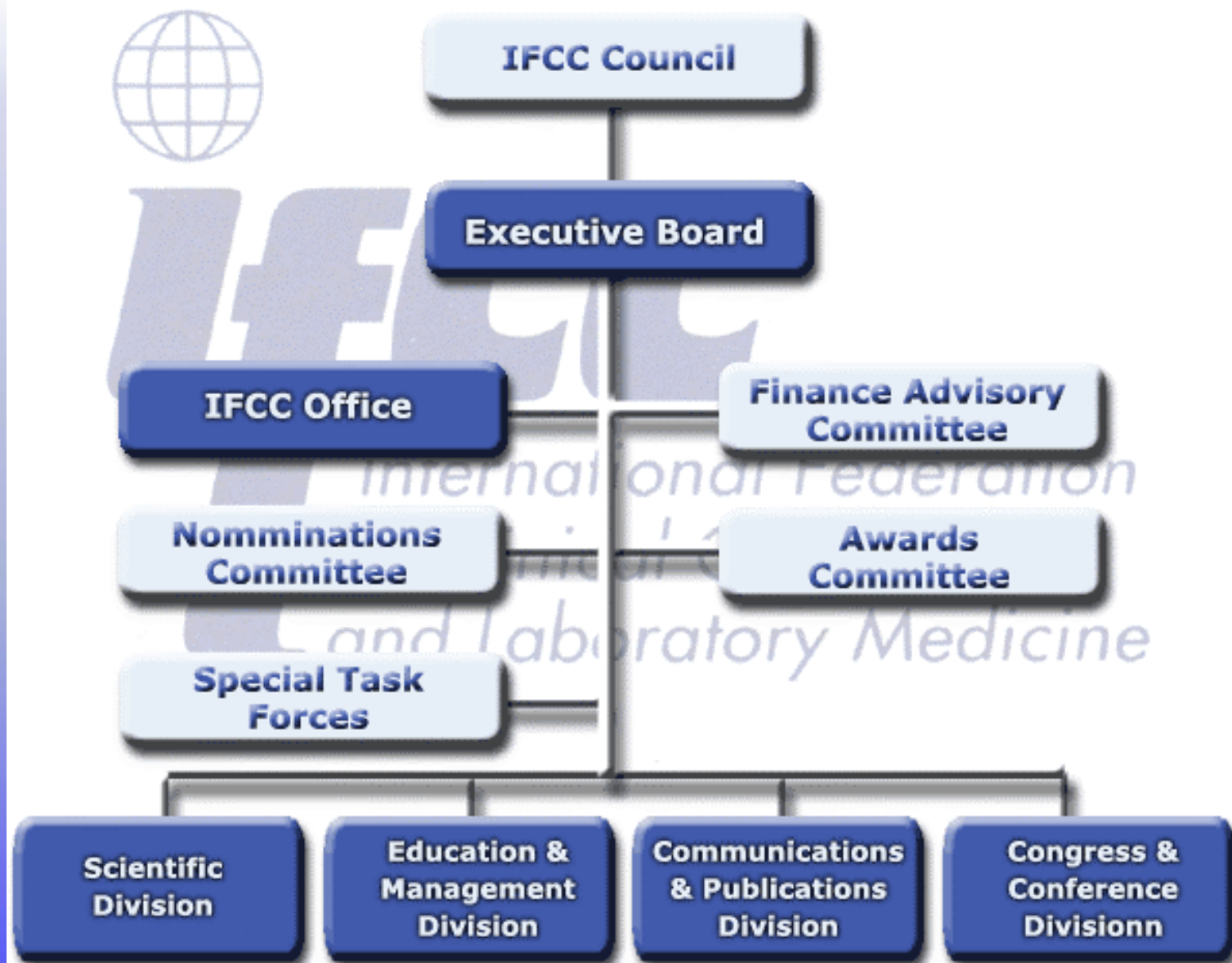




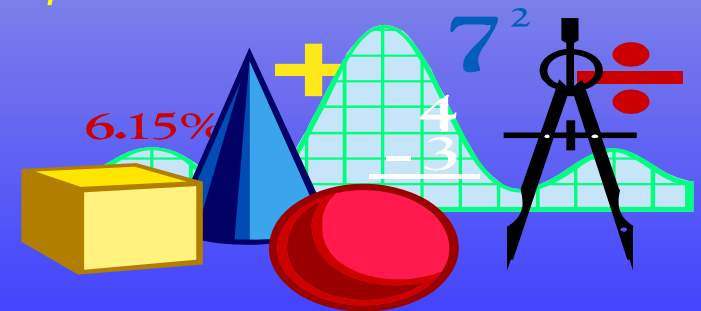
REGIONAL ORGANISATIONS AFFILIATED WITH IFCC

- ▶ Arabic Federation of Clinical Biology
- ▶ Asian Pacific Federation of Clinical Biochemistry
- ▶ Colabiocli - Latin American Federation
- ▶ FESCC - Federation of European Societies
 - ▶ EC4



