Report of the 26th meeting of the JCTLM Executive Committee
4-5 December 2024
Venue: BIPM Hybrid Meeting

List of participants:
Dr G. Miller (JCTLM Chairman, IFCC)
Dr R. Wielgosz (JCTLM Executive Secretary, BIPM)
Dr S. Maniguet (JCTLM Secretariat, BIPM)
Dr G. Jones (ILAC)
Mr A. Griffin (ILAC)
Dr Q. Liu (JCTLM DB WG vice-Chair, AG1)
Prof. M. Panteghini (JCTLM DB WG vice-chair, AG2)
Dr K. Phinney (JCTLM DB WG vice-Chair, AG3)
Mr T. Fawcett (ICSH)
Dr A. Kessler (IFCC)
Dr T. Badrick (JCTLM TEP WG Chair)
Prof. C. Cobbaert (IFCC SD)
Prof. T. Özben (IFCC)

Excused
Dr S-R Park (CIPM)
Dr. W. Louw (CIPM)

1 Approval of the agenda [JCTLM-EXEC/25-01]

The agenda was approved with an additional agenda item under 16 for a brainstorming discussion to reflect on how JCTLM has been progressing over the years.
Dr Wielgosz commented that the establishment of the JCTLM had strengthened metrology for laboratory medicine programmes within the NMI community, including funded research and development projects that had led to new measurement services, and that this aspect should also be included in the discussions of the new agenda point.

2 Report of 25th JCTLM Executive Committee Meeting

2.1 Review of action points arising from the 25th meeting [JCTLM-EXEC/25-02]

2.2 Review of action points arising from mid-year meeting [JCTLM-EXEC/25-03]

The Committee reviewed the action items from the previous meeting and noted those that were still outstanding, which had been delayed in part to limited time resources:

A23-06: Dr Miller to include a Task Group for regulators in the updated terms of reference of the TEP WG engagement.
Dr Miller said that improving JCTLM recognition and engagement of regulators was included in the terms of reference of the TEP WG which would then recommend how best to progress further.

A23-07: Dr Miller/Dr Wielgosz to draft revised text for the DoC and subsequent document on membership categories for consideration of the Executive Member Organizations and Committee.
Dr Wielgosz said that this action was pending agreement of a proposal for tiered membership model which would be discussed under agenda item 4.

A23-16: JCTLM Secretariat to contact NCCL China to clarify if the EQAS was open for laboratories outside China, if the results could be made available outside China, and if it was meeting JCTLM requirements in Section 7 of the DBWG P-02B
Dr Wielgosz said NCCL China was contacted and their response (EXEC24-24) confirmed that NCCL EQAS Scheme for Chinese calibrations laboratories did not meet the JCTLM requirements in Section 7 of the DBWG P-02B**.**

A24-08: Dr Jones to contact IATDMCT (International Association of Therapeutic Drug Monitoring and Clinical Toxicology) for nominations of experts for the JCTLM Drugs Review team.
Dr Jones said he contacted a member of the IATDMCT who confirmed her availability and would ask her to submit an application for the JCTLM Drugs review team.

3 JCTLM Governance

3.1 Representation on the Executive

Dr Wielgosz informed the Committee that the procedure for the selection of the JCTLM Chairman and Secretariat had been followed. The Secretariat contacted the sponsoring organizations, the IFCC, the ILAC, the ICSH and the BIPM for nominations. The IFCC submitted a nomination of Prof Mauro Panteghini for JCTLM Chair, and the BIPM had responded that it was prepared to continue in the role of the JCTLM Secretariat. No other nominations were received.

3.1.1 Agreement on JCTLM Chair for period 2025-2026

The Committee approved the Chairmanship of Prof Mauro Panteghini.
The Committee also thanked Dr. Miller for his great contribution and leadership of JCTLM over the last four years.

3.1.2 Agreement on organization with JCTLM Secretariat role 2025-2026

The Committee approved the BIPM's continued role as Secretariat for the JCTLM for period 2025-2026.

3.2 JCTLM WG Chairs

Dr Wielgosz said that in accordance with JCTLM rules the JCTLM Chairman also acted as JCTLM DB WG Chair.

Prof. Panteghini raised the issue of potential conflict of interest in giving the Chairman roles of the JCTLM and DB WG Chair to the same person, and the possibility to delegate the DB WG Chairmanship to another person designated by the JCTLM Executive Committee. In the discussion that followed, the Committee agreed that the review of the current rule and the potential impact of changing the rule would be further discussed at the mid-year review meeting, noting that no conflict of interest had arisen so far.

Dr Phinney and Dr Liu had confirmed their willingness to continue to chair the Analyte Working Groups 3 and 1, respectively and the Committee re-appointed them for a renewable two-year term.

Following his appointment as the JCTLM Chair, Prof. Panteghini informed the Committee he was stepping down as vice-Chair of the JCTLM DB WG Analyte Working Groups 2 (AG2), and suggested a review team leader from the AG2 should be identified to chair the AG2.
In the discussion that followed, the Committee agreed that Dr Devonshire, who was currently leader of the JCTLM review team for nucleic acids, should be contacted to verify if she would be available to chair the AG2.

Dr. Miller reminded the Committee Dr Badrick was appointed as Chair of the TEP WG in July 2024 and there was a vacancy for the chairmanship of the JCTLM Task Force for promotion.

(A24-01) JCTLM Secretariat to contact Dr Devonshire to verify if she would be available to chair the Analyte Working Group 2.

