

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*

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.

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.

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

3 New entries in the JCTLM database

The JCTLM nomination and review process completed in 2015 has resulted in 13 new entries in the JCTLM Database for available higher-order certified reference materials, as well as 3 new published reference measurement methods, and 18 new measurement services delivered by reference laboratories.

The new entries are listed below. Full information on the reference materials and their producers, methods, measurement services and reference laboratories can be found by searching the database at:

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

New entries for available Certified Reference Materials

Analyte Category	Analyte*	Material / Matrix
Drugs	Sirolimus	High-purity material
Metabolites & Substrates	Glucose Fructose Galactose Lactose Xylose Sucrose	High-purity materials
Proteins	anti-myeloperoxidase immunoglobulin G beta 2-microglobulin C-reactive protein albumin C-peptide, and total C-peptide	Human serum Human serum Aqueous solution Aqueous solution Phosphate buffer

*Complete information for each Certified reference Material entry can be retrieved by clicking on the Analyte name.

New entries for Reference Measurement Methods

Analyte Category	Reference Measurement Method (<i>JCTLM Identification Number</i>)
Proteins	2D- UPLC-tandem mass spectrometric method for analysis of amyloid beta 1-42 in human CSF (JCTLM C12RMP1) Korecka M <i>et al.</i> , <i>J. Alzheimer's Dis.</i> , 2014, 41(2), 441
Vitamins	CDC reference measurement procedure for serum 25-hydroxyvitamin D metabolites (JCTLM C12RMP2 (for 25- hydroxyvitamin D3) and C12RMP3 (for 25-hydroxyvitamin D2). Mineva E M <i>et al.</i> , <i>Anal. Bioanal. Chem.</i> , 2015, 407(19), 5615

Complete information for each method entry can be retrieved by clicking on the JCTLM identification number.

New entries for Reference Measurement Laboratory Services

Analyte Category	Analyte	Location of Laboratory
Enzymes	Alanine aminotransferase Alkaline phosphatase Alpha-amylase Aspartate aminotransferase Creatine kinase Gamma-glutamyltransferase Lactate dehydrogenase	China
Metabolites & Substrates	Glucose, Urea, Total bilirubin, Uric acid, Creatinine, Total cholesterol	China
Non Peptide Hormones	Progesterone	China
Proteins	HbA1c	China

Complete information for each entry can be retrieved from the [Analyte keyword search results](#) for the reference measurement services, e.g. Contact for Reference Laboratory, Scope of the service offered and a link to the results for the inter-laboratory comparison.

4 Call for experts to participate in JCTLM Review Teams

The JCTLM has been working for twelve years in maintaining a database of certified reference materials, measurement methods, and services that relate to the *in vitro* diagnostic area. The database relies on vital contributions from individuals/experts who volunteered to participate in the activity of the [JCTLM Review Teams](#), and in reviewing nominations against agreed criteria.

With the increasing numbers of nominations that are submitted in various fields, the JCTLM is seeking additional experts to

contribute to the following review teams: [Drugs, Electrolytes and Blood gases](#), [Metabolites and substrates](#), [Proteins](#), and [Vitamins](#).

Submission of the nomination/application forms ([WG1-P-06-F-01](#)) for JCTLM Review Team Membership can be made at any time to the [JCTLM Secretariat](#).

5 'Protein and Peptide Therapeutics and Diagnostics' Workshop in China, June 2016

The National Institute of Metrology, China and the BIPM are organizing a workshop on 'Protein and Peptide Therapeutics and Diagnostics: Research and Quality Assurance', to be held on 1-4 June 2016, in Chengdu China under the auspices of the JCTLM. The [meeting website](#) is open for registration and abstract submission, with a deadline of **15 April 2016**.

Abstracts are invited for the three sessions of the workshop:

- a. Standards and Advances in Peptide and Protein Diagnostics
- b. Advances and Challenges in IVD Standards and Research
- c. Advanced Methods for Peptide and Protein Drug Characterization and Quality Assurance.

6 2015 JCTLM Members and Stakeholders Meeting

The biennial JCTLM Members and Stakeholders meeting was held on 30 November and 1 December 2015. A total of 35 presentations, in five sessions, were enjoyed by an international audience.

Session I: Update on JCTLM Activities

The Executive Committee presented a revised structure and governance for the JCTLM; reviewed the current status and operation of the JCTLM Database and announced the creation of a Working Group for Traceability, Education and Promotion.

Session II: JCTLM Member Activities

An impressive range and quality of activities was reported in nine presentations. Several reference materials and measurement procedures are produced by these Members in response to requests from clinicians, users of laboratory services and companies. Some of the presentations referred to EQA schemes based on traceable materials.

