Report of the 24th meeting of the JCTLM Executive Committee
6-7 December 2022
Venue: BIPM Hybrid Meeting

List of participants:
Dr G. Miller (JCTLM Chairman, IFCC)
Dr R. Wielgosz (JCTLM Executive Secretary, BIPM)
Dr G. Myers (IFCC)
Dr S. Maniguet (JCTLM Secretariat, BIPM)
Dr T. Liew (CIPM)
Dr G. Jones (ILAC)
Ms M. Bednarova (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 Sang-Ryoul Park (CIPM)
Dr S. Westwood (Blood cell Counting team Leader, BIPM)
Prof. E. Theodorsson (JCTLM TEP WG Chair)
Prof. C. Cobbaert (IFCC SD)
Prof. P. Gillery (IFCC SD)

1 Approval of the agenda [JCTLM-EXEC/22-01]

The agenda was approved with an additional agenda item under 10 to discuss the extent-of equivalence for new reference materials and reference measurement procedures as a follow-up of the JCTLM meeting on C-reactive Protein held on 1st December 2022 in Milan.

2 Report of 23rd JCTLM Executive Committee Meeting

2.1 Review of action points arising from the 23rd meeting [JCTLM-EXEC/22-02]

2.2 Review of action points arising from mid-year meeting [JCTLM-EXEC/22-03]

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:
(A/20-05): JCTLM Secretariat to finalize the procedure for an induction process for new EC members of JCTLM Executive Member Status for circulation and EC comment.
(A/22-01) JCTLM Secretariat to contact NIST and invite them to nominate SRM 916b, Bilirubin, for review and listing in the JCTLM database.
(A/22-02) JCTLM Secretariat to contact JCTLM listed laboratories with services for Bilirubin measurements on the availability of SRM 916b, and as a route to overcome issues that were raised in reviews on metrological traceability of measurements.

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 Dr Greg Miller 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 2023-2024

The JCTLM Executive approved the Chairmanship of Dr Greg Miller for a second term.

3.1.2 Agreement on organization with JCTLM Secretariat role 2023-2024

The JCTLM Executive approved the BIPM's continued role as Secretariat for the JCTLM for period 2023-2024.

(A/22-16): JCTLM Secretariat to contact the Executive Committee organizations and inform them of the reappointment of the Chairman.

3.2 JCTLM WG Chairs

Dr Wielgosz said that in accordance with JCTLM rules the JCTLM Chairman also acted as JCTLM DB WG Chair.
He also added that Dr Phinney, Prof. Panteghini and Dr Liu had confirmed their willingness to continue to chair the Analyte Working Groups 3, 2 and 1, respectively. The Committee re-appointed them for a renewable two-year term.

Prof. Theodorsson informed the Committee of his availability to continue to act as the Chair of the TEP WG for a second two-year term and asked the Committee if it would be possible for them to appoint a Designate TEP WG Chair in 2023 to ensure continuity in the current ongoing projects. The Committee welcomed his proposal to allow some overlap between Chairs and reappointed him as Chair for a second two-year term. It further agreed with the suggested approach to appoint a Designate Chair.

3.3 JCTLM Review Team Membership

The Committee reviewed the recommendations of the DBWG from its last meeting and supported the recruitment of new experts to serve as members of the review teams for Drugs, Electrolytes and Blood gases, Enzymes, and Vitamins. It was agreed that the process of suspension would be applied for members of the JCTLM review team for Drugs who had not contributed to the last two review cycles.

Dr. Westwood had agreed to continue to act the lead the Blood Cell Counting and typing review team for another year to allow some overlap with his successor who would be identified from the current list of members of the team. The Committee extended his term as leader of the review team.

Action:
(A22-17): JCTLM Secretariat to send a call for new experts in consultation with review teams leaders for Drugs, Electrolytes and blood gases, Enzymes, Vitamins.
(A22-18): JCTLM Secretariat to contact individuals no longer compliant with mandatory requirements for JCTLM Review Team membership, and to send a letter of suspension of their term as a JCTLM review team member.

3.4 JCTLM Membership

The Committee reviewed the current JCTLM membership including four Executive Committee Member Organizations, 11 National and Regional Members and 45 Stakeholder members, and noted the lack of representation of Quality Controls organizations in the area of laboratory medicine. From the discussion that followed, it further requested that an approach to raise awareness about JCTLM activity would be developed as part of the newly established Task Force (discussed under agenda item 3.7) for expanding JCTLM Membership and for identifying and encouraging engagement of organizations in fields of activity that were not currently being represented within the JCTLM.

3.5 JCTLM and JCTLM Secretariat operating costs for 2022 and budget for 2023 [JCTLM-EXEC/22-15, -16]

Dr Wielgosz presented the documents 22-15 and 22-16, which included the details of the operating costs of the JCTLM Secretariat for 2022 and the expected operating costs in 2023. He pointed out that overall costs for 2022 were consistent with the predicted budget and the 2023 budget anticipated an expected increase of activity related to development of a web platform for submissions and review of JCTLM nominations, and 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 cost of the maintenance and depreciation of the newly developed JCTLM Database application as well as the inherent cost when meetings were hosting at the BIPM were not included in the predicted budget for 2023.