SCIENTIFIC DIVISION

- Mission: To advance the science of Clinical Chemistry and Laboratory Medicine by facilitating its clinical practice
- Transfer of research results to the clinical laboratory
- Analytical standardisation: reference systems, new techniques
- Post-analytical standardisation: establish diagnostic strategies for new analytes
- Standards for good laboratory practice
- Collaborations: BIPM, ILAC, IRMM, IUPAC, NCCLS, NIST WHO



SCIENTIFIC DIVISION

ACTIVITIES

- 🌐 Specific work of SD Committees and Working Groups
- 🌐 Collaboration and partnership with other National and International Organizations
- 🌐 Participation to regional IFCC congresses and master discussions

SCIENTIFIC DIVISION

- **COMMITTEES:** Theme-oriented
 - 🌐 Chair (appointed by EB)
 - 🌐 4-5 full members (call for nominations)
 - 🌐 Corresponding members
- **WORKING GROUPS:** Task-oriented
 - 🌐 Chair (appointed by EB)
 - 🌐 Members (appointed by SD)

SCIENTIFIC DIVISION

COMMITTEES (n=8):

- NOMENCLATURE, PROPERTIES AND UNITS (C-NPU)
- MOLECULAR DIAGNOSTICS (C-MD)
- PLASMA PROTEINS (C-PP)
- STANDARDISATION OF MARKERS OF CARDIAC DAMAGE (C-SMCD)
- REFERENCE SYSTEMS OF ENZYMES (C-RSE)
- POINT OF CARE TESTING (C-POCT)
- TRACEABILITY IN LABORATORY MEDICINE (C-TLM)
- REFERENCE INTERVALS AND DECISION LIMITS (C-RIDL)

SCIENTIFIC DIVISION

WORKING GROUPS (n=12):

- SELECTIVE ELECTRODES AND BIOSENSORS (WG-SEB)
- REFERENCE METHODS FOR APOLIPOPROTEINS (WG-MA)
- STANDARD OF HUMAN CHORIONIC GONADOTROPIN (WG-SHCG)
- STANDARDISATION OF HbA1c (WG-HbA1c)
- NANOTECHNOLOGY (WG-NT)
- GUIDELINES IN MONITORING IMMUNOSUPPRESSIVE DRUGS (WG-MID)
- STANDARDISATION OF THYROID FUNCTION TESTS (WG-STFT)
- STANDARDISATION OF HEMOGLOBIN A2 (WG-HbA2)
- STANDARDIZATION OF CARBOHYDRATE-DEFICIENT TRANSFERRIN (WG-SCDT)
- STANDARDIZATION OF CYSTATIN C (WG-SCC)
- STANDARDIZATION OF GLOMERULAR FILTRATION RATE ASSESSMENT (WG-GFRA)
- STANDARDIZATION OF ASSAYS FOR URINARY (MICRO)ALBUMIN (WG-SMA)