Session III: Developments in Traceability Requirements around the Globe. This session:

- Addressed the status of traceability in laboratory medicine in China and Latin America
- Presented the role of the WHO Expert Committee for Biological Standardization
- Learned of the work on method harmonization protocols that is taking place as part of the revision of ISO 17511.

Session IV: Identifying Future Priorities in Traceability in Laboratory Medicine. This session:

- Addressed the opportunities that exist for the production of further reference materials and methods
- Reviewed a gap analysis of assays for commonly performed analytes that do not have entries on the JCTLM Database

- Highlighted assays that perform poorly in EQA schemes that may benefit from traceability
- Presented the International Consortium for the Harmonization of Clinical Laboratory Results and the expanding RELA External Quality Assessment Scheme for Calibration Laboratories.

Session V: New Challenges for Traceability in Laboratory Medicine. This session of 14 presentations:

- Reviewed the current situation in haematology and coagulation
- Addressed the need for and approach to producing reference materials and methods for nucleic acid testing in infectious disease and cancer diagnostics
- Examined the clinical importance of traceable lipid methods and an alternative approach to cardiovascular risk assessment based on counting lipoprotein particles
- Reported the production of the first traceable reference material in autoantibody testing, and a glyco-engineering approach to producing a possible reference preparation of TSH
- Highlighted that once reference materials and methods have been produced there are still challenges of implementation
- Clarified the mysteries of commutability with logical protocols and commutability criteria.

The 2015 JCTLM Members and Stakeholders meeting was a stimulating experience, which indicated increasing recognition of the importance of reference materials and reference methods as anchors for quality assays in laboratory medicine. It justified the adoption by the JCTLM of the strapline 'Accurate Results for Patient Care'.

Presentations can be downloaded from the [JCTLM web pages](#)

7 JCTLM TEP WG

The JCTLM created a Working Group for Traceability: Education and Promotion (TEP WG) to produce and promote educational materials to demonstrate the value of traceability in laboratory medicine as a means to reduce 'between method' variability in the interests of improved clinical outcomes and patient safety. Nominations were invited from JCTLM members and the first meeting was held at the BIPM on 2 December 2015.

Membership

The membership of TEP WG represents a wide geographic spread and range of interests:

Name	Country	Organization
Graham Beastall	United Kingdom	IFCC – WG-TEP Chair
Robert Wielgosz	France	BIPM
Graham Jones	Australia	ILAC
Jeanita Pritchett	United States	NIST
David Armbruster	United States	Abbott
Tony Badrick	Australia	RCPAQAP
Elvar Theodorsson	Sweden	Eurachem
Vincent Delatour	France	LNE
David Ducroq	United Kingdom	WEQAS
Anja Kessler	Germany	RfB
Nanette Brouwer	The Netherlands	SKML
Chen Baorong	China	Beijing Aerospace General Hospital Reference Laboratory
Silvia Quiroga	Argentina	ProgBA
Marta Torres	Argentina	ProgBA
<i>Ex officio</i>		
Gary Myers	United States	JCTLM Chair
Stephanie Maniguet	France	BIPM, TEP WG Secretary

Agreed Activities

The WG agreed a wide range of activities in fulfillment of its mission. These include:

- Creation of two sub-groups to focus on 'meetings' and 'education'.

Meetings sub-group:

- Early announcement of 2017 Members and Stakeholders meeting
- Creation of a list of relevant regional and national conferences at which traceability may be promoted
- Agreement of a strategy to convince conference organizers to include traceability
- Creation of a generic abstract and poster on traceability
- Agreement of a scheme to award JCTLM auspices to conference organizers
- Proposal of speakers for forthcoming international workshop in Chengdu, China.

Education sub-group:

- Nomination and prioritization of scientific concepts to form the basis of educational support projects
- Development of vector graphics for each prioritized project
- Creation of short educational sessions in different formats for each project.

Publicity and promotion:

- Article to be written for JCTLM annual newsletter
- Options and costs to be explored to facilitate creation of a standalone TEP WG website to promote the importance of traceability in laboratory medicine.

More information is available on the [TEP WG web page](#)

For comments on the TEP WG please contact [Graham Beastall](#)

8 Dr Graham Jones awarded the 2015 Barry Inglis Medal

Dr Graham Jones, a chemical pathologist at St Vincent's Hospital in Sydney, Australia, has been awarded the Barry Inglis Medal. The awards acknowledge and celebrate outstanding achievement in measurement research and excellence in practical measurements in Australia. Dr Jones was recognized for his work to improve the accuracy and reliability of chemical pathology testing, via better measurement standards, techniques and clinical reference ranges.

9 Future JCTLM Meetings

- JCTLM Database WG Meeting to be held at the BIPM on 5 December 2016
- JCTLM Executive Meeting to be held at the BIPM on 6-7 December 2016
- JCTLM Members and Stakeholders Meeting to be held at the BIPM on 5-6 December 2017