



# **IFCC Scientific Division Report to Council Durban (South Africa), October 2017**

**Philippe Gillery, MD, PhD**

University Hospital of Reims, France

Chair, IFCC-SD



## IFCC SD

- Mission and objectives
- SD : structure and operating
- Strategic plan
- Recent achievements



# IFCC SD

- Mission and objectives

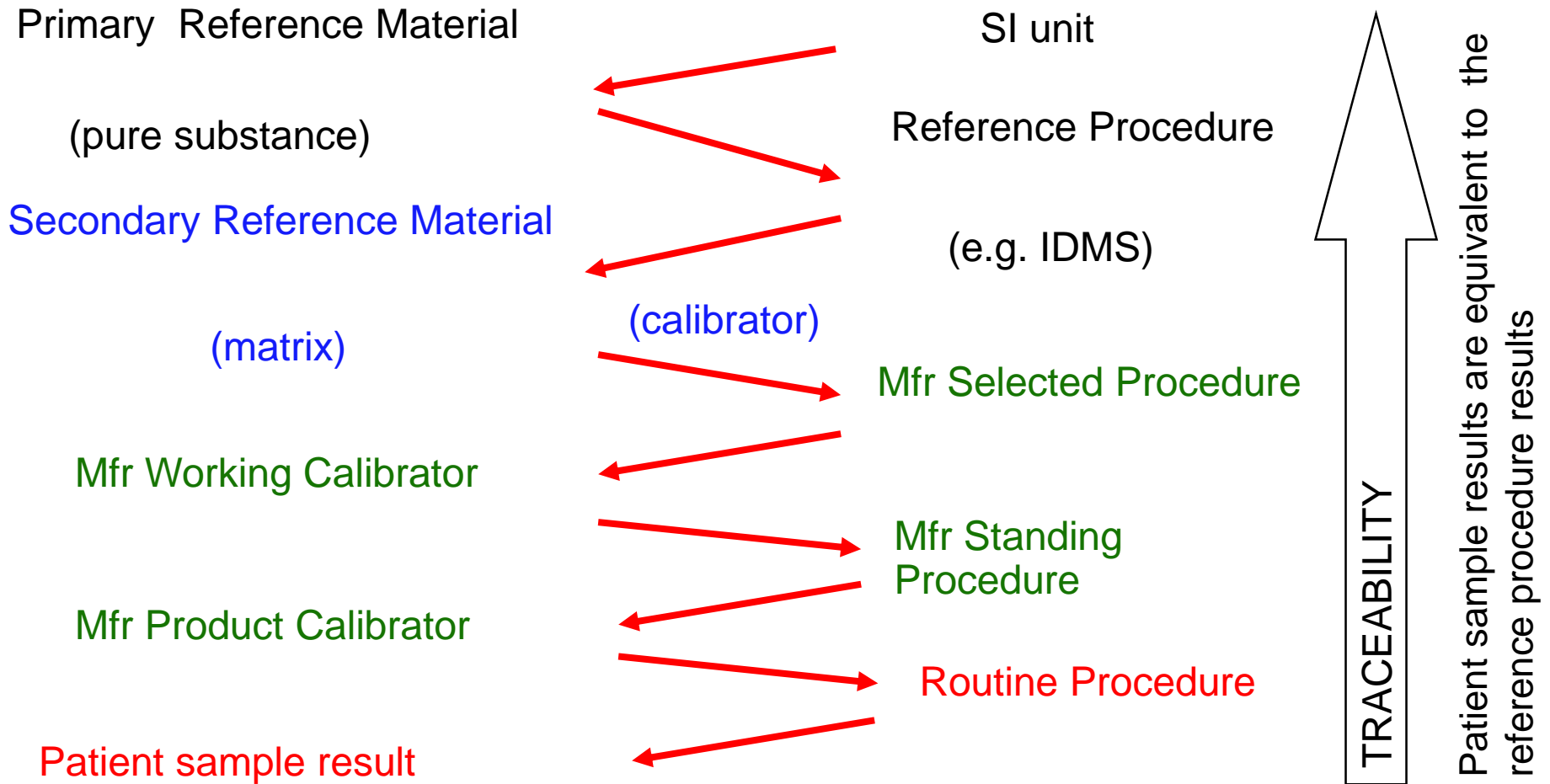


## IFCC SD

Mission: to advance the science of Clinical Chemistry and to apply it to the practice of Clinical Laboratory Medicine