3.3 JCTLM Review Team Membership

3.3.1 Drugs team leader appointment

Dr Liu recommended Dr Wollinger who was currently a member of the Drugs review team as a potential candidate for taking over the role of leader for the review team. He also agreed to lead the team for another year in case of a negative response from the candidate.
The Committee thanked Dr. Liu for his support and leadership of the Drugs review team during this year's review cycle and agreed with his recommendation to invite Dr Wollinger to become leader of the review team.

3.3.2 Coagulation factors team leader appointment

Mr Fawcett suggested that the review team for Coagulation factors should be renamed as the review team for Haemostasis for consistency with ICSH naming approach. The Committee agreed with the proposal.

The Committee supported the DB WG's suggested approach to investigate the availability of a review team leader for temporally leading the review team for Haemostasis and providing an induction process to the group on the JCTLM processes.

3.3.3 Call for new members of review teams

The Committee reviewed the JCTLM review team membership and agreed new experts should be recruited to serve as members of the review teams for Blood cell counting (2), Drugs (2), Enzymes (4), Haemostasis (2), Non-peptide hormones (2), Proteins (2) and Vitamins (2). It further requested that a call of nominations should be made by the JCTLM Secretariat and the EC members organizations having contacts in measurement fields where experts were needed, and a common text should be developed for explaining the role for the member position of the review team.
It also agreed that the process of suspension would be applied for a member of the JCTLM review team for Proteins who had not contributed to the last two review cycles.
Following his appointment as the JCTLM Chair, Prof. Panteghini informed the Committee he was stepping down as review team leader for Enzymes, and recommended Dr Canalias who

was currently a member of the Enzymes review team as a potential candidate for taking over the role of leader for the review team. The Committee agreed with the recommendation.

The Committee recognized the need to develop a long-term approach for recruiting review teams members and agreed on an action item to further investigate an approach for attracting new members and anticipating a systematic process to recruit members.

(A24-02) JCTLM Secretariat to contact Dr Wollinger and Dr Canalias to verify if they would be available to lead the review team for Drugs and Enzymes, respectively.
(A24-03) JCTLM Secretariat to send a call of interest for the *ad-interim* leader position of the Haemostasis review team. (*Alison D. and David D. to be contacted*)
(A24-04) JCTLM Secretariat to send a call for new experts for Blood cell counting, Drugs, Enzymes, Haemostasis, Non-peptide hormones, Proteins and Vitamins.
(A24-05) Dr. Wielgosz to send a call for interest to CCQM CAWG for member position of the Blood Cell counting review team
(A24-06): Prof. C. Cobbaert to send a call for interest to ISTH contact for member position of the Haemostasis review team; and to IFCC contact for Proteins review team
(A24-07): JCTLM Secretariat to contact the Proteins review member no longer active to send a letter of suspension of their term as a JCTLM review team member.
(A24-08): JCTLM to develop a plan for the long-term recruitment process of review members.

3.4 JCTLM and JCTLM Secretariat operating costs for 2024 and budget for 2025 [JCTLM-EXEC/24-26]

Dr Wielgosz presented the document 24-26, which included the details of the operating costs of the JCTLM Secretariat for 2024 and the expected operating costs in 2025. He pointed out that overall costs for 2024 were less than predicted as the work for the development of the JCTLM web platform would be performed in 2025. He added that the 2025 budget anticipated an expected increase of activity related to the development of the web platform for submissions and review of JCTLM nominations, and the development of a new set of procedures on the operation and update of the new database application by the JCTLM Secretariat as well as the ongoing revision of the JCTLM Quality manual.

He added that the agreement signed between IFCC and BIPM on 3 November 2021, has been extended by an addendum signed on 19 March 2024, with annual costs for the operation of the JCTLM Secretariat to be split between the IFCC and BIPM at a 50/50 basis with the IFCC annual contribution limited to a maximum of 50 000 euro. The extended agreement runs until the end of 2026.

The Committee approved the 2025 budget and thanked the BIPM for covering the additional costs related to JCTLM meetings held at the BIPM Headquarters and operation of the database.

(A24-09) JCTLM Secretariat to send the invoice for 2024 costs to the IFCC.

4 Follow up on Task Group on Strategy outcomes

4.1 Progress with tiered membership model [EXEC24-17]

Dr Wielgosz presented the document 24-17, which included an update on the progress with updating the JCTLM Declaration of Cooperation with a Tiered Membership Model developed by the Task Group, with representatives from JCTLM Executive Committee Organisations.

He reminded the Committee that the JCTLM was seeking to establish a tiered membership system, with the aim of raising 40 000 to 50 000 euro annually to cover JCTLM database maintenance costs and depreciation (to have funds to purchase the next version).

The Task Group's proposal was to revise the text of the Annexes in consistency with the following JCTLM Membership structure with a tiered membership model with some fee-paying categories:

1) JCTLM Members status would be open for non-profit and for-profit organizations with annual fees as follows:
   a) Non -profit: 1000 euro per annum
   b) Small for-profit organisation : 2000 euro per annum
   c) Large for-profit organisation : 5000 euro per annum

2) Associate Member status would be open to non-profit organizations with no fee.

The privileges of full membership would include the organization's logo on the JCTLM website, and reduced fees for participation in the JCTLM Stakeholder meeting.

The Committee supported the Task Group's proposed Tiered Membership Model.

(A24-10) A Task Group, with representatives from JCTLM Executive Committee Organisations (RWielgosz, T. Fawcett, T. Özben, A. Griffin) to revise the text of the Annexes in consistency with the agreed tiered membership model, definition of large and small for-profit organizations, and circulate the draft document for comment to the JCTLM Executive Committee and Members bodies.

