

Joint Committee for Traceability in Laboratory Medicine

JCTLM Report for 2017

CCQM Meeting, 19-20 April 2018



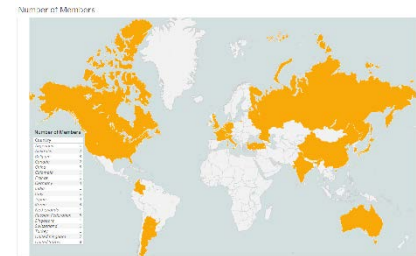
Outline

1. **Status of JCTLM Membership**
2. **Database WG review activity**

Materials, methods & services nominations

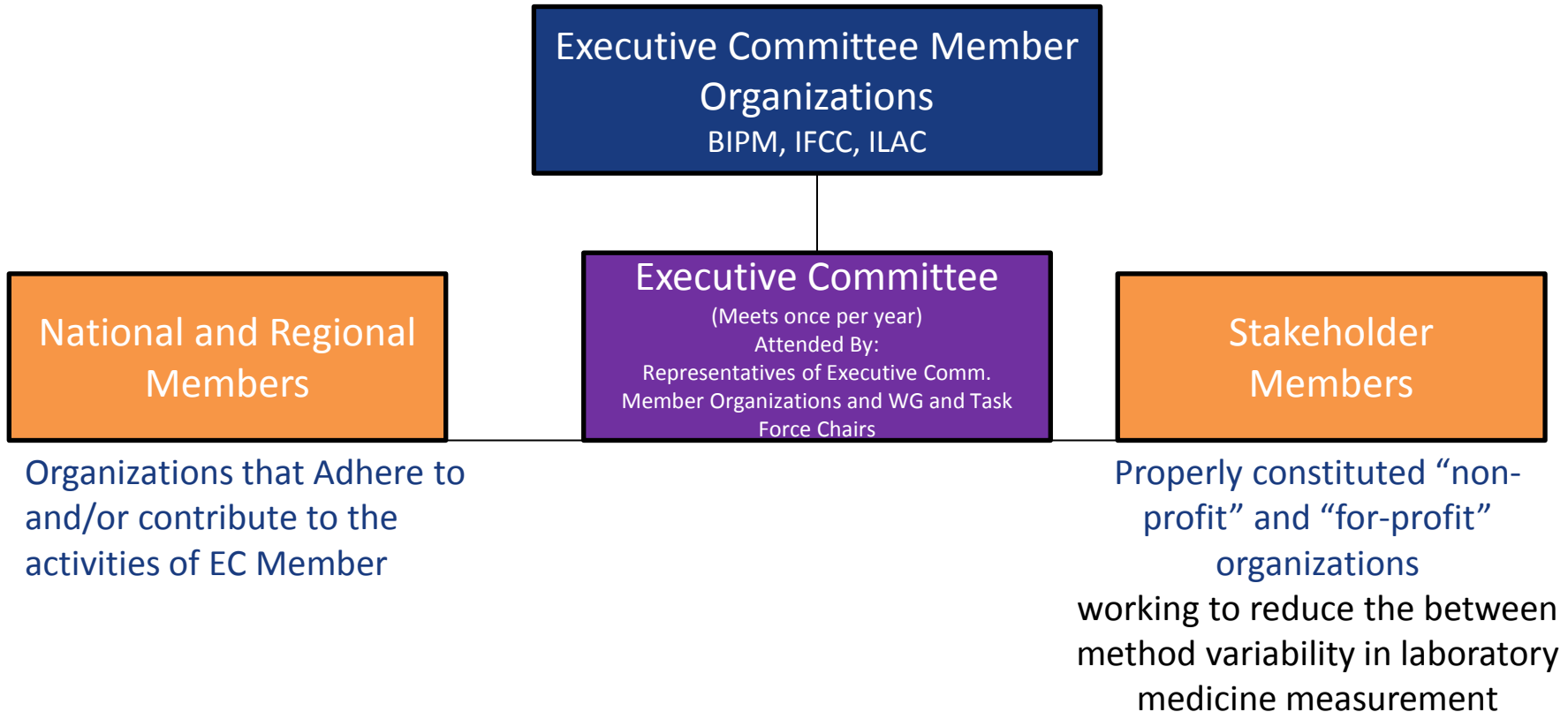
3. **TEP WG progress report**

Traceability Education & Promotion



JCTLM Membership

JCTLM Member designations



National and Regional Members

New organizations approved :