SCIENTIFIC DIVISION

Committee on Traceability in Laboratory Medicine

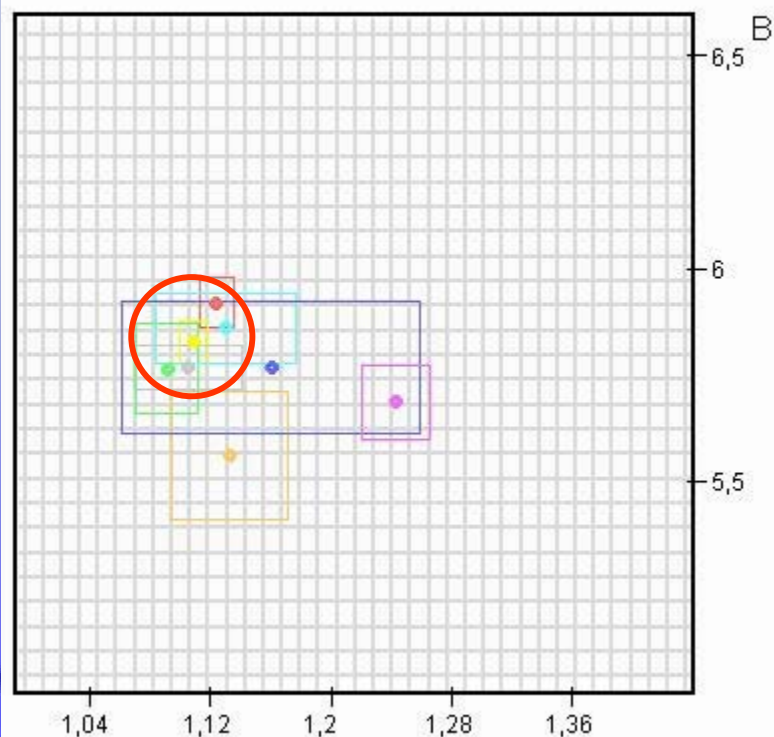
Terms of reference

1. To provide an operating link between IFCC SD and others international organizations, such as JCTLM, NIST, IRMM
2. To monitor the implementation of international directives, such as the EU IVD Directive 98/79, and relevant standards (ISO 17511, 18153, etc)
3. To support reference laboratories in the context of complete reference systems
4. To establish EQAS (ring trials) for reference laboratories for monitoring their competence

Committee on Traceability in Laboratory Medicine

RELA 1/2004

Creatinine [mg/dl]



Lab	A	p.e.u.	B	p.e.u.	method	
01	1,124	0,011	5,919	0,060	ID-MS	Univ. Bonn
09	1,133	0,038	5,559	0,150	HPLC	
11	1,109	0,009	5,827	0,050	ID-MS	Univ. Ghent
21	1,091	0,020	5,764	0,104	ID-MS	Korea
27	1,13	0,046	5,86	0,082	ID-MS	Instand GE
34	1,160	0,098	5,768	0,155	Jaffe (Dimension RxL)	
37	1,243	0,022	5,685	0,088	Jaffe (Olympus)	
40	1,105	0,035	5,765	0,051	HPLC	

A

Simple Cystatin C–Based Prediction Equations for Glomerular Filtration Rate Compared with the Modification of Diet in Renal Disease Prediction Equation for Adults and the Schwartz and the Counahan–Barratt Prediction Equations for Children

ANDERS GRUBB,^{1*} ULF NYMAN,² JONAS BJÖRK,³ VERONICA LINDSTRÖM,¹ BENGT RIPPE,⁴
GUNNAR STERNER,⁵ and ANDERS CHRISTENSSON⁵

Conclusion: A GFR prediction equation based solely on cystatin C (in mg/L) and a prepubertal factor might replace the simplified MDRD prediction equation for adults and the Schwartz and Counahan–Barratt prediction equations for children.

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Achievements of Cs & WGs

- **IMPLEMENTATION OF REFERENCE MEASUREMENT SYSTEMS IN LABORATORY MEDICINE**
 - Reference Materials
 - Reference Measurement Procedures
 - Networks of Reference Laboratories
- **PUBLICATIONS**
- **COLLABORATIONS**

INTERNATIONAL COLLABORATION

2003 NCCLS (CLSI)

Update of Memorandum of
Understanding and Collaboration

**2003-05 JCTLM – Joint Committee on
Traceability in Laboratory Medicine**



International Federation Of Clinical Chemistry And Laboratory Medicine

Joint Committee on Traceability in Laboratory Medicine



Other key stakeholders:

- Producers of Reference Materials
- Regulatory Bodies
- IVD Industry
- EQAS Organizations

Objectives and Purpose

To support comparability and equivalence of measurement results in Laboratory Medicine for the purpose of improving healthcare, through worldwide accepted traceability effort following the principles of metrology



To support IVD manufacturers in registration and licensing the CE label conforming with the EU directive

JCTLM



Major tasks:

- Establishment of a directory of RMs & RMPs
- Establishment of networks of Ref. Laboratories
- Collaboration in further development of RMs & RMPs
- Establishment of procedures for approval of new RMs & RMPs



JCTLM



The initial list of higher order Reference Materials and Reference Measurement Procedures (published 01 April 2004) contains:

Certified Reference Materials and Reference Measurement Procedures for well-defined chemical entities or internationally recognized reference method-defined measurands, such as enzymes.