5 Opportunities for Method developers to publish modified methods [EXEC24-18]

Dr Miller presented the document EXEC24-18, which included a report from the JCTLM Task Group on journals, which was formed to investigate how best JCTLM could assist the community to identify journals that would be open to publish modified RMPs, and the proposal that JCTLM should develop a webpage that describes what service was being sought from journals, what criteria needed to be fulfilled by the journal, and a list of journals that self-declared to the JCTLM that they met these criteria.
He added that, following previous EC discussion, JCTLM contacted the editor in chief of the CCLM journal who committed to publish, after peer review, new or modified RMPs, and the editors of the IFCC e-journal and CCA would also be contacted.

The Committee supported the proposal for developing a new webpage for listing journals that are receptive to publish and agreed with the suggested text for the webpage, providing editorial comments raised during the discussion were included.
It further agreed that JCTLM should raise awareness of journals of this new opportunity and send a call for interest to journals in the field of laboratory medicine, requesting EC members to send the names of journals.

(A24-11) Task Group on journals to finalise the text of the new page for publication of modified RMPs that would be accessible on the jctlm.org website.
(A24-12) R. Wielgosz and T. Özben to draft a joint letter to the editors of the IFCC e-journal and CCA to ask if they are open to receiving and considering publication of modified RMPs.
(A24-13) EC Members to send the names of journals that could be contacted and potentially interested in being listed on the new publication page.

6 Outputs of Task Group on Knowledge Transfer

6.1 Progress on e-learning module development

Dr Miller gave an update on the recent activity of the JCTLM Task Force on Knowledge Transfer (TF KT) which is developing training resources for submitters and reviewers on the JCTLM nomination and review processes. A series of short videos are currently being developed and foreseen to be sent for review to the JCTLM review teams in January 2025 and made available for the next review cycle. These videos would be freely available from both the IFCC website and BIPM e-Learning website.

The question of ISO Standards copyright was raised and whether it would be acceptable to include extracts of the standard in the training videos. Mr Griffin commented that use of excerpts of the clauses of ISO Standards for training purposes was at the discretion of each ISO member body and permission should be sought in the country of the requester.

The Committee noted that the e-Learning modules would need to be updated when the revised versions of the ISO 15193 and ISO 15194 standards and new web platform will be implemented which would be a new task for the TF KT. The TF KT also agreed to develop training materials for new RT members in a next phase.

7 Update on the progress for JCTLM Database Development

Dr Maniguet reported that the development of the new JCTLM web platform with an external contractor started in October and a prototype was expected to be delivered for BIPM testing in September 2025. The technical functionalities and mock-ups of the web platform were currently being drafted based on the revised JCTLM nomination and review processes' flowcharts discussed with the JCTLM Task Group on Database extension. The main change in the operational processes using the new platform would be the lowering of the work of the Review Teams and the JCTLM Secretariat.

She added that the provisional time schedule of deliverables for the project was as follows:
January 2026: Prototype platform operational and available for beta testing by a group of external users
May 2026: Training material for the new platform available
June 2026: Training platform available for users
December 2026: Launch of the new platform
1 January 2027: New platform in use for JCTLM Nominations

Dr Miller said that at the last Database WG meeting the general issue of adding new non-compliances that were not previously observed when reviewing resubmissions was raised and that there was currently no written policy in the JCTLM procedures.
In the discussion that followed, the Committee agreed that in the new web-based platform, the default option would be that only observations that were made in the first review could be the basis of continued exchange between the review team and nominator in subsequent reviews of the same nomination where there were non-compliances to clear. If in this process the review team discovered additional non-compliances, they will need to raise this with the relevant Analyte WG Chair, who will be able to open the nomination for listing of new non-compliance if they decide this is justified, and not raising the compliance would constitute a significant risk to the user of the material/method/service. It was agreed that the question of

who should be responsible for authorizing the assessment of criteria from a previous review cycle and how control settings should be implemented in the web form for completing the review, should be discussed with the experts of the JCTLM Task group on JCTLM Database expansion.

8 Report from the JCTLM WG on Traceability Education and Promotion

8.1 Activity update of JCTLM TEP WG

Dr Badrick gave an update on the activity of the JCTLM TEP WG, which held three meetings since he was appointed as the Chair of the TEP WG in August 2024. He reported that the main focuses of the meetings were the development of the programme of the 2025 JCTLM Members and Stakeholders Meeting that was in a well-advanced stage with regards to topics and speakers, and the progress with a newly established Task Group on Promotion.

He added that a group reviewed the JCTLM websites in terms of accessibility of the information and made a few comments and suggestions for improvement that were communicated to the JCTLM Secretariat for further consideration; a drafting team would assist the JCTLM Secretariat for developing the next issue of the JCTLM Newsletter; and a small group would draft a Special Report for the upcoming 150th Anniversary of the Metre Convention on 20 May 2025.

8.2 Progress with Promotion Task Group in the TEP WG [EXEC24-16]

Dr Badrick presented the document 24-16, which included a report on the progress towards establishing a promotion activity for JCTLM during 2024, and pointed out the terms of reference for a Task Team on Promotion were developed (Annexe 2) and efforts to recruit a Chair, preferably with marketing experience in the IVD industry, were in progress.