- 1. Canadian Society of Clinical Chemists / Société Canadienne de Clinico-Chimistes [CSCC/SCCC)**
- 2. All-Russian Scientific Research Institute for Metrological Service, (VNIIMS)**
- 3. All-Russian Scientific Research Institute for Optical and Physical Measurements, Rosstandart (VNIIOFI)**
- 4. D.I. Mendeleev Institute for Metrology (VNIIM)**

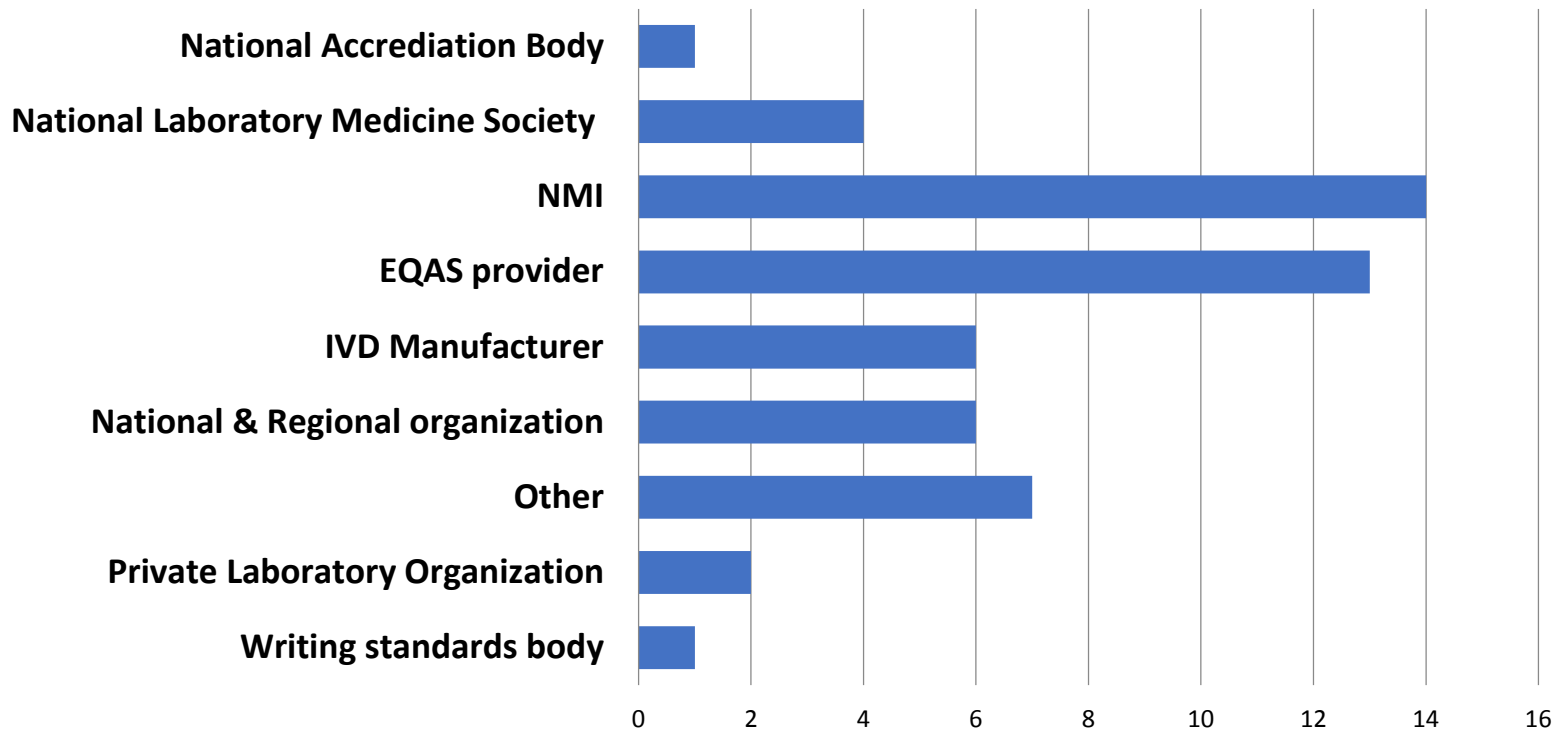
Stakeholder Members

New organizations approved :