The Committee approved the 2023 budget and thanked the BIPM for covering the additional costs related to JCTLM meetings held at the BIPM Headquarters.

(A22-19): JCTLM Secretariat to contact the JCTLM Executive Committee organizations and inform them of the cost of the JCTLM Secretariat for 2022 and expected budget for 2023.

3.6 Outcome of informal meeting requested by IFCC President on 5 September

3.6.1 Education activity with IFCC SD on metrological traceability (and SD chair to attend EC meetings)

Dr Miller informed the Committee of the new initiative on education activity on metrological traceability which had been discussed with the IFCC SD for developing educational materials.

The IFCC viewed that such an activity would be beneficial to both the JCTLM and the IFCC SD which when developing new guidance documents on the establishment of new reference measurement procedures could anticipate how best to comply with JCTLM review and acceptance criteria.

Prof. Cobbaert said that the JCTLM /IFCC meeting which was held on 5th September had been helpful in raising awareness among participants of both organizations' understanding of the ISO Standards, and supported collaboration to develop education materials for all parties involved in the JCTLM nomination and review process.

The Committee supported this initiative and commented that such a project would require the allocation of adequate technical and financial resources with key outputs defined.

Dr Miller suggested that this project be processed in two steps, including an immediate action that would be conducted in consultation with the JCTLM Review Team Leaders for

developing a checklist which would describe the key requirements and challenges that a nominating organization would need to consider when submitting a material and method application for JCTLM review, based upon Review Teams' experiences of main reasons why nominations could be unsuccessful. A second step of the process would be the development of a series of e-learning modules which would require additional resources to develop but could be made available without charge through both BIPM and IFCC e-learning platforms.

From the following discussion, the Committee agreed to establish a Task group for developing educational materials for organizations submitting nomination and individuals engaging in the activity of the review team.
The Task Group would be led by G. Miller and a call for participation would be launched amongst the members of the JCTLM Review teams and the IFCC SD, who had been involved in the nomination and review of materials and methods for compliance with ISO 15194 and 15193, respectively. Draft terms of reference for such a task group are included as an annex to this report.

Action (A/22-20): G. Miller and R. Wielgosz to draft the Terms of reference of the Task Group on educational activity for comments and approval by the EC and the IFCC SD by February 2023
Action (A/22-21): G. Miller/ JCTLM Secretariat to launch a call for members for the Task Group on educational activity

3.7 Funding models for the JCTLM Secretariat (SWOT and feedback from 4 organizations) [EXEC22-04, -06]

R. Wielgosz presented the documents EXEC22-04 and -06, which included the feedback from the JCTLM Executive Committee Organizations to the request for input concerning a future funding model for the JCTLM.

He commented that the current JCTLM model had been established in 2002 in response to the understood need of IVD industry to identify the reference materials and methods of a higher metrological order that were required to fulfill the metrological traceability requirements of the EU IVD Directive, and this had led to the development of the JCTLM database.

During the discussion that followed the Committee noted the following points that would need to be addressed in a review of future funding models for the JCTLM:
- The cost of the maintenance and eventual replacement (approximately 10 years) of the JCTLM database requires a secure budget;
- Whether a third-party peer review process as currently used by the JCTLM for database listing is still a valued output for the IVD community or would a less resource intensive self-declaration process be sufficient for the end users of the JCTLM Database;
- The level of visibility of the services provided by JCTLM to its Members and awareness of the impact of metrological traceability amongst the regulators and other stakeholders and the need to market this.

The Committee recognized the need that the IFCC and the JCTLM develop a common vision and strategy for sustainability of the JCTLM, noting that a JCTLM database web platform for facilitating the submission and review of JCTLM nominations, would reduce the running costs for the Secretariat.

The Committee agreed to establish a Task Group to review the possible funding models to ensure the sustainability of the current JCTLM model and to address the cost of the maintenance the current JCTLM services and the development of the new services discussed during the meeting.

It was agreed that a Task Group should also develop a future vision and strategy for the JCTLM taking into account the expectations from all parties contributing to the laboratory medicine traceability chain.

Prof Cobbaert commented that JCTLM should develop a strategy and vision in consultation with regulators, and this would be timely as the implementation of the recently published IVDR was taking place and the importance of metrological traceability requirements in the legislation could be confirmed. It was agreed that the development of a future JCTLM operational model would require the involvement of the IVD industries.

It was agreed that the membership of the Task Group should comprise a representative from the four Executive Committee Organizations as well as other stakeholders. The group would be led by G. Miller (JCTLM Chairman) and the following members agreed to participate C. Cobbaert (IFCC SD), T. Fawcett (ICSH), S-R. Park (CIPM/BIPM), R. Wielgosz (BIPM), Q. Liu (HSA). It was agreed that the membership should be extended to the European Metrology Network for Traceability in Laboratory medicine and IVD industry representatives.