He added that Dr Weston (ICSH) provided a JCTLM Marketing Review Plan with an outline of the activities that an initial promotion campaign for JCTLM would involve and an estimated cost for this, for a JCTLM EC review and development of a consensus position on the promotional activities to be undertaken in 2025.

The JCTLM Committee recognized that an implementation of the proposed JCTLM Marketing plan would require additional funds and resources that were yet to be sought.

Prof. Özben informed the Committee that the IFCC would be ready to contribute actively to the promotion of JCTLM using their communication channels, including mass mailing via their corporate and associate members, publication division, e-Newsletter and an invitation for JCTLM to participate at the IFCC General Conference. The Committee welcomed this proposal for enhanced cooperation with the IFCC for promoting JCTLM activity.

It further agreed it would be beneficial to form a Task Team to progress the activities of a future Task Group on promotion in collaboration with the IFCC Communication and Publication Division. The task team would include R. Wielgosz, C. Cobbaert, T. Fawcett and T. Badrick, and a representative from IFCC CDP. T. Özben agreed nominate a contact person from IFCC CPD for this activity that would be contacted by the JCTLM Secretariat.

(A24-14) Task Team to develop a communication plan that can be implemented by the JCTLM Task Group on Promotion.

8.3 JCTLM at events in 2025 and 2026

Dr Badrick reported that a JCTLM Workshop proposal was submitted to the organizing committee of the ADLM 2025 and IFCC WORLDLAB 2026.
He further reported that the IFCC CTLM was approached for developing training webinars jointly with the JCTLM TEP WG for publication via eAcademy module available from the IFCC.

8.4 Identifiers for JCTLM Database measurands

Dr Wielgosz said that a recommendation from a CCQM Digital Workshop (https://ccqmws2024.org/) held online from 9 to 12 September 2024, was to establish a CCQM Data Digitalization Task Group which would work to identify a system for unique identifiers for chemical and biological reference data that can be applied in the KCDB and JCTLM DB and potentially for broader application. Experts would be invited from CCQM, JCTLM and the IFCC-N-PU system.

8.5 JCTLM Members and Stakeholders meeting 2025 [EXEC24-27]

Dr Badrick circulated the latest version of the programme for the 2025 JCTLM Members and Stakeholders Meeting on *Result harmonization in medical laboratories: accomplishments and challenges* and invited them to send their comments by the end of the year.

9 Report from Task Force on Reference Measurement System Implementation [EXEC24-07, 29]

Prof. Panteghini reported on the activity of the JCTLM TF RMSI with the publication of two papers covering the review of JCTLM listed reference measurement components for 30 measurands using the approach described in the publication *Clin. Chem.* 67(12) 2021 1590-1605, which consisted in looking at the uncertainties of the listed entries relative to the defined analytical performance specifications. This analysis showed that for 28 out of 30 measurands, conditions existed to correctly implement metrological traceability and fulfilled at least the maximum allowable measurement uncertainty of the minimum quality level derived according to the internationally recommended models. For 2 measurands (serum albumin and chloride) further improvements in measurement uncertainty (MU) of high-order references would be necessary. He said that an important conclusion of this work was that the JCTLM Database was a suitable practical tool on which the IVD manufacturers could rely to fulfil the requirements for implementation of metrological traceability and work with MU relevant for clinical application.

He commented on a future activity of the JCTLM TF RMSI and suggested that an analysis of the performance of the JCTLM listed reference measurement service providers in the RELA EQAS for the same studied 30 common measurands could be conducted for investigating whether potential deviations from the measurement uncertainties and change in the reference measurement procedure (RMP) used were observed compared with that listed in the JCTLM Database. The aim of this analysis would be to look at the potential impacts for users of the service providers and also raise awareness of laboratories using not listed RMP to deliver a service to nominate the method to JCTLM. A potentially dangerous significant bias, if any, in the provided services for the same measurand should be also highlighted and causes discussed (see total bilirubin example in https://doi.org/10.1515/cclm-2024-1110).

The Committee recognized the need to further raise awareness on the results of the study and recommended a communication should be made amongst the parties involved in laboratory measurement development and the production of reference materials. Dr Wielgosz said the

JCTLM statement should be communicated to the CCQM community at its next meeting in April 2025.

10 Inclusion of harmonization components in the JCTLM Database [EXEC24-21]

Dr. Miller reported that following previous discussions and decision 22-27, a first draft of the nomination and review procedures for harmonization protocols and associated reference materials based on ISO 21151 were developed and submitted as working document 24-21. He confirmed that data supporting the successful implementation of the protocol should be part of the submission, including the publication of the final trial demonstrating full implementation of the protocol by end users (laboratories/IVD Manufacturers), and the panel of materials used, which was not expected to be compliant with ISO 15194 (due to the lack of stability study) but was expected to be compliant with ISO 21151 with a thorough description of their preparation, storage and value assignment, including measurement uncertainty.

Dr. Wielgosz questioned whether harmonizations protocols should be part of the reference measurement procedures listing category or listed as a separate item in the JCTLM Database. Dr. Miller said his view was that listing harmonization protocols should be a new and separate item in the JCTLM Database that would require amendment to the text of Declaration of Cooperation.

The Committee noted that the expected time for the development of the first harmonization protocols would be in 3 years' time, and the addition of a new nomination and additional review options for harmonization protocols for inclusion in the JCTLM Database would require modifications to the database (not covered in the current project for developing the new web platform) and these would need to be costed and funds found for this.

