

# JCTLM Update: Organization and Achievements

Gary L. Myers, PhD; Chair, JCTLM



Accurate results  
for patient care

JCTLM Members' and Stakeholders' Meeting  
December 4 and 5, 2017, BIPM, Sevres, FRANCE

# Outline of Presentation

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- Overview of JCTLM Organization and Structure
- Status of JCTLM Membership
- JCTLM: 2015-2017 Strategic Achievements

# JCTLM Formation

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The JCTLM was created in 2002 in response to the implementation of the European Community Directive 98/79/EC on *in vitro* medical devices.

## Essential Requirement of the IVD Directive

**"The traceability of values assigned to calibrators and/or control materials must be assured through available reference measurement procedures and/or available reference materials of a higher order.. "**

# JCTLM Formation

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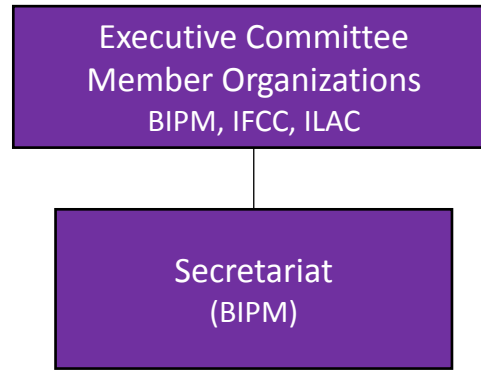
Formation of the JCTLM brought together the sciences of metrology, laboratory medicine and laboratory quality management to promote global traceability



# JCTLM Database

- **JCTLM** through **BIPM** maintains a database of **Reference Measurement Systems** <http://www.bipm.org/jctlm/>
- **JCTLM database** was developed to help the **IVD industry** meet metrological traceability requirements of the **EU IVD Directive**
- **JCTLM** coordinates the nomination and review process for database entries for compliance with appropriate ISO Standards

# JCTLM Organizational Structure



## Executive Committee

Chairperson: Dr Gary Myers (IFCC)

Executive Secretary: Dr Robert Wielgosz (BIPM)

Stéphanie Maniguet (BIPM)

Members:

Dr Graham Beastall (IFCC)

Dr Graham Jones (ILAC)

Dr Anja Kessler (IFCC)

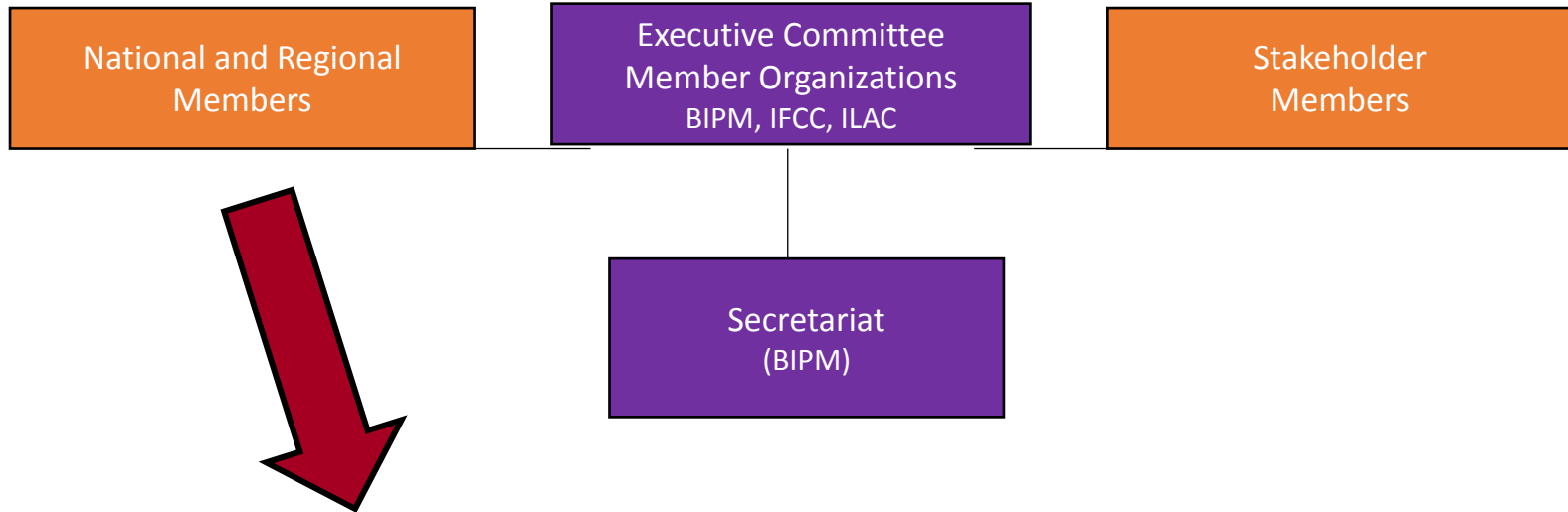
Dr Willie May (CIPM)