Action (A/22-22): Dr Miller/ Dr Wielgosz to draft the Terms of reference of the Task Group for developing a future vision and strategy for JCTLM as well as discussing more immediate funding issues for approval by the EC by February 2023 (draft attached as an Annex)

4 New JCTLM Database Development

4.1 Current status of voluntary funding pledges for additional developments of the database

Dr Wielgosz said that in accordance with last December's Executive meeting, the JCTLM secretariat had worked with the IFCC and ICSH representatives on drafting a communication letter to the IFCC Corporate Members to get extraordinary funding for additional development of the database to enable electronic nominations and review processes. Prof Cobbaert informed the Committee that she would liaise with the IFCC EB to follow-up with sending a reminder. Dr Park suggested that the JCTLM Secretariat should contact NMIs active in JCTLM, as IFCC had done with its corporate Members, to see if they would provide funding to enable the development of the web-based database submission platform.

Action (A/22-23): JCTLM Secretariat to contact NMIs involved in the JCTLM and request donations for the updated of the JCTLM Database.

4.2 Expected changes required to the database due to ISO standard revisions (15193 and 15194)

Dr Wielgosz said that changes in the database as well as in the Quality manual procedures would need to be anticipated to accommodate changes in the ISO standards. It was agreed that Drs Kessler and Westwood were to report on the current revision status of the documents under agenda point 13, would update JCTLM on the expected changes and timeline for publication of the standards.

5 JCTLM websites update project

Prof. Theodorsson reported on the work in progress for updating the JCTLM website maintained by the IFCC and for restructuring the three JCTLM websites aiming at facilitating users and members' access to JCTLM information. He highlighted that the web features and designs defined for the JCTLM database website would be implemented in all websites whilst the web content management would still be undertaken separately using the IFCC and the BIPM systems where appropriate. He added that the revision of the web content from all three websites was currently underway with the planned updates described hereafter.

5.1 Updates planned for www.jctlm.org

www.jctlm.org would be maintained by a new IFCC content management system and would include general information about the JCTLM Executive Committee, Declaration of Cooperation, Membership, WGs, TFs and Funding and Sponsorship in addition to TEP WG's education resources. New webpages including a new JCTLM landing page which would provide a direct link to the external sections of information maintained by the BIPM including the JCTLM Database and new intermediate pages were being developed by an IFCC external contractor.
Prof. Theodorsson presented the draft of the landing page which was welcomed by the Committee.

Action (A/22-24): TEP WG to develop new intermediate webpages and finalize the new landing page.

5.2 Updates planned for www.bipm.org/en/committees/jc/jctlm

A major revision of the BIPM JCTLM webpages would be undertaken following the decision that information related to the activity of the JCTLM Secretariat for meetings and documents management as well as Database documentation and review teams' management would remain at the BIPM while other sections of information would be transferred to www.jctlm.org.

Action (A/22-25): BIPM to finalize the update of the webpages related to review teams, nomination and review process by 31 January 2023, and provide the new urls for inclusion in the www.jctlm.org instant access boxes.

5.3 Updates planned for www.jctlmdb.org

The new JCTLM Database website was published in October 2022 and will be updated to include a link to go to jctlm.org in the header.

6 Revision of JCTLM quality manuals

6.1 Update on procedure reviews and updates

Dr Maniguet reported on the JCTLM Quality System Review Team review activity and the suggested modifications of the JCTLM DBWG procedures documents for clarifying some points in the nomination and review process of materials, methods, and services. The suggested amendments in the text of the procedures were related to the proposal to add guidance for clarifying that the subject of JCTLM review was limited to the highest available reference measurement procedures and materials in an end-user IVD measuring system calibration hierarchy, with reference to the guidance in ISO 17511; to describe how the nominating organization should provide responses to review comments within a time period

as advised by the review team; to clarify the process when comparison results with listed materials intended for the same purpose show poor equivalence; to describe the process for excluding members who are also representatives of the nominating organization from the evaluation of a nomination in case of possible conflict of interest; to clarify the lack of extent of equivalence study as a major non-compliance in the review process; and to revise the study model for initiating the extent-of-equivalence evaluation when at least one JCTLM listed CRMs was identified as being fit for the same purpose; and to be able to use already available data whenever possible as an alternative for performing relative measurements against listed CRMs.

Dr Miller commented that the issues raised during the Workshop on CRP reference measurement system on 1 December would also need to be addressed within the JCTLM Quality documents (e.g. how to address the impact on the calibration hierarchy/clinical laboratory use, and how to demonstrate compatibility with listed materials when new primary calibrator for complex measurands were nominated). Dr Miller suggested that these should also be included in the next version of the revised JCTLM policy and agreed to review the suggested changes in the text of the procedures for facilitating the implementation of the revised procedures in 2023 review cycle.
The Committee agreed with the suggested approach for an implementation of the revised policies documents in the 2023 review cycle.

Action (A/22-26): Dr Miller to review the last version of the revised DBWG procedures for review and approval by the EC by 30 January.

6.2 Revision of JCTLM rules for regular participation in EQAS Scheme

Dr Maniguet presented the results of the survey on the participation frequency in EQA Schemes that was conducted amongst the 18 laboratories with reference measurement services listed in the JCTLM Database. There were 15 laboratories that provided feedback to the survey demonstrating that 80% of the respondents were of the opinion that the current requirement to participate in an interlaboratory comparison every year for at least one analyte in a group of analytes was adequate to demonstrate quality of the service; and 60 % of the respondents have indicated that the current other requirement to participate in an interlaboratory comparison for each analyte listed in the JCTLM database at least once in a time period of three years was adequate frequency as well.