The Committee agreed that a presentation on the implementation of harmonization protocols should be added to the program of the next JCTLM Members and Stakeholders meeting. It also recognized that it would be beneficial to seek feedback from the developers of harmonization protocols (IFCC WGs) to better understand what their expectation for the JCTLM Database would be and also from the end users (IVD Manufacturers) to understand what their needs are.

11 JCTLM DB WG: Approval of Recommendations

11.1 Outcome of the review of listed measurands

11.1.1 Bilirubin method and services listed in the JCTLM DB [EXEC24-05, 06]

Dr Miller said that a review of issues with the reference measurement system for bilirubin listed in the JCTLM Database was conducted in 2024 and the outcomes were recently published in CCLM (https://doi.org/10.1515/cclm-2024-1110).

He summarized the follow-up of the actions agreed during this review meeting:

a) Dr. Stan Lo at the Medical College of Wisconsin, USA, who is member of the IFCC Working Group on neonatal bilirubin, agreed to nominate an updated Doumas RMP to replace the current two slightly conflicting entries, namely Doumas reference method for bilirubin NRMeth29 and AACC reference method for total bilirubin C3RMMP28. The nomination is pending.

b) JCTLM Secretariat contacted the 3 reference measurement service providers to request clarification of the calibration hierarchy for their reference measurement procedures for total bilirubin. A laboratory confirmed using a procedurally defined RMP (Klauke R, Clin Chim Acta. 2018 Jun;481:115-120), that is different from the Doumas procedure declared by the service provider when it submitted its service for listing in the database and not listed in the JCTLM database.

c) JCTLM Secretariat contacted the German laboratory for re-nominating the Klauke's procedurally defined bilirubin measurand RMP, with the provision of extent of equivalence data with the Doumas RMP and information on the uncertainty of the adsorption coefficient value employed, as well as any other non-conformances noted in the nomination submitted in 2018. The laboratory responded they were working towards resolving the issues and possible resubmission of the RMP in a future review cycle.

The Committee noted that the existing submission for NIST bilirubin primary reference material in 2024 review cycle for possible inclusion in the JCTLM Database would resolve the lack of primary calibrator for bilirubin RMP which had been discussed in the past. It recognized the need of having additional sources of similar materials to prevent the risk of future material disruption when relying on only one producer. It recommended to inform the national metrology institutes of the necessity to consider the production of additional primary and also matrix reference materials for bilirubin measurand, the latter also currently not available.

The Committee requested the delisting of the service that uses a different method from the one declared when it submitted its service for listing in the database.

(A24-15): JCTLM Chair to inform and invite the NMIs at the next CCQM meeting to consider the necessity for having additional sources of primary RM and novel matrix reference material for bilirubin measurand.
(A24-16): JCTLM Secretariat to delist the reference measurement service provider using a different method from the one declared when it submitted its service for listing in the database.

11.1.2 Aldosterone methods and services listed in the JCTLM DB

Dr Miller said that following last year's discussions and a review on the listed methods for aldosterone, the laboratory RfB from Germany agreed to publish in a peer-reviewed journal their LC-MS/MS RMP for aldosterone for further JCTLM submission in a next review cycle, in replacement of their currently listed GC-based method and service. It was also agreed that their service would be kept in the JCTLM database until the end of the 2026 nomination cycle when the expectation is the LC-MS/MS method (and service) would be nominated and listed. In addition, a note would be added to their currently listed service that a modified LC-MS/MS RMP is used in providing the service.

The Committee recognized the need to raise awareness among the listed reference measurement services providers that they should inform the JCTLM when they use a different procedure from the one declared when they submitted their service for listing in the database and to resubmit their service when major changes were applied to the original procedure. The Committee agreed that the approach would be based on a risk-based analysis of the impact of the changes when change criteria were yet to be defined.

It requested that a reminder should be sent to services providers via an article in the Newsletter.

(A24-17): JCTLM Secretariat to draft a note for informing users the listed Rfb service for aldosterone is using a modified procedure using LC-MS/MS principle.
(A24-18): Dr Kessler to draft a Newsletter article for raising awareness among listed services providers to use a listed procedures and inform JCTLM if the procedure has been modified with any major changes.

11.2 Overview of nominations received in 2024

Dr Maniguet presented the summary of the nominations for reference materials (RM), reference measurement procedures (RMP) and reference measurement services (RMS), with the final DB WG's recommendations, that had been submitted for review as part of cycle 21 for materials and methods and cycle 19 for services.
There were 117 nominations made up of 18 materials, 40 methods and 59 services that were distributed for consideration to nine JCTLM review teams in 2024.

Dr Miller said that the Database WG held a hybrid meeting on 3 December and successfully completed the review of all review teams' recommendations concerning these 117 nominations. All of these are summarized in the following sub-sections for each group of analytes including final Database WG recommendations.

He further indicated that in the interest of time, only specific outstanding nominations and general issues that were raised during the DBWG meeting would be discussed by the committee, considering that other reported issues were resolved during the DBWG Meeting sessions.

11.3 Approval of Cycle 21 RM and RMP and Cycle 19 RMS

11.3.1 Analyte Group 1

11.3.1.1 Non-Peptide Hormones [EXEC/24-08]

There were nine nominations for RMPs and 17 nominations for RMSs that were reviewed by the Non-peptide Hormones review team, and of these a LC-MS-based RMP for aldosterone in serum was being recommended for listing and 13 RMSs for the following measurands: total 3,3′,5-triiodothyronine, 17α- hydroxyprogesterone, cortisol, estriol, progesterone in blood serum/plasma, were recommended for listing in the JCTLM Database.