- By identifying technical innovations and diagnostic strategies and assisting the transfer of these to the profession
- By promoting the standardization of laboratory tests and the comparability of patient results through the development of reference measurement systems, or harmonization activities where this is not currently possible
- By establishing standards for scientific and technical aspects of good laboratory practice

# Traceability (based on ISO 17511)



The SD roadmap to Heaven !



# IFCC SD

## Working in Partnership

- IFCC Divisions
- Corporate members
- Metrology institutions
- Governmental bodies and non-Governmental organisations
- Other professional bodies
- Clinicians and clinical organisations



## IFCC SD

- Mission and objectives
- SD : structure and operating



Name	Position	Country	Term	Time in Office
P. Gillery	Chair	FR	1st	2017 01 - 2019 12
C.M. Cobbaert	Vice-Chair	NL	1st	2017 01 - 2019 12
J. Passarelli	Secretary	US	1st	2015 01 - 2017 12
K. Makris	Member	GR	1st	2017 01 - 2019 12
T. Nobori	Member	JP	1st	2015 02 - 2017 12
M. Plebani	Member	IT	1st	2017 02 - 2019 12
J.F. Pierson-Perry	Corporate Member	US	1st	2015 02 - 2017 12
G. Myers	JCTLM Chair / SD Consultant	US		
H. Schimmel	JRC Observer	BE		
C. Burns	NISBC Consultant	UK		
K. Phinney	NIST Consultant	US		

## SD - Executive Committee (SD-EC)





**SD - EC in Athens (June 2017)**



# Scientific Division

## Committees

Theme orientated

**Appointed Chair** plus **four/five elected members** among nominees from national societies and/or corporate members

## Working Groups

Task orientated

**Appointed Chair** plus **unlimited members**

**Corresponding members**  
**nominated by the national**  
**societies**



## SD Committees

- Nomenclature, Properties and Units (C-NPU) in collaboration with International Union of Pure and Applied Chemistry (IUPAC) R. Flatman (AUS)
- Molecular Diagnostics (C-MD) D. Payne (US)
- Traceability in Laboratory Medicine (C-TLM) L. Siekmann (DE)
- Reference Intervals and Decision Limits (C-RIDL) Y. Ozarda (TR)
- Standardization of Thyroid Function Tests (C-STFT) L. Thienpont (BE)
- Harmonization of Autoimmune Tests (C-HAT) J. Sheldon (UK)  
*Newly created*

# SD Working Groups



- Standardisation of Haemoglobin A2 (WG-HbA2) A. Mosca (IT)
- Standardisation of Carbohydrate-Deficient Transferrin (WG-CDT) J. Wielders (NL)
- Standardisation of Albumin Assay in Urine (WG-SAU) in collaboration with NKEDP L. Bachmann(US)
- Standardisation of Pregnancy-Associated Plasma Protein A (WG-PAPP A) S. Wittfooth (UK)
- Growth Hormone (WG-GH) E. Lentjes (NL)
- Standardisation of Insulin Assays (WG-SIA) in collaboration with ADA/EASD A. Saenger (US)
- Standardisation of Troponin I (WG-TNI) R. Christenson (US)
- Parathyroid Hormone (WG-PTH) C. Sturgeon (UK)
- CSF Proteins (WG-CSF) K. Blenow (SE)
- Standardization of Bone Marker Assays (WG-SBMA) H. Morris (AU)
- Commutability (WG-C) G. Miller (US)