The Committee noted that the results of the survey demonstrated JCTLM rules for regular participation in EQAS Scheme were fit for purpose in ensuring the quality of reference measurement services and confirmed no further revision was required.

Prof. Panteghini brought to the Committee members' attention that a Spanish calibration laboratory has recently been delisted, having decided to stop being accredited for its services due to the cost of accreditation, and raised concern that the number of listed laboratories would diminish further due to the same reason. The Committee noted this point and proposed that criteria for listing laboratories be discussed within a Task Group on Strategy and future planning that would be established.

6.3 Inclusion of harmonization components in the JCTLM Database [EXEC22-05]

Dr Myers said that he had reviewed JCTLM DBWG procedures with respect to QS procedures needed for reviewing harmonization protocols based on ISO 21151 that could be

nominated for listing on the JCTLM database, summarizing the outcomes in the document EXEC22-05, which had been provided for comment to the members of the Committee. The Committee approved the recommendations and requested that new procedure documents be developed for nomination and review of harmonization protocols and associated harmonization reference materials, which could be used for the JCTLM nomination and review process.

Action (A/22-27): Dr Myers to draft new procedures for nomination and review of harmonization protocols and associated reference materials for review at the next December JCTLM EC meeting.

6.4 Dec 2021 workshop recommendation that 'JCTLM should consider if and how materials that would be considered useful for international standardization but may not meet all ISO requirements could be referenced or listed by the JCTLM'

The Committee agreed that this December 2021 workshop recommendation would be followed up within a Task Force on Strategy and future planning as to determine whether JCTLM should provide a new service for informing the IVD manufacturers on the suitability of reference materials and methods without full compliance with ISO requirements. Prof Panteghini said that the two major stumbling blocks preventing full compliance of higher order references had often been the availability of commutability information or the consistency of both the commutability and the intended use statements of nominated CRMs, as well as the issue with calculation of the uncertainty of nominated reference measurement procedures, and these two key requirements would need to be considered for ensuring metrological traceability.

It was also noted that the JCTLM had been established to provide information on materials and methods that would allow the requirement of the EU IVD Directive to be met. Listing materials that were non-compliant would represent a different goal, and should be considered in detail.

It was agreed that in reviewing its services the JCTLM should liaise and get feedback from EU IVD regulators on whether revised versions of ISO 17511, ISO15193 and ISO 15194 remained within the list of harmonized standards that supported the EU IVD Regulation.

6.5 Dec 2021 workshop recommendation that 'Matrix-based CRMs known as not commutable with clinical samples when used with particular IVD-MDs should be catalogued in a central database to avoid their inappropriate use.'

Dr Miller questioned whether a process should be developed to list matrix-based CRMs known as not commutable with clinical samples when used with particular IVD-MDs. The Committee agreed that the JCTLM DBWG procedure documents should be modified to require reviewers to verify that intended use statements of materials identified IVD Manufacturers' methods for which the commutability had been assessed and demonstrated. In addition, it further suggested that guidance on commutability assessment as published by the IFCC WG on Commutability should be included as a reference in the JCTLM Procedures documents.

Action (A/22-28): JCTLM Secretariat to modify the relevant JCTLM procedure documents to add the new acceptance review criteria that the intended use statement of a nominated material should describe the IVD measurement procedures for which commutability of the material was demonstrated.

6.6 Can all RMP validation data be provided in the JCTLM submission, but without requiring formal journal publication when there is already a published RMP for the same measurand?

Dr Miller questioned whether a process could be developed to overcome the issue of rejection of newly developed reference measurement procedures using the same measurement principle as an already published method in a peer reviewed journal, as this prevented listing of methods in the JCTLM database for which a publication was required.

The Committee recognized the usefulness for the community of finding a way for such methods to be published.
Prof. Panteghini suggested to liaise with the editors of the CCLM and investigate the possibility of acceptance of such manuscripts. The Committee agreed and suggested that a guidance document for journal editors on the scientific importance of such publication would be useful.

Action (A/22-29): Prof. Panteghini to contact the CCLM editor to discuss acceptance of such manuscripts and whether additional guidance is required.

7 Report from the JCTLM WG on Traceability Education and Promotion

7.1 Activity update of JCTLM TEP WG

Prof. Theodorsson gave an update on the activity of the TEP WG during the last year, and highlighted the two main work items, including the revision of the jctlm.org website undertaken by a small group within the TEP WG (discussed under agenda item 5) and the task from the Executive meeting in 2021 on the determination of suitable names and codes for facilitating traceability projects. He further added that he contacted experts of the IFCC N-PU Coding system, and who were involved in the FDA, EU and WHO organizations to form a group. From a first investigation of existing coding systems, he anticipated that recommendation on appropriate ontology to be used would developed within the next two years. Dr Wielgosz commented that the requirement for the JCTLM Database was to have identifiers that could be used in the appropriate box to identify entries that represented the same analyte, noting that guidance on which identifiers to use for the 700 or so database entries would be the first requirement to be met.