Dr. James W. McLaren (CIPM)

Dr Martin J.T. Milton (BIPM)

Ms Regina Robertson (ILAC)

# JCTLM Organizational Structure



## Eligible organizations can currently include:

- National and international metrology institutes and organizations that are signatories to the CIPM MRA, or to Regional Metrology Organizations recognized by CIPM
- National medicine societies affiliated with IFCC
- Accreditation bodies that are signatories to ILAC MRA

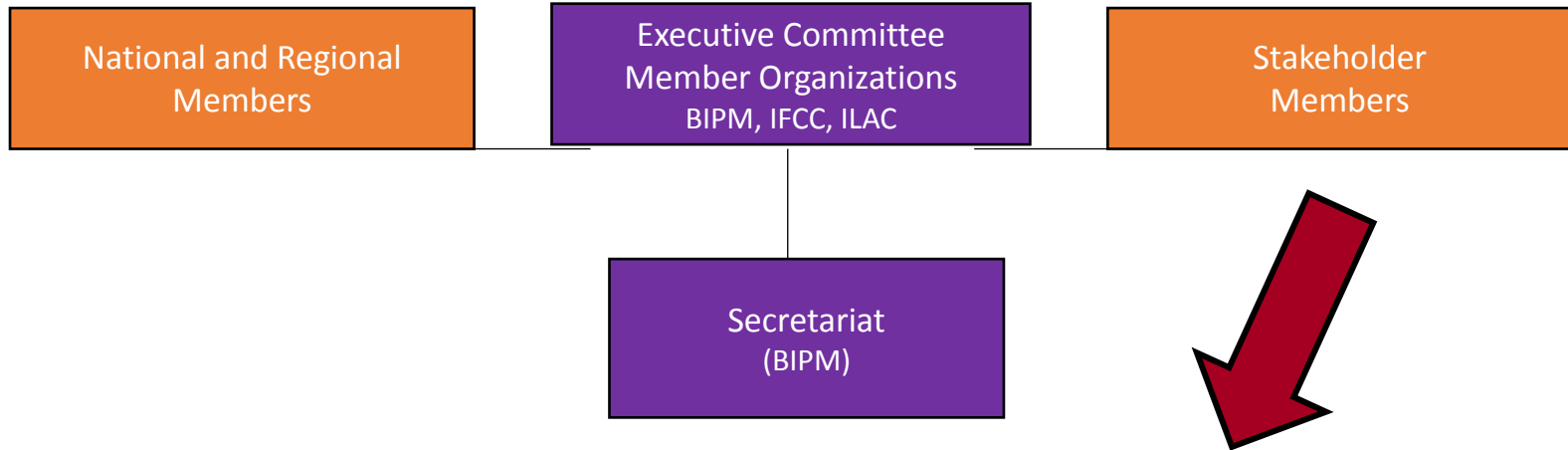
# JCTLM Organizational Structure

## National and Regional Members

- All-Russian Scientific Research Institute for Metrological Service, Rosstandart [VNIIMS], Russia
- American Association for Clinical Chemistry [AACC], USA
- China Accreditation Service For Conformity Assessment [CNAS], China
- European Commission - Joint Research Centre [JRC-Geel], Belgium
- Health Sciences Authority [HSA], Singapore
- Korea Research Institute of Standards and Science [KRISS], Korea
- Korean Society of Clinical Chemistry [KSCC], Korea
- Laboratoire National de Métrologie et d'Essais [LNE], France
- LGC [LGC Ltd], UK
- National Association of Testing Authorities [NATA], Australia
- National Institute for Biological Standards and Control [NIBSC], UK
- National Institute of Metrology [NIM], China
- National Institute of Standards and Technology [NIST], USA
- National Metrology Institute of Japan, AIST [NMIJ/AIST], Japan
- National Metrology Institute of Turkey [UME], Turkey
- Physikalisch-Technische Bundesanstalt [PTB], Germany