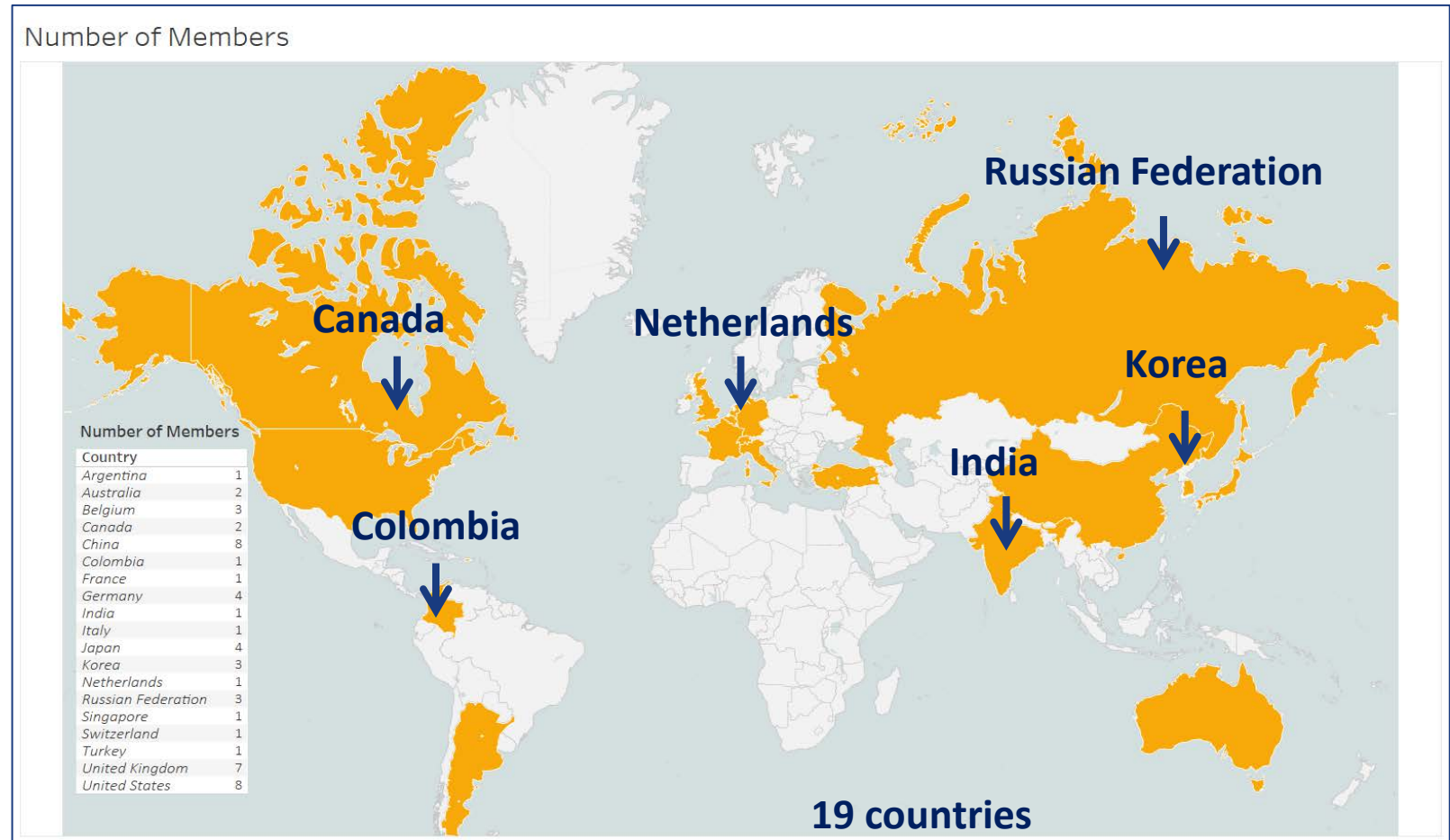
1. **Maccura Biotechnology Co., Ltd., China**
2. **MedicalSystem Biotechnology Co., Ltd, China**
3. **Fujirebio Europe NV , Belgium**
4. **Bio-Rad Laboratories, United States**
5. **Roche Diagnostics, United States**
6. **Siemens Healthcare Diagnostics , United States**
7. **Institute for Quality Management in Healthcare, Centre for Proficiency Testing, Canada**
8. **Shanghai Center for Clinical Laboratory (SCCL), China**
9. **UK National External Quality Assessment Scheme for Leucocyte Immunophenotyping (UK NEQAS LI)**
10. **Vitamin D External Quality Assessment Scheme (DEQAS), UK**
11. **Birmingham Quality / UK National External Quality Assessment Scheme (BQ /UK NEQAS)**
12. **National Center for Clinical laboratories (NCCL), China**
13. **Association for Quality Management in Laboratory Medicine (AQMLM)**
14. **R B Diagnostic Private Limited (RBDiagnostic), India**