7.2 JCTLM Members and Stakeholders meeting 2023

Prof. Theodorsson reported that a draft programme of the next JCTLM Members and Stakeholders meeting on *EQA schemes elucidating the clinical suitability of laboratory results* had been finalized. The final draft version of the meeting programme would be sent for publication on the website after the Executive meeting.
He added that the meeting would be held as a hybrid meeting at the BIPM on 4-5 December 2023 and the workshop findings and recommendations would be summarized in a manuscript prepared by the organizing committee and submitted for publication in a clinical laboratory journal.

8 Report from Task Force on Reference Measurement System Implementation

Prof. Panteghini reported that the JCTLM TF RMSI was currently reviewing JCTLM listed reference measurement components for a second group of measurands using the same approach described in the publication *Clin. Chem.* 67(12) 2021 1590-1605, and that published

recommendations on how IVDs can incorporate traceability via higher order RMPs within the defined APS were presented at two international conferences in 2022.

He pointed out the need to further raise awareness on the results and recommendation of the TF RMSI amongst the parties involved in laboratory measurement development and the production of reference materials.
Dr Wielgosz said he would circulate the information amongst the CCQM community.
The Committee also requested that the TF RMSI publication should be advertised in the next issue of the Newsletter.

9 JCTLM DB WG: Approval of Recommendations

Dr Maniguet presented the summary of the nominations for reference materials, reference measurement methods and reference measurement services with the final DB WG's recommendations that had been submitted for review as part of cycle 19 for materials and methods and cycle 17 for services.
There were 124 new nominations made up of 39 material, 29 method and 56 service nominations that were distributed for consideration to ten JCTLM review teams in 2022.

Dr Miller said that the Database WG held a hybrid meeting on 5 December and successfully completed the review of all review teams' recommendations concerning these 124 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.

9.1 Approval of Cycle 19 RM and RMP and Cycle 17 RMS

9.1.1 Analyte Group 1

9.1.1.1 Non-Peptide Hormones [JCTLM-EXEC/22-07]

There were three nominations for reference measurement methods and 11 nominations for reference measurement services that were reviewed by the review team for Non-Peptide Hormones, and of these, a resubmitted ID LC MS-based reference measurement method for 17 hydroxyprogesterone in blood plasma and a resubmitted reference measurement service for cortisol in human serum/plasma were being recommended for listing in the database.

The Committee approved the DB WG's recommendation for Non-peptide hormones nominations.

9.1.1.2 Metabolites and Substrates [JCTLM-EXEC/22-08]

There were 16 nominations for certified reference materials and eight nominations for reference measurement services that were reviewed by the review team for Metabolites and Substrates, and of these eight new nominations regarding two multi components matrix materials for creatinine, glucose, urea and uric acid in frozen human serum and HDL-cholesterol, LDL-cholesterol and total glycerides in frozen human serum, as well as three reference measurement services for serum urea, total cholesterol and homocysteine were being recommended for inclusion in the JCTLM Database.

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

9.1.1.3 Drugs [JCTLM-EXEC/22-09]

There was one nomination for certified reference materials and nine nominations for reference measurement methods that were reviewed by the review team for Drugs and of these the resubmitted carbamazepine certified reference material was being recommended.
There were four methods that were withdrawn by the nominating laboratory during the review process and other nominations were not accepted for listing due to the lack of a peer-reviewed publication.
The Committee approved the DB WG's recommendation for the Drugs nominations.

9.1.2 Analyte Group 2

9.1.2.1 Proteins [JCTLM-EXEC/22-16]

There were three nominations for certified reference materials and two nominations for reference measurement methods, and of these none were being recommended for inclusion in the JCTLM database.

9.1.2.2 Enzymes [JCTLM-EXEC/22-10]

There were two nominations for certified reference materials and 28 nominations for reference measurement services that were reviewed by the review team for Enzymes, and of these two resubmissions for a serum γGT and alkaline phosphatase material and 17 services that were being recommended for approval and publication in the JCTLM Database.

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

9.1.2.3 Nucleic acid [JCTLM-EXEC/22-11]

There were 17 resubmitted nominations for certified reference materials and 12 nominations for reference measurement methods that were reviewed by the review team for Nucleic acids and of these a material for a human DNA mixture in serum for noninvasive prenatal testing of Downsyndrome was being recommended for listing with the provision that updated certification documents would be provided by the material producer for confirmation by the review team.

The DB WG also recommended to defer the recommendations for the remaining resubmitted materials and methods nominations until after the review team's experts have re-reviewed the classification of the observations and non-compliances and to keep those which would need to be resolved to prevent the wrong implementation of the RMP for Nucleic acid nominations by a potential user.

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

Action (A/22-31): Prof. Panteghini to contact the team leader to review the reports for NA resubmissions with regards to the classification of non-compliances

9.1.2.4 Blood cell counting and typing

There were two resubmitted nominations for reference measurement procedures for leukocytes and erythrocytes in whole blood that were not being recommended for approval as

technical review observations reported by the review team last year were partially addressed by the laboratory.

The Committee approved the DB WG's recommendation for Blood cell counting review team.