The Committee noted this would be the second LC-MS-based method for aldosterone listed in the JCTLM Database and compatibility of the two RMPs had been checked and confirmed from the RELA results. It further approved the DB WG's recommendation for Non-peptide hormones nominations.

11.3.1.2 Metabolites and Substrates [EXEC/24-09]

There were six nominations for RMs, and ten nominations for RMSs that were reviewed by the Metabolites and Substrates review team, and of these a material for creatinine in human urine and seven RMSs for the following measurands: cholesterol, creatinine, glucose, total bilirubin and urea in blood serum/plasma and calibration solution, were recommended for listing in the JCTLM Database.

The DB WG also recommended that NIST should be contacted for provision of responses to the observed major non-compliances regarding their Bilirubin material by 15 January 2025, for further review by the review team and possible inclusion in the JCTLM Database.

The Committee approved the DB WG's recommendation for Metabolites and substrates nominations.

11.3.1.3 Drugs [JCTLM-EXEC/24-10]

There were two nominations for RMs, six nominations for RMPs and a nomination for a RMS that were reviewed by the Drugs review team, and of these a high purity material for sibutramine hydrochloride monohydrate was being recommended for publication in the JCTLM Database.

The Committee approved the DB WG's recommendation for Drugs nominations.

11.3.2 Analyte Group 2

11.3.2.1 Proteins [JCTLM-EXEC/24-11]

There were four nominations for RMs, four nominations for RMPs and five nominations for RMSs that were reviewed by the Proteins review team, and of these a RM with a certified value for albumin in human urine and a primary certified RM for amyloid-beta 40 in standard aqueous solutions were recommended for listing in the JCTLM Database.

The Committee noted that another nomination for a primary certified RM for amyloid-beta 42 in standard aqueous solutions was not being recommended for listing as the review team had concerns on the impact of the material use on the existing traceability chain/reference measurement system in place, and this would need to be assessed.

There were two RMPs for albumin in human urine with significantly different MU budgets submitted, which were not being recommended for listing, due to observed major non-compliances. A request for the provision of a full MU budget was made to both nominators during the review process, in order to understand potential significant MU differences between the two methods.

The review team considered that NIST provided appropriate clarifications that addressed major issues and suggested that two remaining minor issues could be easily resolved.

The DBWG agreed that NIST should be contacted for provision of responses to the observed minor non-compliance by 15 January 2025, for further review by the review team and possible inclusion in the JCTLM Database in this review cycle.

The Committee discussed whether the second method for albumin in human urine from the laboratory from Singapore, for which a number of major non-compliances remained, should follow the same fast track follow up approach. It was agreed that the second procedure should be resubmitted in the next review cycle.

There were five nominations for RMSs from four Chinese calibration laboratories for the following measurands: total protein in serum (with removal of the matrix blood plasma in the nomination form) and total haemoglobin, HbA_{1c} and HbA_0 in whole blood, that were recommended for listing.

The Committee approved the DB WG's recommendation for Proteins nominations.

11.3.2.2 Enzymes [JCTLM-EXEC/24-12]

There were 21 nominations for RMSs reviewed by the Enzymes review team, and of these nine services were being recommended for listing.

The DB WG recommended to defer the recommendation for listing of the remaining services until after the two service providers clarify the relative MU within the measurement range, noting the services were reviewed as compliant with JCTLM criteria by the JCTLM review team.

The Committee approved the DB WG's recommendation for Enzymes nominations.

11.3.2.3 Nucleic acids [JCTLM-EXEC/24-13]

There were five nominations for RMs, and 14 nominations for RMPs that were reviewed by the Nucleic Acid review team, and of these a PTB RMP for HIV-1 RNA quantification by RT-dPCR and seven RMP nominations for NIM (China) for KRAS SNV quantification by dPCR were recommended for listing, with provision that additional information from employed standard operating procedures (SOP) should be available in the JCTLM database to ensure clarity of aspects not included in the respective publication.

The Committee approved the DB WG's recommendations for Nucleic acids nominations.

The Committee also discussed the review team's recommendation for possible publication of the SOPs along with the listing of the nominated RMPs in the JCTLM DB when the publication does not cover all ISO 15193 requested information.
It was agreed that full laboratory SOPs should not be published in the JCTLM Database and requested that the review team leader should be contacted to clarify what extracted information from SOPs should be added on the website to ensure end users have all necessary information when implementing the procedures.

(A24-19): JCTLM Secretariat to contact the NA review team leader about the information from SOPs should be added on the website to ensure that end users have all necessary information when implementing the procedures.

11.3.2.4 Blood cell counting and typing [EXEC/24-19]

There were two resubmitted nominations for JSLH/ICSH RMPs for leukocytes and erythrocytes counting in whole blood that were reviewed by the Blood Cell Counting review team.

The DB WG agreed during its meeting that the remaining observed non-compliance related to the missing numerical MU estimate definition would require resolution and the recommendation for listing the procedures in the JCTLM database would be deferred after discussion among ICSH representative, JCTLM Chair, the method's nominator and JCTLM review team Leader to clarify the issue. R. Wielgosz would act as a mediator for following up on the action of providing an estimate of the MU.

The Committee approved the DB WG's recommendation for Blood Cell Counting nominations.

(A24-20): R. Wielgosz to liaise with the ICSH representative, method's nominator, JCTLM Chair and review team Leader and clarify the corrective actions required for the method to be compliant with JCTLM criteria for providing an estimate of the method MU.