JCTLM Membership

54 JCTLM Members (April 2018)



Global reach of JCTLM Membership



Executive Committee Member
Organizations
BIPM, IFCC, ILAC

Progress in expanding JCTLM Executive Member organizations to include other disciplines in laboratory medicine

- Engaged discussion with the International Council for Standardization in Haematology (ICSH)
- ICSH /JCTLM Meeting planned in May 2018 at BIPM to discuss technical issues in the field

2017 JCTLM New nominations

Cycle 14 (Materials & Methods) and Cycle 12 (Services)

	Materials	Methods	Services	All
Analyte category	# submissions in 2017	# submissions in 2017	# submissions in 2017	# submissions in 2017
Drugs	1	1		2
Electrolytes	18	5	3	26
Enzymes	7		14	21
Metabolites & Substrates	10	2	4	16
Non-Peptide Hormones	1			1
Non-electrolyte Metals		1		1
Proteins	7	2	1	10
Vitamins	2			2
Total:	8	11	22	79

2018 JCTLM Database Publication

+ 3 CRMs

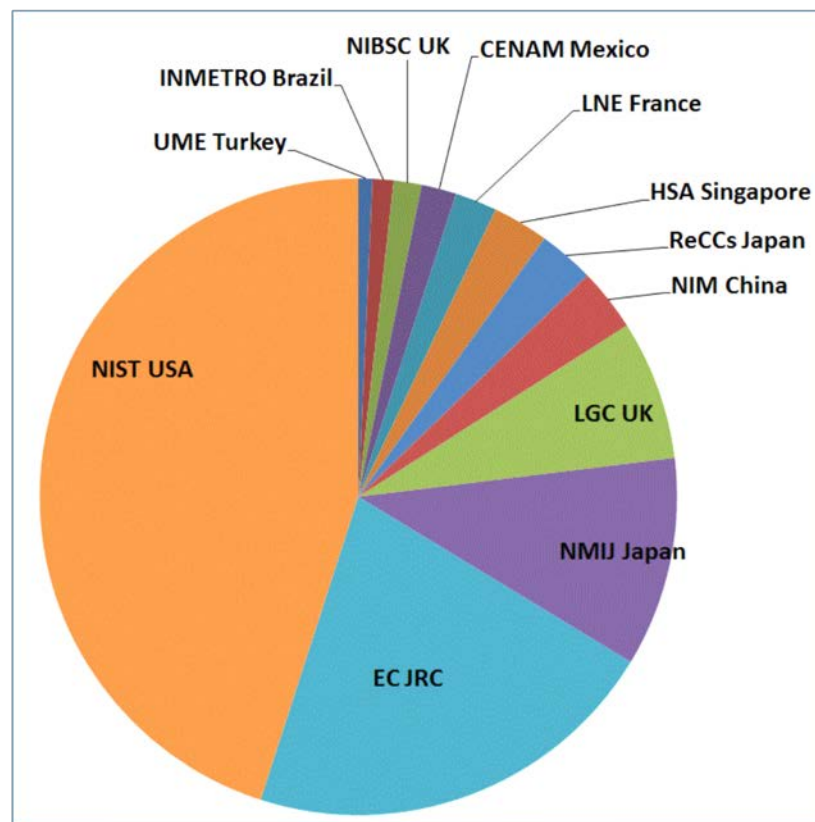
LGC (UK) : Tacrolimus

UME (TR): 25-hydroxyVitamin D2 & D3 /serum

296 CRMs in the database

**12 producers including 11
NMIs/DIs**

95 % CRMs listed from NMIs/DIs



2018 JCTLM Database Publication

+ 8 RMPs

Roche Diagnostics, Germany

An LC-MS/MS based candidate reference method for the quantification of carbamazepine in human serum

RMIT University, Australia

Quantitation of sweat chloride by ICP-MS.