9.1.3 Analyte Group 3

9.1.3.1 Electrolytes and blood gases [JCTLM-EXEC/22-12]

There were nine nominations for reference measurement services that were reviewed by the review team for Electrolytes and blood gases, and of these four reference measurement services for serum/plasma calcium, magnesium, potassium, or sodium from a provider were being recommended for listing in the JCTLM database. There was another submitted service for magnesium which was being recommended for listing with the provision that a clarification of its stated relative expanded uncertainty be clarified for consistency with the value quoted in the calibration laboratory's accreditation certificate.

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

9.1.3.2 Vitamins [JCTLM-EXEC/22-17]

There was a nomination for an ID LC MS-based reference measurement method for 25-hydroxyvitamin D3 in serum which was not being recommended for listing in the JCTLM Database after the third review assessment from the review team for Vitamins.

The DBWG also recommended that a generic text/letter should be drafted to the laboratory that had submitted this and other nominations, to ensure that the generic issues could be addressed by the laboratory prior to making any further submissions.

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

9.1.3.3 Non-Electrolyte metals [JCTLM-EXEC/22-13]

There was a nomination for a certified value for Colbalt matrix material which was not being recommended for listing in the JCTLM Database after the second review assessment from the review team for Non-electrolyte metals.

The Committee approved the DB WG's recommendation for Non-electrolyte metals nominations.

Action (A/22-30): Prof. Panteghini to review the reports for NA resubmission with regards to the classification of non-compliances

Action (A/22-31): Secretariat to publish the nominations recommended for publication in the JCTLM Database and send out the report on the outcomes of the review to the nominating organizations.

9.2 IFCC CDT method submission follow up [EXEC22-14]

Dr Westwood presented the document EXEC22-14 which included an updated report of the IFCC CDT reference method review and a potential way forward for re-review by JCTLM. The Committee agreed with the suggested approach and requested that the recommendation should be submitted for consideration to the IFCC.

Action (A/22-32): Prof Cobbaert to forward to the IFCC the JCTLM response regarding the IFCC WG CDT Method report update and its recommendation for a potential re-review by JCTLM.

9.3 Update on IFCC EQAS results

Dr Kessler gave an update on the IFCC EQAS Scheme and the RELA exercise completed in 2022 and announced the launch of a new project for 17β-Estradiol in collaboration with the EU JRC for RELA 2025 and possible linking to a CCQM comparison.

9.4 Plan for Cycle 20 for RMs and RMPs and Cycle 18 for RMSs

Dr Maniguet said 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 2023.

10 Workshops on competing traceability models for the same measurand

10.1 CRP (Outcomes)

Dr Miller said that the JCTLM meeting on developments in reference measurement systems for C-reactive protein and the importance of maintaining currently used clinical decision-making criteria, was held in Milan on 1 December 2022.
The meeting presentations demonstrated that further investigation to determine the best suited source of the material (recombinant material or purified material) and comparison studies amongst currently available CRP materials would need to be carried out to investigate any potential sources of bias in the clinical laboratory measurement results.
He added that the JCTLM was requested to coordinate the drafting of a paper planning for the evolution of the work.

He pointed out that from the meeting discussions the key issues that would need to be considered by JCTLM were how to address the impact on the calibration hierarchy, and on the clinical laboratory use as well as how to demonstrate compatibility with listed materials for newly nominated primary calibrators for CRP. The Committee commented that for complex analytes such as CRP, when it was not clear whether a newly nominated primary CRM was useable with existing calibration hierarchies, the CRM producer should be requested to nominate the reference measurement procedure for which the material would be used at the same time as the material nomination.

The Committee agreed with the proposed approach.

Action (A/22-33): Dr Miller/Prof Panteghini to develop a paper in collaboration with parties involved in the CRP reference measurement system development.

10.2 Total Hb (Planned Activity)

Mr Fawcett informed the Committee that a draft proposal for joint meeting on Reference Measurement Systems for Total Haemoglobin was to be discussed.
The ICSH and the BIPM are both Executive Member Organizations of the JCTLM and have on-going activities related to reference methods for the measurements of Total Haemoglobin within their organizations.

The Committee welcomed the meeting proposal.

10.3 PTH (1-84) (Planned Activity)

Dr Wielgosz informed the Committee that a Joint meeting on Reference Measurement Systems for PTH 1-84 was planned in February 2023.
At least three groups have prioritized or are considering prioritizing developments in reference measurements systems for PTH 1-84 and it will be highly beneficial for groups from these organizations to work together.
The aims of the meeting are:

a) For the groups to inform each other of their current plans and timescales of their activities;
b) For the groups to consider whether there are opportunities to progress their activities more efficiently or effectively by coordinating their activities;
c) To create an overall roadmap for standardization projects for PTH 1-84, so that the activities of the different groups provide a single comprehensive route forward for improving the equivalence of PTH 1-84 measurements worldwide

The Committee welcomed the meeting proposal.

11 The future role of JCTLM in bringing together different groups working on standardization projects

The Committee noted the JCTLM submissions were currently made at the end of the standardization projects, and that bringing together different groups working on the same analytes would be better at the start of these projects.

It was agreed that this issue could also be considered by the Task Group looking at the future strategy for the JCTLM.