# JCTLM Organizational Structure



## Eligible organizations can currently include:

Any “non-profit” and “for-profit” organizations with interest, expertise and a demonstrated record of working to reduce the between method variability in laboratory measurements

Examples include:

- National and regional organizations active in lab medicine
- EQAS providers
- *In-vitro* diagnostic instrument and reagent manufacturers
- Private laboratory organizations
- Standards writing bodies

# JCTLM Organizational Structure

## Stakeholder Members

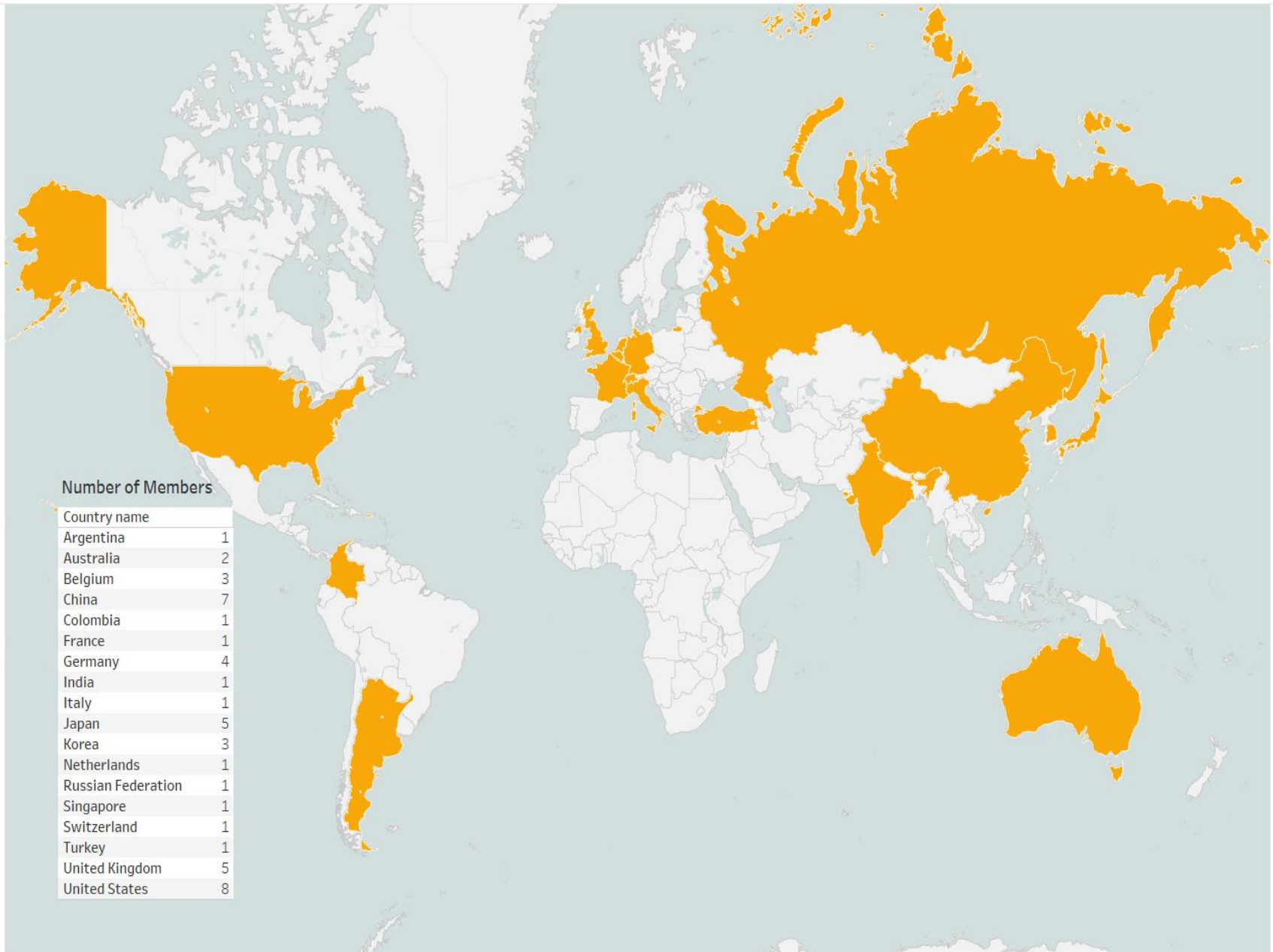
- Advanced Medical Technology Association [AdvaMed], USA
- Beijing Aerospace General Hospital [711], CHINA
- Bio-Rad Laboratories, Inc [Bio-Rad], USA
- Buenos Aires External Quality Assessment Scheme [ProgBA], ARGENTINA
- Centers for Disease Control and Prevention [CDC], USA
- Clinical and Laboratory Standards Institute [CLSI], USA
- ECAT Foundation [ECAT], NETHERLANDS
- European Organisation For External Quality Assurance Providers in Laboratory Medicine [EQALM]
- Fujirebio Europe NV [FRE], BELGIUM
- Guangdong Provincial Hospital of Chinese Medicine [GPHCM], CHINA
- Institution for Standardisation and Documentation in the Medical Laboratory [INSTAND e.V.], GERMANY
- Interdepartmental Centre for Metrological Traceability in Laboratory Medicine [CIRME], ITALY
- Japan Association of Clinical Reagents Industries [JACRI], JAPAN
- Japanese Committee for Clinical Laboratory Standards [JCCLS], JAPAN
- Korean Association of External Quality Assessment Service [KEQAS], KOREA
- Maccura Biotechnology Co., Ltd. [Maccura], CHINA