National Center for Clinical laboratories (NCCL), China

ICP-MS reference measurement procedures for serum Calcium, Potassium, Magnesium, and Sodium in serum

CDC, US

Evaluation of an isotope dilution HPLC tandem mass spectrometry candidate reference measurement procedure for total 17- β Estradiol in human

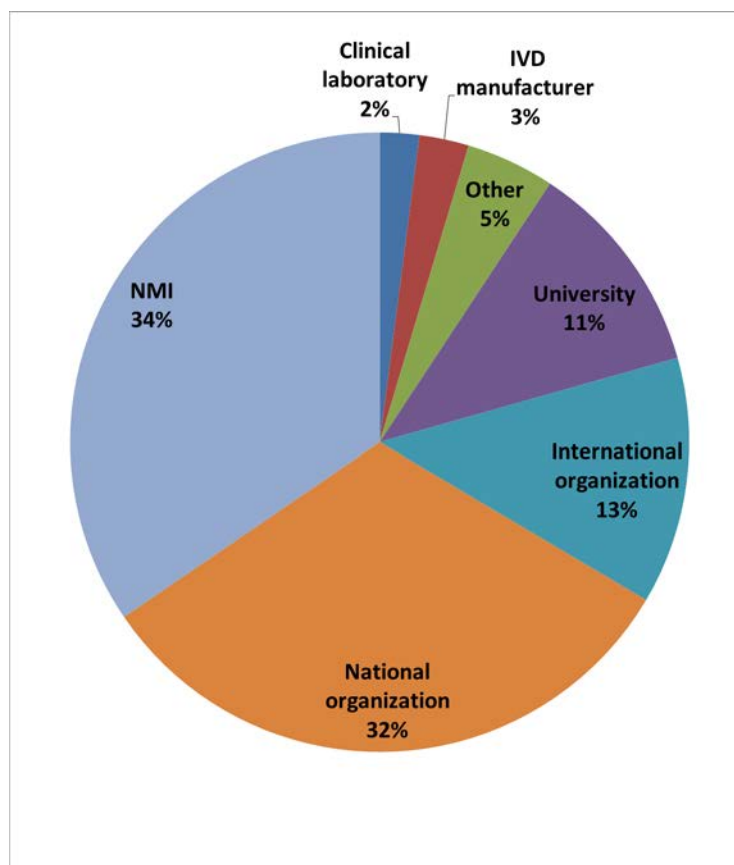
NMIA, Australia

Accurate analysis of Testosterone in human serum using a heart-cutting 2D-UPLC MS/MS procedure

2018 JCTLM Database Publication

Distribution of methods by organizations

194 RMPs in the database



2018 JCTLM Database Publication

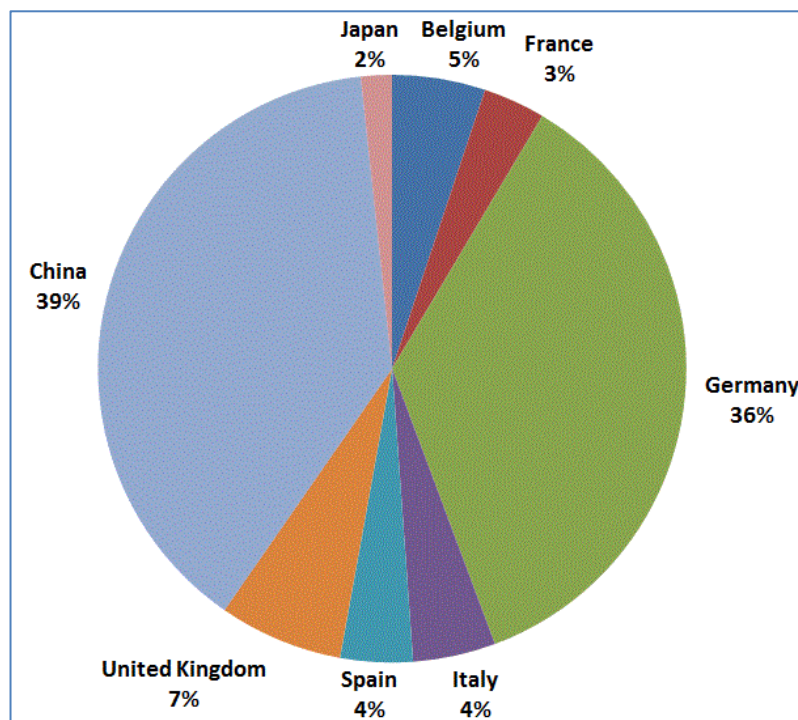
Cycle 14 (Materials & Methods) and Cycle 12 (Services)