12 Reports from related activities / meetings

12.1 IFCC SD

Prof. Cobbaert gave a presentation report on the future of perspectives and strategic implication of the IFCC SD to respond to challenges of precision diagnostics.

12.2 ICSH GA (T. Fawcett)

Mr Fawcett gave a presentation report on the International Council for Standardization in Haematology General Assembly Meeting which was held on 4-5 October 2022.
He pointed out the agenda point of interest for the Committee, notably the invited presentation on JCTLM activity given by Dr Wielgosz; the new project Eurotrol HbA and Total Hgb from Dr Harteveld Netherlands and Dr Swart PTB; and the project on the immunoplatelet submission to JCTLM which would be reinitiated.

12.3 ILAC

M. Bednarova reported on the ILAC contribution to the revisions of the standards ISO 15189 published in December 2022 and ISO/IEC 17043 for which the publication was expected in March/April 2023. She added that the standard ISO/IEC 17025:2017 was under systematic review and there were no changes expected.
The Committee noted the wording of the traceability statement in the revised version of the standard ISO 15189 could be more consistent with ISO 17511 and future revision could consider whether the ISO 17511 standard should be a normative reference in ISO 15189.

12.4 CCQM

R. Wielgosz presented an overview of the CCQM activity which was overlapping with the JCTLM and highlighted a new joint comparison study for Estradiol-17beta which would be carried out in collaboration with the IFCC RELA. In addition, the ICSH became a liaison organization of the CCQM.

13 Activities within ISO TC 212

13.1 ISO 15194: 2022 – expected changes from current standard

Dr Westwood said the working group for drafting the revised version ISO 15194 had received a large number of comments and the process for responding to comments was underway. He added that the distribution of DIS was planned in the first of quarter 2023.

13.2 ISO 15193: 2022 - expected changes from current standard

Dr Kessler said the working group for drafting the revised version ISO 15193 had received a large number of comments and the process for responding to comments was underway. She added that the main structure of the standard would remain unchanged.

13.3 Implementation date of new standards into JCTLM processes and impact of JCTLM DB and nomination process

Dr Wielgosz commented that it would be beneficial for JCTLM to review the expected changes in the requirements in the next version of the standards as soon as available to anticipate the changes in the JCTLM Quality Manual review criteria for listing items in the JCTLM database.

Action (A/22-34): Dr Kessler and Dr Westwood to clarify the expected publication date of the revised ISO 15193 and ISO 15194 respectively, and whether the revised ISO standards would be automatically reconducted in the list of harmonized standards related to the EU IVD Regulation.

14 Liaison with the WHO

The committee noted that liaison should be revived and this could also be considered by the Task Group on JCTLM Strategy.

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 4 December 2023. This would be followed by a TEP-WG workshop on 4 (afternoon) and 5 December, a Database WG meeting on 6 December, and a JCTLM Executive Committee meeting on 7 and 8 December 2023.

The Chairman closed the meeting at 16:00.

Annex 1: Summary List of Actions

Outstanding Actions from the previous Executive Meeting:

(A/22-01) JCTLM Secretariat to contact NIST and invite them to nominate SRM 916b, Bilirubin, for review and listing in the JCTLM database.

(A/22-02) JCTLM Secretariat to contact JCTLM listed laboratories with services for Bilirubin measurements on the availability of SRM 916b, and as a route to overcome issues that were raised in reviews on metrological traceability of measurements.

Actions from the 24th Executive Meeting:

(A/22-16): JCTLM Secretariat to contact the Executive Committee organizations and inform them of the reappointment of the Chairman

(A22-17): JCTLM Secretariat to send a call for new experts in consultation with review teams leaders for Drugs, Electrolytes and blood gases, Enzymes, Vitamins.

(A22-18): JCTLM Secretariat to contact individuals no longer compliant with mandatory requirements for JCTLM Review Team membership, and to send a letter of suspension of their term as a JCTLM review team member.

(A22-19): JCTLM Secretariat to contact the Executive Committee organizations and inform them of the cost of the JCTLM Secretariat for 2022 and expected budget for 2023.

(A/22-20): G. Miller to draft the Terms of reference of the Task Force on educational activity for comments and approval by the EC by February 2023

(A/22-21): G. Miller/ JCTLM Secretariat to launch a call for members for the Task Group on educational activity

(A/22-22): Dr Miller/ Dr Wielgosz to draft the Terms of reference of the Task Group for developing a future vision and strategy for JCTLM as well as discussing more immediate funding issues for approval by the EC by February 2023 (draft attached as an Annex)

(A/22-23): JCTLM Secretariat to contact NMIs involved in the JCTLM and request donations for the updated of the JCTLM Database.

(A/22-24): TEP WG to develop new intermediate webpages and finalize the new landing page.

(A/22-25): BIPM to finalize the update of the webpages related to Review teams, nomination and review process by 30 January 2023, and provide the new urls for inclusion in the jctlm web portal.

(A/22-26): Dr Miller to review the last version of the revised DBWG procedures for review and approval by the EC by 30 January.

(A/22-27): Dr Myers to draft new procedures for nomination and review of harmonization protocols and associated reference materials at the December 2023 JCTLM EC meeting.