11.3.3 Analyte Group 3

11.3.3.1 Electrolytes and blood gases [EXEC/24-20]

There was a resubmitted nomination for an ICP-MS-based RMP for sodium in serum that was reviewed by the Electrolytes review team and was being recommended for listing in the JCTLM Database after observations were addressed by the nominator.

The Committee noted that the NIM CRM GBW09124/5/6 for Electrolytes in human serum was no longer available and left the chloride measurand in the JCTLM Database without a matrix RM. As a consequence, the provision of matrix RM for chloride would become an immediate priority for materials producers. This will be communicated to NMIs at the next CCQM meeting.

The Committee approved the DB WG's recommendation for Electrolyte nomination.

11.3.3.2 Vitamins [JCTLM-EXEC/24-32]

There were four nominations for RMPs and five nominations for RMSs and of these three RMSs for 25-hydroxyvitamin D3 were recommended for listing in the JCTLM Database.

The Committee approved the DB WG's recommendation for Vitamins nominations.

(A24-21): JCTLM Secretariat to publish the 2024 approved nominations.

11.4 Update on IFCC EQAS results [EXEC24-28]

Dr Kessler first reported that the English version of the *Guideline of the German Medical Association on Quality Assurance in Medical Laboratory Examination* -Rili-BAEK, was published and more importantly included JCTLM as a route for Calibration laboratories to fulfil the requirement when they are listed in the JCTLM Database.
She gave an update of the activity of the IFCC RELA 2024 where the number of results was continuing to increase, and the number of participating laboratories was being stable. There will be two new measurands for 2025 RELA EQAS, valproic acid and pancreatic amylase, as an RMP for the latter by the IFCC WG PE is expected to be published soon.

11.4.1 Application of APS proposed by the TF RMSI to RELA graphs showing only listed RMS and accredited laboratories using listed RMPs

Dr Kessler reported on the comparison of the Educational median ranges (EMR) and the proposed APS from the TF RMSI to RELA graphs showing only listed RMS and accredited laboratories using listed RMPs, which is available in the document EXEC24-28.
It was agreed that these graphs would be reviewed by the TF RMSI for the 30 measurands recently considered in the TF evaluation to determine the appropriate statistical model for performance laboratory evaluation and estimate of result equivalence, for final consideration by the JCTLM Executive.

(A24-22): Dr Kessler to send to the TF RMSI for further review the APS graphs for 30 measurands reviewed by the TF RMSI.

11.5 Plan for Cycle 22 for RMs and RMPs and Cycle 20 for RMSs

The usual schedule for the nomination and review process would be followed with the start of the next call for nominations planned on 1st February 2025.

12 Reports from related activities / meetings

12.1 IFCC SD [EXEC24-30]

Prof. Cobbaert gave an update of the IFCC SD activities.

12.2 ICSH GA [EXEC24-22]

Mr. Fawcett reported on the last ICSH GA held in October 2024.

12.3 ILAC [EXEC24-15,23,25]

Dr. Griffin gave an update on the ILAC activity in 2024.

12.4 CCQM [EXEC24-31]

Dr. Wielgosz gave an update on the CCQM activity in 2024.

13 Activities within ISO TC 212

Publication of revised ISO 15194 and ISO 15193

Dr Miller informed the Committee that the FDIS versions of the ISO 15194 and ISO 15193 would be sent for voting after resolution of minor editorial revisions. He also noted that the question on whether the revised version of the standards would be considered as harmonized standard with regard to the EU IVD Regulation (IVDR) has yet to be resolved.
He added that there are two new proposals for developing standards or technical specifications that were approved, namely a new project on commutability assessment and another project defining approaches for establishing analytical performance specifications.

(24-23) Dr Kessler to contact ISO Secretariat (or ISO /TC 212 WG2 convenor) to confirm the expected date for publication of revised ISO 15194 and ISO 15193 and to clarify if these will become harmonized standards with regard to the IVDR.

14 Liaison with the WHO

The Committee agreed with the approach that the BIPM and IFCC, having signed MoUs with WHO, would draft a joint letter and plan for a joint meeting during the IFCC General Conference (GC) in May 2025.

(A24-24): Dr Wielgosz and Prof. Özben to draft a letter for organizing a meeting with WHO at the the IFCC GC in May 2025.

15 Future meetings of the JCTLM

The Committee confirmed that the next JCTLM Members' and Stakeholders' meeting would be held at the BIPM on the morning of 1st December 2025. This would be followed by a TEP-WG workshop on 1 (afternoon) and 2 December (full day), TEP WG and Database WG meetings on 3 December, and a JCTLM Executive Committee meeting on 4 and 5 December 2025.

16 General discussion on JCTLM impact and gap analysis

Dr Jones showed the gap analysis he completed in 2015 and presented at the JCTLM Members' and Stakeholders' on 1 December 2015, which was based on a comparison of what was in the JCTLM database and what analytes where routinely measured in his laboratory and other hospital laboratories. He questioned the members of the Committee whether an update

of this analysis would be useful for presentation at the 2025 JCTLM Members and Stakeholders Meeting.

The Committee agreed that an update would be highly valuable, both in analysing the proportion of high volume tests that were covered within the JCTLM database and where high priority gaps for RM and RMP still exist.

(A24-25): Dr Jones to update the analysis which would address the proportion of high volume tests that were covered within the JCTLM database and where high priority gaps for RM and RMP exist for presentation at the 2025 JCTLM Members and Stakeholders Meeting.

The Chairman closed the meeting at 16:00.