# SD Working Groups

Newly created

- Immunosuppressive Drugs (WG-ID) L. Langman (US)
- Apolipoproteins by Mass Spectrometry (WG-APO MS) C. Cobbaert (NL)
- Pancreatic enzymes (WG-PE) D. Grote-Koska (DE)
- Fecal Immunochemical Testing (WG-FIT) S. Benton (UK)



## IFCC SD

- Mission and objectives
- SD: structure and operating
- Strategic plan



# IFCC - Scientific Division Strategic plan 2017 - 2019

1. Keep and amplify the high level of involvement of IFCC-SD in the field of standardization / harmonization
2. Keep and amplify the visibility of IFCC scientific activities inside and outside IFCC
3. Prepare the future



# IFCC - Scientific Division

## Strategic plan 2017 - 2019

1. **Keep and amplify the high level of involvement of IFCC-SD in the field of standardization / harmonization**
  - Continuation and/or completion of ongoing projects
  - Picking up priority measurements from the harmonization consortium (ICHCLR)
  - Identification of new areas
    - Molecular biology and Proteomics
    - Other areas of Laboratory Medicine (Immunology, Pharmacology, Hematology)
      - Automimmune tests (WG  $\Rightarrow$  C)
      - Drugs (WG-ID)
      - Immunochemical fecal Hb testing (WG-FIT)





## 1. **Keep and amplify the high level of involvement of IFCC-SD in the field of standardization / harmonization (continued 1)**

- Committees: Keep a sustained activity in these theme – oriented groups of major strategic interest for IFCC
  - C-NPU: Links with other international organizations (IUPAC)
  - C-MD: Creation of an IFCC network / identification of new tests / new diagnostic strategies
  - C-TLM: Maintenance of IFCC networks (eg HbA<sub>1c</sub>)
  - C-RIDL: Establishment of reference values worldwide
  - C-STFT: Important advances in standardization / harmonization and clinical outcomes



## 1. **Keep and amplify the high level of involvement of IFCC-SD in the field of standardization / harmonization (continued 2)**

- Working groups: Carefully check the creation / evolution / productivity of WGs on specific tasks for limited lifetime
  - Near to achievement: WG-CDT, WG-HbA<sub>2</sub> (reference procedures and/or materials)
  - New scientific items: eg WG-PAPPA, WG-CSF, WG Apolipoproteins by MS
  - Collaborative WGs : eg WG HbA<sub>2</sub> (ISTH), WG-SAU (NKPED), WG-SIA (ADA/EASD), WG-BMA (IDF)
- Ensure a dynamic process
  - WGs to close and/or transform
  - Task ⇒ theme: WG-HAT ⇒ C-HAT
  - New WGs on specific application: WG-cMSP (general reflexion ⇒ specific applications) (eg apolipoproteins)



## 2. **Keep and amplify the visibility of IFCC scientific activities inside and outside IFCC**

- Active participation in all IFCC and regional federation meetings
- Systematic preparation of a special issue in the official IFCC journal every 2 to 3 years (last achievement: 2016 in CCA)
- Participation in scientific meetings of clinical societies in areas covered by SD (eg endocrinology, immunology, cardiology)
- Participation and reinforced relations with partners (BIPM, NMIs, WHO), focussing on specific expertise areas of SD (eg HbA<sub>2</sub> for WHO)



## 2. **Keep and amplify the visibility of IFCC scientific activities inside and outside IFCC (continued)**

- Increased interactions with other IFCC divisions or task forces for identifying new markers suitable for standardization / harmonization, in cooperation with corporate members (importance of clinical relevance and interest for effective implementation of the tests in laboratories)  
[e.g. Markers of diabetes (AGEs): C-EUBD (EMD)]
- Participation in IFCC structural changes : ensuring synergy with the newly created Emerging Technology Division



### 3. Prepare the future

- Focus SD activities on new areas of clinical chemistry and laboratory medicine (eg molecular biology, proteomics)
- Select and involve new members in SD Cs and WGs (key actors getting older or retiring, new skills required in new areas of interest).
- Promote the involvement of young scientists in SD activities with EB support
- Ensure the maintenance of IFCC networks (cf C-TLM).