+ 15 reference measurement services

Analyte Category	Analyte	Location of Laboratory
Electrolytes	Potassium Magnesium Calcium	China
Enzymes	Alanine aminotransferase (ALT) Aspartate aminotransferase (AST) Creatine kinase (CK) Lactate dehydrogenase (LDH) Gamma-glutamyltransferase (GGT) Alpha-amylase Alkaline phosphatase (ALP)	China
Metabolites and substrates	Creatinine Uric acid Glucose Bilirubin (total)	China
Proteins	HbA1c	China

2018 JCTLM Database Publication

Distribution RMS providers by country of origin



176 reference measurement services in the database

18 services providers including 2 NMIs

2018 JCTLM Database WG review outcomes

1. Large number of nominations for RMs and RMPs rejected

Need to provide adequate guidance/training to the JCTLM stakeholders with regards to the **ISO 15194 and 15193 for clarifying key requirements and how to implement** certain concepts such as **commutability study, method validation, extent of equivalence demonstration.**

- DB WG's session will be held at the next PPTD-2018 conference in Chengdu
 - ISO 15194 (K. Phinney, NIST)
 - ISO 15193 (A. Kessler, RfB)
 - ISO 15195 (M. Pantheghini, CIRME)
- Suitable examples for CRM and RMP nominations will be developed

2. Large number of submissions

Review team Leaders requested additional experts to help for the review

Other issues raised

1. possibility to produce the documentation partly or fully in English?

Certified Reference Material Certificates and Certification Reports

JCTLM will conduct an opinion survey amongst NMIs having CRM listed in the JCTLM Database

2. possibility to streamline the nomination process?

2.1 Nomination of replacement materials

JCTLM will conduct a survey among NMIs with CRMs in the JCTLM Database in compliance with ISO 17034/ISO 15194 in order to identify critical criteria for renewing batches of the certified reference materials that would be produced under the same procedures.

2.2 Nomination of materials listed in KCDB

JCTLM will conduct a comparison study of the CIPM MRA review process against the JCTLM review acceptance criteria

JCTLM TEP WG Report



MEETINGS

Organizes the JCTLM Members & Stakeholders Meeting

'Accurate Results for Patient Care Workshop 2017'

4-5 December 2017, BIPM

117 participants from 27 countries

Medical researchers; NMI; EQAS , Laboratory medicine specialists,





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Day 1 -Traceability in Action

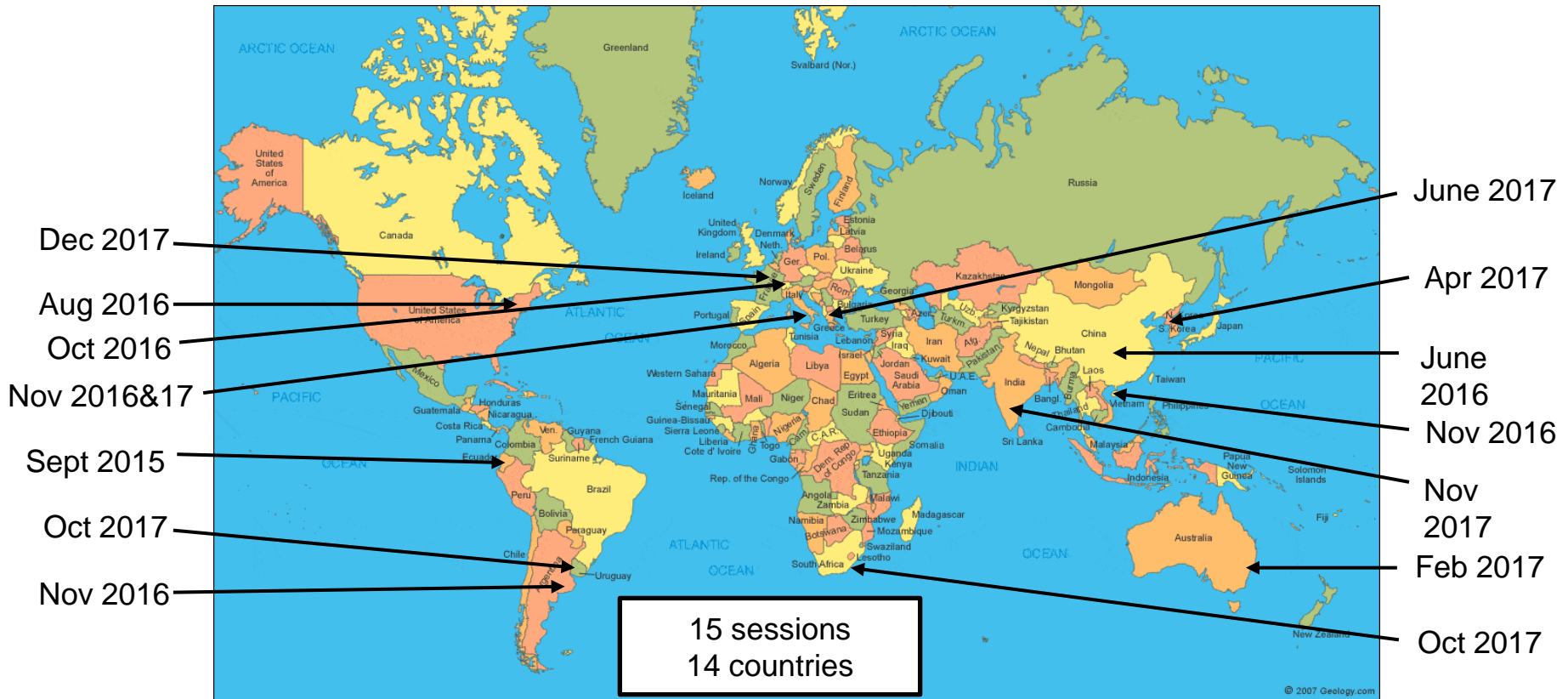
- Update from JCTLM
- Why traceability matters to patients
- Traceability in external quality assessment
- Why traceability matters to manufacturers