Annex 1: Summary List of Actions
Actions from the 26th Executive Meeting:

(A24-01) JCTLM Secretariat to contact Dr Devonshire to verify if she would be available to chair the Analyte Working Group 2.
(A24-02) JCTLM Secretariat to contact Dr Wollinger and Dr Canalias to verify if they would be available to lead the review team for Drugs and Enzymes, respectively.
(A24-03) JCTLM Secretariat to send a call of interest for the *ad-interim* leader position of the Haemostasis review team. (*Alison D. and David D. to be contacted*)
(A24-04) JCTLM Secretariat to send a call for new experts for Blood cell counting, Drugs, Enzymes, Haemostasis, Non-peptide hormones, Proteins and Vitamins.
(A24-05) Dr. Wielgosz to send a call for interest to CCQM CAWG for member position of the Blood Cell counting review team
(A24-06): Prof. C. Cobbaert to send a call for interest to ISTH contact for member position of the Haemostasis review team; and to IFCC contact for Proteins review team
(A24-07): JCTLM Secretariat to contact the Proteins review member no longer active to send a letter of suspension of their term as a JCTLM review team member.
(A24-08): JCTLM to develop a plan for the long-term recruitment process of review members.
(A24-09) JCTLM Secretariat to send the invoice for 2024 costs to the IFCC.
(A24-10) A Task Group, with representatives from JCTLM Executive Committee Organisations (RWielgosz, T. Fawcett, T. Özben, A. Griffin) to revise the text of the Annexes in consistency with the agreed tiered membership model, definition of large and small for-profit organizations, and circulate the draft document for comment to the JCTLM Executive Committee and Members bodies.
(A24-11) Task Group on journals to finalise the text of the new page for publication of modified RMPs that would be accessible on the jctlm.org website.
(A24-12) R. Wielgosz and T. Özben to draft a joint letter to the editors of the IFCC e-journal and CCA to ask if they are open to receiving and considering publication of modified RMPs.
(A24-13) EC Members to send the names of journals that could be contacted and potentially interested in being listed on the new publication page.
(A24-14) Task Team to develop a communication plan that can be implemented by the JCTLM Task Group on Promotion.
(A24-15): JCTLM Chair to inform and invite the NMIs at the next CCQM meeting to consider the necessity for having additional sources of primary RM and novel matrix reference material for bilirubin measurand.
(A24-16): JCTLM Secretariat to delist the reference measurement service provider using a different method from the one declared when it submitted its service for listing in the database.
(A24-17): JCTLM Secretariat to draft a note for informing users the listed Rfb service for aldosterone is using a modified procedure using LC-MS/MS principle.
(A24-18): Dr Kessler to draft a Newsletter article for raising awareness among listed services providers to use a listed procedures and inform JCTLM if the procedure has been modified with any major changes.
(A24-19): JCTLM Secretariat to contact the NA review team leader about the information from SOPs should be added on the website to ensure that end users have all necessary information when implementing the procedures.

(A24-20): R. Wielgosz to liaise with the ICSH representative, method's nominator, JCTLM Chair and review team Leader and clarify the corrective actions required for the method to be compliant with JCTLM criteria for providing an estimate of the method MU.
(A24-21): JCTLM Secretariat to publish the 2024 approved nominations.
(A24-22): Dr Kessler to send to the TF RMSI for further review the APS graphs for 30 measurands reviewed by the TF RMSI.
(A24-23) Dr Kessler to contact ISO Secretariat (or ISO /TC 212 WG2 convenor) to confirm the expected date for publication of revised ISO 15194 and ISO 15193 and to clarify if these will become harmonized standards with regard to the IVDR.
(A24-24): Dr Wielgosz and Prof. Özben to draft a letter for organizing a meeting with WHO at the the IFCC GC in May 2025.
(A24-25): Dr Jones to update the analysis which would address the proportion of high volume tests that were covered within the JCTLM database and where high priority gaps for RM and RMP exist for presentation at the 2025 JCTLM Members and Stakeholders Meeting.

Annexe 2

Terms of Reference for the Task Group (TG) for Promotion of JCTLM, 2024

The Task Group is a sub-unit of the Traceability, Education and Promotion (TEP) Working Group

The aims of the TEP are restated below from the TEP Terms of Reference
To promote the importance of metrological traceability in laboratory medicine as a means to reduce between method variability to improve clinical outcomes and patient safety.
To increase visibility of the JCTLM Database and visibility for those organizations applying Metrological Traceability in conformity with International Standards as a means of reducing between method variability to improving clinical outcomes and patient safety.
To increase awareness of the JCTLM Database amongst regulators and promote its usefulness in supporting regulatory frameworks, including meeting requirements for metrological traceability.

The Aims of the Task Group for Promotion of JCTLM are:
To develop promotional materials and dissemination activities to increase awareness of the role and value of JCTLM in establishing metrological traceability of clinical laboratory measurement procedure results. The target professional groups are the IVD industry, developers of reference materials and measurement procedures, laboratory professionals, and regulatory agencies with responsibility to approve IVD medical devices for use in medical laboratories. The goal is to improve standardization and harmonization of results from IVD medical devices for use in laboratory medicine.

Tasks to be completed:
1. Develop media (e.g. printed, video, electronic) to explain and promote the value of JCTLM in metrological traceability.
2. Identify professional meetings at which the promotional media will be disseminated. Develop procedures for disseminating the promotional media at those meetings.
3. Organize sessions in conjunction with professional meetings for dissemination of the promotional media and adoption of metrological traceability.
4. Identify other communication strategies for disseminating the promotional media.