## IFCC SD

- Mission and objectives
- SD : structure and operating
- Strategic plan
- Recent achievements



# IFCC SD

## Some key achievements

- More than 150 scientists and clinicians from all IFCC regions involved as members of Cs / WGs
- SD symposia at most major international congresses
- Bergmeyer conferences (Tumor markers - 2016)
- Key publications (Special issues in IFCC Official Journal)

2016 : CCA special issue



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The Official Journal of the International  
Federation of Clinical Chemistry  
and Laboratory Medicine (IFCC).

# CLINICA CHIMICA ACTA

*International Journal of  
Clinical Chemistry and  
Diagnostic Laboratory Medicine*

Special Issue  
Current contributions of the IFCC Scientific Division to standardization

Guest Editors:  
P. Gillery  
I.S. Young







Committee/working group	Chair in 2016
Committee on Nomenclature, Properties and Units (C-NPU)	R. Flatman (AU)
Committee on Molecular Diagnostics (C-MD)	D. Payne (US)
Committee on Reference Systems of Enzymes (C-RSE)	F. Ceriotti (IT)
Committee on Traceability in Laboratory Medicine (C-TLM)	L. Siekmann (DE)
Committee on Reference Intervals and Decision Limits (C-RIDL)	Y. Özarda (TR)
Committee on Standardization of Thyroid Function Tests (C-STFT)	L. Thienpont (BE)
Working group on Standardization of Hemoglobin A <sub>2</sub> (WG-HbA <sub>2</sub> )	R. Paleari (IT)
Working group on Standardization of Carbohydrate-Deficient Transferrin (WG-CDT)	J.P.M. Wielders (NL)
Working group on Standardization of Albumin Assays in Urine (WG-SAU)	L.M. Bachmann (US)
Working group on Pregnancy-Associated Plasma Protein A Standardization (WG-PAPPA)	S. Wittfoot (UK)
Working group on Growth Hormone (WG-GH)	E. Lentjes (NL)
Working group on Standardization of Insulin Assays (WG-SIA)	M. Steffes (US)
Working group on Standardization of Troponin I (WG-TNI)	D. Bunk (US)
Working group on Harmonization of Autoantibody Tests (WG-HAT)	J. Sheldon (UK)
Working group on Clinical Quantitative Mass Spectrometry Proteomics (WG-cMSP)	S. Lehmann (FR)
Working group on Parathyroid Hormone (WG-PTH)	C. Sturgeon (UK)
Working group on Cerebrospinal Fluid Proteins (WG-CSF)	K. Blennow (SE)
Working group on Standardization of Bone Markers Assays (WG-BMA)	H. Morris (AU)
Working group on Commutability (WG-CM)	G. Miller (US)



# Committees

## Update on activities



## Committee on Nomenclature, Properties and Units : Robert Flatman (AU)

### ■ 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.

## Committee on Molecular Diagnostics : Debs Payne (US)

### ■ Current Projects

- Establish an International Network of IFCC Reference Centres in Molecular Diagnostics
- Develop a checklist for technology transfer from development to clinical laboratory testing
- Standardise formats for reporting of molecular diagnostic results

Conference  
in Durban



## Committee on Traceability in Laboratory Medicine : Lothar Siekmann (DE)

### ■ Current Projects

- Organization of IFCC Ring Trials for reference laboratories

## Reference Intervals and Decision Limits : Yesim Ozarda (TR)

### ■ 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 the distinction of Reference Intervals and Clinical Decision Limits



# Committee Thyroid Function Tests

Linda Thienpont (BE)