Day 2 -Traceability into the future

- Clinical challenge - biomarkers in neurodegenerative disease
- Developments in traceability in infectious diseases
- Recent advances in traceability - a global perspective
- Responding to the future of traceability

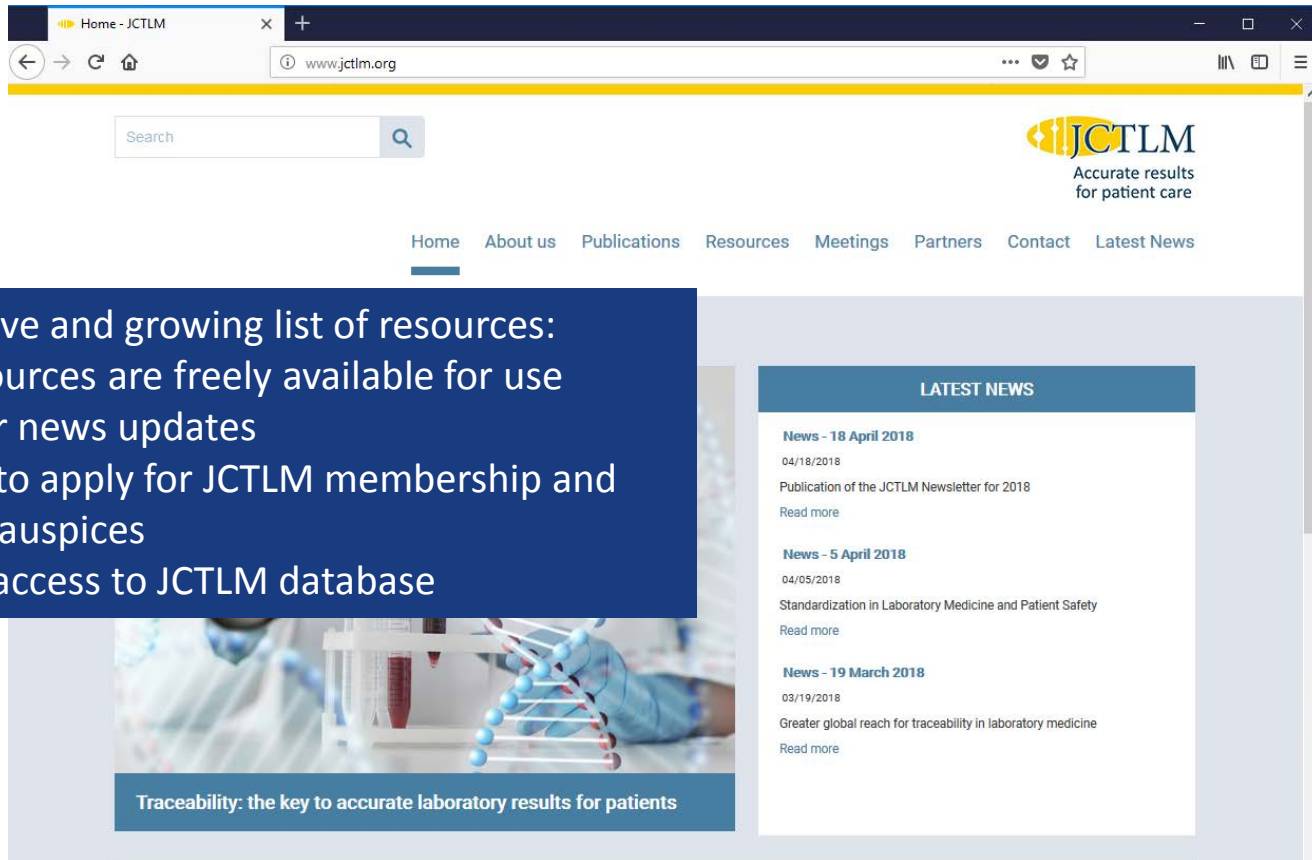
JCTLM TEP WG Report

Organised sessions on traceability at conferences



JCTLM TEP WG Report

Maintains Website – www.jctlm.org



The screenshot shows the JCTLM website homepage. The browser address bar displays 'www.jctlm.org'. The website features a search bar, a navigation menu with links for Home, About us, Publications, Resources, Meetings, Partners, Contact, and Latest News, and a 'LATEST NEWS' section. The 'LATEST NEWS' section lists three news items: 'News - 18 April 2018' (04/18/2018) about the JCTLM Newsletter for 2018, 'News - 5 April 2018' (04/05/2018) about standardization in laboratory medicine, and 'News - 19 March 2018' (03/19/2018) about global reach for traceability. A banner at the bottom of the page reads 'Traceability: the key to accurate laboratory results for patients'.

- Extensive and growing list of resources:
- All resources are freely available for use
- Regular news updates
- Forms to apply for JCTLM membership and JCTLM auspices
- Direct access to JCTLM database



Published on www.jctlm.org

1 . Glossary of terms and definitions

14 terms with **Everyday easy to understand definitions** and a **formal definition (VIM 3 source)**

2 . Webinars of scientific concepts

1. Basics of traceability applied to laboratory medicine. **Anja Kessler** (RfB).
2. Basic traceability chains. **Jeanita Pritchett** (NIST).
3. Examples of reference materials. **Jeanita Pritchett** (NIST).
4. Examples of reference measurement procedures **Jeanita Pritchett** (NIST).
5. Commutability explained. **Vincent Delatour** (LNE).