Analytes included in this category are those that are traceable to the SI units. [*Electrolytes, Drugs, Metabolites & Substrates, Non-Peptide Hormones, Enzymes and some other Proteins*]



International Federation of Clinical Chemistry and Laboratory Medicine

Reference Measurement Procedures Approved by JCTLM for Creatinine Measurement

Method

Institution

ID-GC/MS

NIST

ID-GC/MS

University of Ghent, BE

ID-GC/MS

DGKC



Secondary Reference Materials Accepted by JCTLM for Creatinine Measurement

Name	Concentration by ID-GCMS	Available from
BCR 573	0.777±0.016 mg/dL	IRMM ¹
BCR 574	1.188±0.015 mg/dL	IRMM
BCR 575	4.571±0.08 mg/dL	IRMM
SRM 909b-1	0.635±0.006 mg/dL	NIST ²
SRM 909b-2	5.286±0.061 mg/dL	NIST

¹ Institute for Reference Materials and Measurements, Geel, Belgium

² National Institute of Standards and Technology, Gaithersburg, MD



International Federation Of Clinical Chemistry And Laboratory Medicine

Secondary Reference Materials Accepted by JCTLM for Creatinine Measurement: Caveat

- Although these are human serum based materials, the matrix has been altered by converting plasma to serum and by lyophilization potentially altering the recovery of creatinine in these fluids by field methods.
- Because the commutability of these materials with native human sera has not been established, they may be unsuitable for direct use in calibration of field methods.

The Reference Measurement System for Creatinine

Primary reference material
(pure substance)

NIST SRM 914

Ref. procedure
(ID-GC/MS)

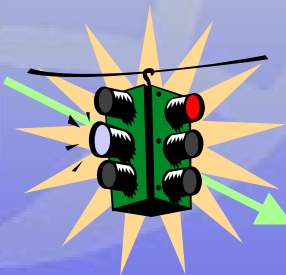
Reference laboratory

Secondary ref. material
(creatinine in human serum)