# JCTLM Organizational Structure

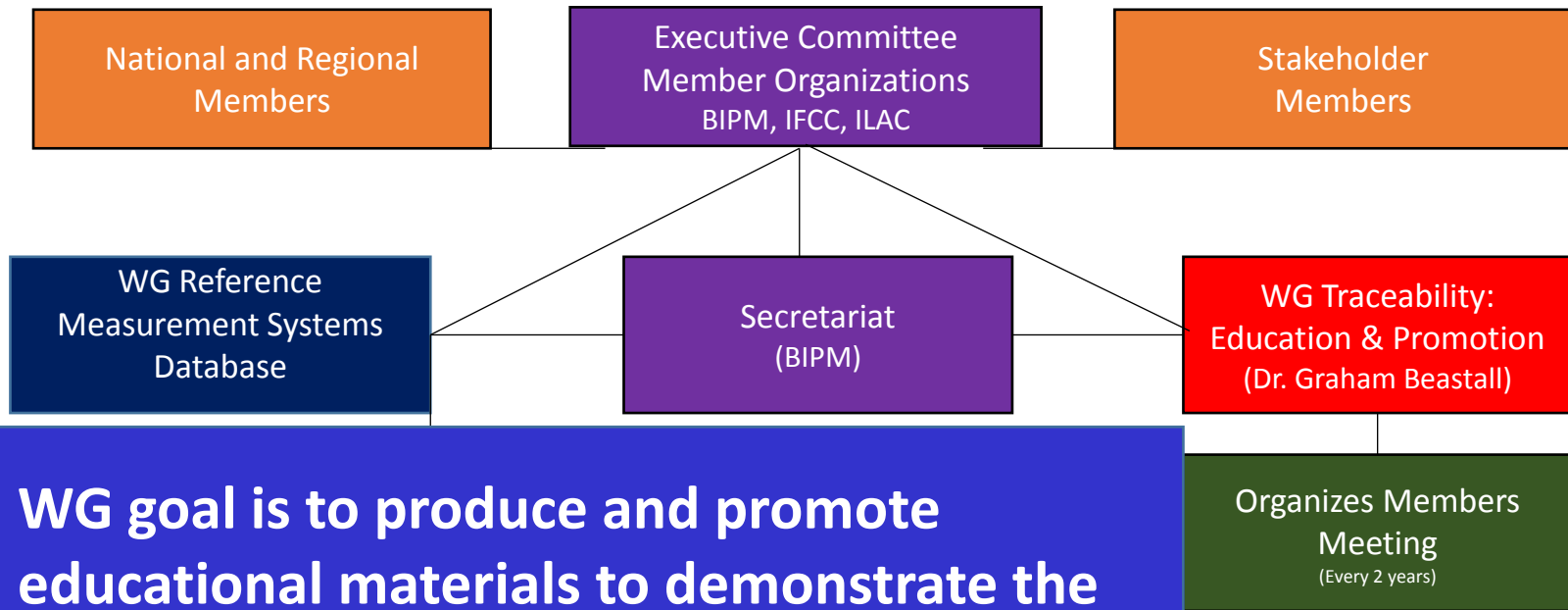
## Stakeholder Members

- MedicalSystem Biotechnology Co., Ltd [MedicalSystem], CHINA
- MedTech Europe [MedTech Europe], BELGIUM
- Paul-Ehrlich-Institut [PEI], GERMANY
- Quik S.A.S. "Quality is the Key" [QUIK], COLUMBIA
- R B Diagnostic Private Limited [RBDiagnostic], INDIA
- RCPA Quality Assurance Programs Pty Limited [RCPA QAP], AUSTRALIA
- Ref4U, Laboratory of Toxicology, Faculty of Pharmaceutical Sciences, Ghent University [Ref4U], BELGIUM
- Reference Institute of Bioanalysis [RfB], GERMANY
- Reference Material Institute for Clinical Chemistry Standards [ReCCS], JAPAN
- Roche Diagnostics [Roche], USA
- Shanghai Center for Clinical Laboratory [SCCL], CHINA
- Siemens Healthcare Diagnostics [Siemens DX], USA
- UK National External Quality Assessment Scheme for Leucocyte Immunophenotyping [UK NEQAS LI], UK
- Vitamin D External Quality Assessment Scheme [DEQAS], UK
- Wales External Quality Assessment Scheme [WEQAS], UK

# JCTLM Members by Country



# JCTLM Organizational Structure



**WG goal is to produce and promote educational materials to demonstrate the value of traceability in lab medicine as a means to reduce between method variability in the interest of improved clinical outcomes and patient safety..**



**Traceability: the key to accurate laboratory results for patients**

**LATEST NEWS**

**News - 29 March 2017**

03/29/2017

The 4th JCTLM Database Newsletter was published in March 2017

[Read more](#)

**News - 14 March 2017**

03/15/2017

Laboratory medicine training should include method standardization

[Read more](#)

**News - 10 March 2017**

03/10/2017

Traceability in laboratory medicine makes an impression in Latin

America

[Read more](#)

# JCTLM: 2015-2017 Strategic Achievements

- Completed full governance review of JCTLM
  - Reorganized work areas into the JCTLM Database Working Group
  - Revised and renewed the Declaration of Cooperation between BIPM, the IFCC and ILAC
  - Created the Stakeholder Member category
  
- Raised awareness of the importance of traceability in laboratory medicine
  - Created tag line “Accurate results for patient care” for JCTLM logo
