten	Member/Abbott	US		
A. Rybin	Member/Siemens	US		
L. Seaver	Member/Abbott	US		

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 standardization of PCT assays
- Evaluate the feasibility for standardization of PCT assays
- Perform standardization 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 characterization of candidate primary calibrators
- Development of a candidate reference method for absolute quantification of PCT by IDMS

8.3.59 Vitamin D Standardization Program (WG-Vit D)

Membership

Name	Position	Country	Term	Time in Office
C. Sempos	Chair	US	1st	2018 01 - 2020 12
N. Binkley	Member	US		
J. Camara	Member	US		
É. Cavalier	Member	BE		
V. Chen	Member	CN		
S. Durham	Member	US		
R. Durazo	Member	US		
G. El-Hajj Fuleihan	Member	LB		
A. Ghoshal	Member	US		
N. Heureux	Member	BE		
B. Holmquist	Member	US		
A. Hoofnagle	Member	US		
D. Markowski	Member	US		
G. Myers	Member	US		
C. Munns	Member	AU		
D. O'Dell	Member	US		
K. Phinney	Member	US		
P. Sibley	Member	UK		
L. Tian	Member	US		
P. Twomey	Member	IE		
H. Vesper	Member	US		
S. Wise	Member	US		

Terms of Reference

Re-evaluate current Vitamin D Standardization Program (VDSP) performance guidelines for serum total 25-hydroxyvitamin D measurement, i.e. Total CV ≤ 10% and Mean Bias ≤ 5% (Clin Chem Acta 2009; 408:8-13).
Establish VDSP performance guidelines for 3-epi-25-hydroxyvitamin D and 24,25-dihydroxyvitamin D3.

Current Projects

To be defined

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

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