IRMM-BCR 573/4/5 – NIST SRM 909

Measurement of clinical
samples by commercial
assays

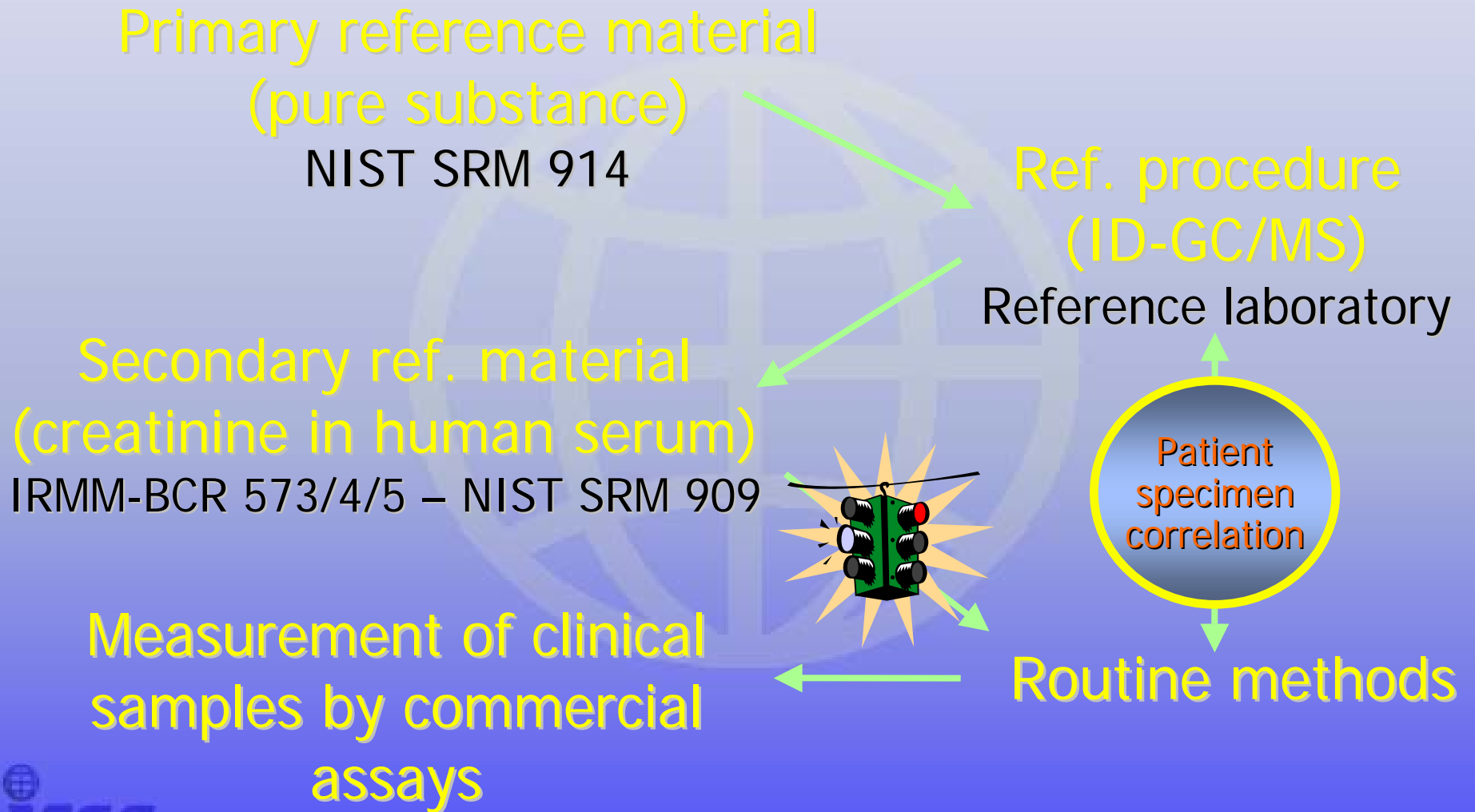
Calibration of
routine methods



Implementing creatinine standardization

- An alternative approach to standardizing creatinine results and establishing traceability to a reference measurement procedure, particularly when the commutability of reference materials is not known, is for IVD manufacturers to split samples with a laboratory performing a reference measurement procedure.

The Reference Measurement System for Creatinine



NKDEP Recommendations for Standardizing Creatinine Measurement

1. Develop a reference measurement procedure with high throughput (e.g. LC/MS) that can assist IVD manufacturers in validating assay traceability and trueness.
2. Develop secondary reference material(s) for serum creatinine with proven commutability to patient sera with a wide variety of field methods.
3. Establish a network of reference laboratories that can provide reference services with reasonable turnaround time and cost.
4. Introduce a fresh-frozen serum-based EQAS, which is value assigned by the reference measurement procedure, that interested parties can use to assess the performance of field methods on an ongoing basis.

NKDEP Recommendations for Standardizing Creatinine Measurement

Collaborate with other professional organizations to:

- ④ Identify the impact on clinical decision criteria that may result from re-calibration of creatinine measurements to be traceable to IDMS
- ④ Validate a revised GFR estimating equation that uses creatinine results traceable to IDMS
- ④ Coordinate the introduction of creatinine traceability to IDMS with the revised GFR estimating equation
- ④ Develop guidelines to communicate the clinical interpretation issues and to implement appropriate GFR estimating equations for standardized creatinine

IFCC WG on Standardization of GFR Assessment (WG-GFRA)

- ④ First meeting at IFCC/AACC congress July 27th, 2005
- ④ Invited representatives of NKDEP LWG, EC4 WG, Australian WG, IFCC C-TLM & WG-SCC, etc.
- ④ Terms of reference:
 - ④ Coordinate, support, and publicize at the international level the activities and recommendations directed to standardize GFR estimation;
 - ④ Establish a reference laboratory network for creatinine.

IFCC WG on Standardization of GFR Assessment (WG-GFRA)

🌐 Proposed chair: N. Greenberg (US)

🌐 Proposed Members:

🌐 C. Cobbaert (NT)

🌐 J. Delanghe (BE)

🌐 G. Jones (AU)

🌐 G. Miller (US)

🌐 G. Myers (US)

🌐 D. Seccombe (CA)

🌐 L. Siekmann (GE)

🌐 L. Thienpont (BE)

🌐 M. Welch (US)

🌐 Others.....

🌐 IFCC SD liaison: M. Panteghini

IFCC WG on Standardization of GFR Assessment (WG-GFRA)

Proposed goals:

- ④ Support the international circulation of relevant documents and education materials;
- ④ Preparation of an IFCC recommendation for the use of enzymatic assays;
- ④ In cooperation with C-TLM, establishment of an IFCC reference laboratory network for creatinine;
- ④ In cooperation with NKDEP, development of guidelines to coordinate the global introduction of standardized creatinine together with the new GFR estimating equation and to educate lab professionals regarding the importance of assessing CKD risk.