  - Established WG on Traceability: Education and Promotion
  - Created [WWW.JCTLM.org](http://WWW.JCTLM.org) website with focus on traceability
  - Organized workshop on traceability in collaboration with China’s National Institute of Metrology in Chengdu, China (2016)



# JCTLM: 2015-2017 Strategic Achievements

- Raised awareness of the importance of traceability in laboratory medicine
  - Organized symposia on traceability for EuroMedLab, Greece and IFCC WorldLab, South Africa.
  - JCTLM publications:
    - The Joint Committee for Traceability in Laboratory Medicine – its history and operation. Jones GRD, Jackson C, Clin Chim Acta 2016; 453: 86-94
    - Traceability in laboratory medicine: a global driver for accurate results in patient care. Beastall GH, Brouwer N, Quiroga S, Myers GL. Clin Chem Lab Med 2017; 55(8): 1100-1108.
  - Convened biennial Members' and Stakeholders' Meetings in 2015 and 2017 focused on aspects of traceability in lab medicine



# JCTLM: 2015-2017 Strategic Achievements

- Expand JCTLM Executive Member organizations to include other disciplines in laboratory medicine
  - For example: The International Council for Standardization in Haematology (ICSH)
  
- Completed A GAP analysis for the JCTLM Database
  
- Publish an annual JCTLM Database Newsletter

# ➤ Annual publication of JCTLM Database Newsletter

(first released in April 2014)

- New entries in the database
- Content of the database
- Call for nomination announcement
- Call for experts nominations
- Quality Manual Modifications

Issues can be found on the website at:

<http://www.bipm.org/en/committees/jc/jctlm/#resources>

Reference Materials, Measurement Methods and Services for *In Vitro* Diagnostics



## Database Newsletter

<http://www.bipm.org/jctlm/>

Issue 3 | February 2016

We are pleased to present the third issue of the Newsletter which reports on new entries published in the database; the announcement of the 2016 call for materials, methods and services nominations as well as the call for expert reviewers; the 2015 JCTLM Members and Stakeholders Meeting; highlights from the 2015 Executive meetings; TEP WG activity and plans for 2016 JCTLM Meetings.