(A/22-28): JCTLM Secretariat to modify the relevant JCTLM procedure documents to add the new acceptance review criteria that the intended use statement of a nominated material should describe the IVD measurement procedures for which commutability of the material was demonstrated.

(A/22-29): Prof. Panteghini to contact the CCLM editor to discuss acceptance of such manuscripts and whether additional guidance is required.

(A/22-30): Prof. Panteghini to review the reports for NA resubmission with regards to the classification of non-compliances

(A/22-31): Secretariat to publish the nominations recommended for publication in the JCTLM Database and send out the report on the outcome of the review to the nominating organizations.

(A/22-32): Prof Cobbaert to forward to the IFCC the JCTLM response regarding the IFCC WG CDT Method report update and its recommendation for a potential re-review by JCTLM.

(A/22-33): Dr Miller/Prof Panteghini to develop a paper in collaboration with parties involved in the CRP reference measurement system development.
(A/22-34): Dr Kessler and Dr Westwood to clarify the expected publication date of the revised ISO 15193 and ISO 15194 respectively, and whether the revised ISO standards would be automatically reconducted in the list of harmonized standards related to the EU IVD Regulation.

Annex 2:
Draft terms of Reference for JCTLM Strategy Task Group

Chair: Greg Miller

Members: Group of 14 from JCTLM Executive Member Organization representatives; NMI representatives: Reference Laboratory representatives; IVD Manufacturers)

Aims: To review and recommend how to address the current and future challenges facing the JCTLM relative to its past successes. Specific items to address include, but are not limited to: its role, its outputs (including its database), its operation, and its funding. The Task Group will develop a strategy for these aims for the period 2024 to 2033. The strategy will be presented at the 2023 JCTLM Stakeholder's meeting for discussion, and submitted to the JCTLM Executive Committee for approval.

Background: The JCTLM was established in 2002 to provide a framework to identify higher order metrological traceability references that could be used by IVD industry to meet the metrological traceability requirements laid out in the EU IVD Directive. Initial meetings leading to JCTLM's formation were held in the US due to concerns from IVD manufacturers outside the European Union on how to meet the traceability requirement and continue sales of their IVD-MDs in Europe. In addition, CRM manufacturers outside of Europe had concerns regarding their materials being recognized as higher order standards.

To meet these concerns the JCTLM developed an independent third-party review process for materials, methods and measurement services against the requirements laid out in ISO standards (developed by ISO TC 212 WG2) that were designated as the harmonized standards for the EU IVD Directive. JCTLM published and continues to publish those higher order references that are in conformity with the ISO standards in a publicly consultable database. The database (www.jctlmdb.org) is updated annually, and currently contains 265 Materials; 215 Methods; 224 Services.

Tasks to be completed

By July 2023:

1. Review the full costs of maintaining the current JCTLM activities including the JCTLM database and develop an implementable and sustainable financial plan to support current activities for the next several years (note, this plan will merge into the strategy for funding in item 2 below).

By December 2023:

2. Develop a strategy for JCTLM's role, its outputs (including its database), its operation, and its funding for the period 2024 to 2033. Specific tasks should include:
    a. Consult stakeholders to determine their use and the importance they place on the continued provision of a database of higher order reference materials, methods and services for IVD-MDs?
    b. Consult stakeholders to determine how effectively third-party independent review of materials/methods and accredited services meets their needs and whether other processes should be used to identify potentially suitable materials/methods/services?

c. Consult EU regulators for confirmation of the status of ISO TC 212 WG2 standards as harmonized standards for the EU IVD regulation, and any processes that will be implemented to verify traceability statements of IVD-MDs sold in the EU?

d. Repeat the consultations regarding the role of ISO TC 212 WG2 standards for other regions of the world.

3. Define a communication and promotion plan to raise the visibility of JCTLM listed Reference Material/Methods and Services within individual stakeholder and user communities.

Annex 3:
Draft terms of Reference for JCTLM Knowledge Transfer Task Group

Chair: Greg Miller

Members: Ask IFCC to nominate 2 people. JCTLM will ask RT leaders to suggest experienced people likely to be active contributors; then select 2-3 people.

Aims: To develop e-learning materials to transfer knowledge on the requirements of the ISO standards and the JCTLM review procedures for evaluating materials, methods and services. The intended users are those wishing to make nominations to the JCTLM Database or who are new members of JCTLM Review Teams. The e-learning modules will be made available both through the BIPM and IFCC e-learning platforms.

Tasks to be completed:

1. Develop a check list of nomination requirements based on experiences of review teams regarding the most common non-compliances with ISO standards used for JCTLM listing. The goal for the checklist is to increase the likelihood of acceptance of JCTLM submitted nominations (by 30 April 2022).
2. Develop e-learning modules for developing and documenting ISO compliant reference methods, covering the requirements of ISO 15193:2009 including examples of successful JCTLM nominations with supporting documentation and validation data. Relevant updates to include likely changes in revised ISO 15193 should be included.
3. Develop e-learning modules for developing and documenting ISO compliant certified reference materials, covering the requirements of ISO 15194:2009 including examples of successful JCTLM nominations with supporting documentation and validation data. Relevant updates to include likely changes in revised ISO 15194 should be included.