6. Commutability – why it matters. **Vincent Delatour** (LNE).
7. Traceable and commutable calibrators. **David Ducroc** (weqas).
8. The pillars of standardization. **Elvar Theodorsson** (Eurachem).
9. Standardization and harmonization. **Elvar Theodorsson** (Eurachem).
10. All results are made and interpreted by comparison. **Elvar Theodorsson** (Eurachem).

3. Webinars produced to assist trainees in laboratory medicine.



Published on www.jctlm.org

4. Review article on Global Significance of TML

published in *Clin Chem Lab Med* with permission to translate into other languages and submit to national journals

DE GRUYTER

Clin Chem Lab Med 2017; x(x): xxx-xxx

Opinion Paper

Graham H. Beastall*, Nannette Brouwer, Silvia Quiroga and Gary L. Myers, prepared on behalf of the Joint Committee for Traceability In Laboratory Medicine

Traceability in laboratory medicine: a global driver for accurate results for patient care

DOI 10.1515/cclm-2017-0060
Received January 20, 2017; accepted March 15, 2017

Keywords: action plan; commutability; standardization; traceability.

JCTLM TEP WG Report



Published on www.jctlm.org

5. Library of scientific publications

- ~100 References for publications both general and analyte specific
- **Other references :**
ISO references; Publications from JCTLM

6. Annual JCTLM Newsletter



Call for materials, methods and services nominations **Closing date 30 May 2018**

Future meetings under JCTLM Auspices

10 - 12 October 2018

Protein and Peptide Therapeutics and Diagnostics Workshop (PPTD-2018),
Chengdu (China), Workshop website : <http://pptd.ncrm.org.cn/>

29 November 2018 “Every day is patient safety day”,
12th International Scientific Meeting of the Centre of Metrological Traceability
in Laboratory Medicine (CIRME) Milan (Italy), [Programme of the meeting](#)

Future JCTLM Members’ and Stakeholders meeting **2 - 3 December 2019, BIPM**