### 1 Highlights from the 2015 JCTLM Executive Meetings

The 14th and 15th meetings of the Executive Committee of the Joint Committee for Traceability in Laboratory Medicine (JCTLM) took place at the BIPM on 25-26 June 2015 and 3-4 December 2015. The Committee convened under the Chairmanship of Dr Gary Myers. Full text of the 2015 JCTLM Executive Meeting reports can be downloaded from [JCTLM web pages](#).

1. **Revision of the JCTLM Declaration of Cooperation**  
The Committee approved the revised text of the Declaration of Cooperation (DoC) between the BIPM, IFCC and ILAC, and its Appendices. The amendments to the text relate to the JCTLM Structure and Operation. It opens the JCTLM Executive Committee Member Status to international and non-governmental organizations having technical competence in the field or sub-speciality, and organizes the JCTLM Membership in two categories of members:
  - National and regional Members being defined as organizations that adhere to and/or contribute to the activities of the intergovernmental and international non-governmental organizations that are members of the JCTLM Executive Committee and that have expertise in traceability in laboratory medicine and demonstrate a willingness to provide experts for JCTLM Working Groups and Review Teams
  - JCTLM Stakeholders Members being defined as properly constituted "non-profit" and "for-profit" organizations, with interest, expertise and a demonstrable record of working to reduce the between method variability in laboratory medicine measurements and a commitment to promote the JCTLM database and activities.

This will come into force on signature of the revised DoC in the first quarter of 2016

2. **New structure for JCTLM Working Groups**  
The Executive approved the recommendation of the *ad hoc*

### 2 JCTLM 2016 call for nominations now open

The JCTLM invites certified reference material producers, authors of reference method publications, and laboratories that provide reference measurement services for laboratory medicine and clinical chemistry to submit nominations for review against JCTLM criteria and possible publication in the database.

Working Group on JCTLM Governance to reorganize JCTLM WG1 (materials and methods) and WG2 (services) in one Database WG with a Chair and three vice chairs. The Committee decided to extend the role of JCTLM chairman to the role of Database WG Chair, and that each vice-Chair be responsible for an Analyte Group comprising three or more review teams. This new WG structure and review policy was trialled during the 2015 review cycle for materials, methods and services. Dr Myers convened a meeting on 2 December 2015 where the vice-Chairs of the Database WG and the leaders of the review teams reported on their recommendations proposed for each of the nominations reviewed. This meeting was successful in regard to the feedback and discussion and, thus, recommendations were formally approved at the 15th Executive meeting.

3. **Appointment of Database WG vice Chairs**  
The Executive Committee appointed three Database WG vice Chairs each being responsible for an Analyte Group, and assigned Review Teams to each Analyte Group as follows:
  - Prof. Dr Siekmann is responsible for Analyte Group 1 composed of the Drugs, Metabolites and Substrates, and Non-Peptide Hormones Review Teams
  - Dr Schimmel is responsible for Analyte Group 2 composed of the Coagulation Factors, Enzymes, Proteins, Nucleic Acid, Infectious diseases, Blood Grouping and Cell typing, and Blood cell counting Review teams
  - Dr Phinney is responsible for Analyte Group 3 composed of the Vitamins, Non-Electrolyte Metals and Electrolytes and Blood gases Review teams.

4. **Adoption of a tag line for the JCTLM logo**  
The Committee agreed on the tag line 'Accurate results for patient care' which is attached to the JCTLM Logo, and would be included in layouts for promotional materials developed by the JCTLM. The new logo can be seen at the top of this page.

Nominations should be made using the procedures and forms available at:

- [Call for Material and Method nominations](#)
  - [Call for Laboratory Measurement Service nominations](#)
- The closing date for submission of nominations is 30 May 2016

**Thank You!!**



Accurate results  
for patient care