## ■ Current Projects

- Recalibration of FT4 and TSH assays after the Phase IV method comparison studies on clinically relevant samples: is intended as technical standardization/harmonization process, by which FT4 assays will become traceable to the conventional reference measurement procedure based on equilibrium dialysis (ED) isotope dilution-liquid chromatography-/tandem mass spectrometry (ID-LC/MS/MS), TSH assays to the statistically inferred all-procedure trimmed mean (APTM).
- Measure a FT4 and TSH panel of each 120 American apparently healthy volunteers with the recalibrated assays; measure the FT4 panel also with the conventional reference measurement procedure; use the data as proof-of-concept for standardization of FT4 and harmonization of TSH by demonstrating that the traceable assays can use a common reference interval; use this as a basis for further elaboration of the reference intervals by the IVD manufacturers.
- Get into contact with all involved stakeholders for benefit-risk analysis in preparation of the implementation of the standardized/harmonized assays.
- Promotion of the concept of Traceability in Latin America



# A new Committee : C-HAT

## Harmonization of Autoimmune Tests

Joanna Sheldon (UK)

### ■ 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.



# Working groups

## Examples of recent achievements

# Standardization of CDT (WG-CDT)

Chair : Dr Jos Wielders



- Public health problem : Alcohol abuse / abstinence among top 5 causes of disease / disability
- CDT: Carbohydrate deficient transferrin : clinical and forensic alcohol biomarker
- Strategic approach
  - Establishment of standardization scheme (RMP, reference materials, network of reference laboratories)
  - Implementation of reference system
- Reference Measurement Procedure established and IFCC approved
  - Measurand and target analyte for standardization: Disialotransferrin
  - Method : HPLC with photometric detection (approved)
  - Reference materials : serum based (approved)
  - New thresholds (decision limits: 2.0%)
- Outcome : "Standardized % CDT<sub>IFCC</sub> Units"  
(general use : 01 July, 2018)





# Standardization of HbA<sub>2</sub> (WG-HbA<sub>2</sub>)

Chair : Prof. Andrea Mosca (IT)

- Public health problem: Thalassemia
- Strategic approach
  - Establishment of standardization scheme (RMP / reference materials / networks)
  - Ensuring implementation and comparability of HbA<sub>2</sub> values
  - Collaboration with ICSH
- Candidate reference measurement procedure: HPLC - ID-MS/MS
  - Peptide mapping
  - Calibration: HbA<sub>0</sub> and HbA<sub>2</sub> materials / traceable to SI
  - Recombinant <sup>15</sup>N-labelled Hb used as internal standards
- Certified reference materials: in preparation (JRC)
- Network of reference laboratories: in constitution (3 worldwide)

Conference  
in Durban



# Development of New Projects

SD horizon scanning

Third party approach



Assessment of need  
Development and submission of formal proposal  
Agreement on terms of reference



Approval by SD and EB  
Establishment of WG or C



Work cycle with ongoing review



09.00-11.00

## IFCC S1: IFCC SD (Conference 4)



### Recent Advances in Standardisation

Chair: G. Miller (USA)

Commutability issues in standardization of laboratory measurement procedures  
*G. Miller (USA)*

WG-C

Standardization of Pregnancy-Associated Plasma Protein A  
*S. Wittfooth (Finland)*

WG-PAPP A

Standardization of urine albumin assays  
*L. Bachmann (USA)*

WG-SIA

Standardization of CSF proteins  
*K. Blennow (Sweden)*

WG-CSF

09.00-10.30

## IFCC S6: IFCC SD (Conference 4)



### Standardisation in laboratory medicine beyond clinical chemistry

Chair: P. Gillery (France)

Standardization: a universal need  
*P. Gillery (France)*

WG-HbA<sub>2</sub>

Standardization of Hb A<sub>2</sub>  
*A. Mosca (Italy)*

C-HAT

Standardization of autoimmune tests  
*J. Sheldon (UK)*

C-MD

Standardization in molecular diagnostics  
*D. Payne (USA)*



# Scientific Division :

## A tool for every IFCC member :

### ⇒ becoming involved in the work of SD

- Apply for positions on SD or C's
- Become a corresponding member of a C
- Become a member of a WG
- Propose a new WG or C
- Promote young scientists

Thank you !