

## EFLM Annual Report 2024

*by Snežana Jovičić, EFLM Executive Board Secretary*

Internal reorganization of EFLM Functional units was the principal EFLM EB activity throughout the year 2024. Instead of previous Committees, Working Groups (WG), Task Forces (TF), Task and Finish Groups (TFG) and Task Groups (TG), three new functional unit categories are defined. The four Divisions correspond to the previous Committees. The difference is that each Division is composed of an Executive Committee formed by the Chair (appointed by the EB) and four Members nominated by EFLM Full Member NSs and selected/appointed by the EB. There are no Corresponding Members nor Experts/Consultants in this functional unit.

The four Divisions are:

1. Science: Value Based Laboratory Medicine;
2. Education and Profession
3. Quality, Standards and Regulations; and
4. Communication.

Under each Division there are several Committees that correspond to the current WG / TF / TG / TFG. Each Committee has a Chair (appointed by the EB), 3 Full Members and 1 Young Scientist (YS) Member nominated by EFLM Full Member NSs and selected/appointed by the Division and Committee Chairs who notify the EB. Corresponding Members and Experts/Consultants can be part of a Committee. The rule of the geographical distribution applies for both Divisions and Committees. Technical Committee (TC) is a functional unit with technical tasks (e.g. EFLMLabX, EuSpLM Register, BV Database). Each TC has a Chair (appointed by the EB) and 4 Full Members directly identified by TC Chair; these are evaluated by the Division Chair and then notified to the EB. The rule of the geographical distribution does not have to apply. Experts/Consultants can be part of the Committee but there are no Corresponding Members in a TC. There must not be any duplication of roles for Chairs and Full Members of all Functional Units.

At the EFLM General Meeting (GM) held online on June 7<sup>th</sup>, 2024 the reorganization plan was presented to the NS National Representatives and the proposal of change of Articles of Associations was put to a vote. The GM unanimously approved all the proposed changes at the EFLM Articles of Associations. In addition, the GM unanimously approved the application from the Spanish Association of Medical Biopathology-Clinical Laboratory Medicine (AEBM-ML) to become EFLM Affiliate Member and the application from Radiometer Medical ApS to become an EFLM Corporate Member.

The activities of EFLM Functional Units continued with great intensity resulting in 25 publications in total. The highlight is the publication of European Urinalysis Guideline which represent a great example of an integrated diagnostics, being jointly produced by laboratory medicine specialists, microbiologists, and

clinicians. Furthermore, the EFLM Syllabus Course was supplemented with new lectures, thus completing 5 modules. EFLM session on WorldLab Dubai 2024 was dedicated to the Green and Sustainable Laboratories project, that continued to grow and left the borders of Europe. In 2024, 15 new laboratories applied and received EFLM Green Labs Certificate. In total, up to now, 20 laboratories are certified by EFLM as "Green & Sustainable Laboratory". During 2024, EFLM's CPECS® - Continuing Professional Education Credit System was used for accrediting major educational events in 2024 – IFCC WorldLab 2024 in Dubai and EFLM Strategic Conference in Padova.

EFLM Strategic Conference 2024 "A Vision to the future: value-based Laboratory Medicine" was held in Padova on 23-24 September. It was a hybrid event, where EFLM Academy members could follow the presentations and discussions online. With over 300 registered participants attending in-person and about the same number of registered virtual attendees, the Conference was a great success, demonstrating great interest of the laboratory medicine community to be actively engaged in shaping the future of the profession.

After reviewing comments and suggestions received from Functional unit's chairs, Presidents and National Representatives of EFLM National Society Members, EFLM EB finalized the EFLM Strategic Plan 2024–2025. Among the principal actions of the new Strategic Plan was establishing new FU that would facilitate reaching one of the major strategic goals of promoting and supporting the value-based laboratory medicine. The new FU that will be established are:

- "Value-score for clinical laboratories" dealing with the process of traceability (starting from pre-analytical steps), level of automation (number of manual procedures), performance on quality indicators and data management, quality of reported information and clinical interaction,
- "One health and exposome" dealing with the holistic vision of the relationship between human health and the environment, and
- "International standardized exchange of laboratory data" supporting efforts to standardize the exchange of laboratory data between laboratories and between countries in view of the future decision of the European Union on the format of standardized exchange of laboratory test results in Europe.

In 2024 EFLM continued strategic collaboration with other associations. The agreement with EQALM was renewed and the MoU with MedTech Europe was signed. The collaboration with BioMedAlliance (BMA) has intensified: Christa Cobbaert was appointed as the new liaison for EFLM and former EFLM President Michael Neumaier was appointed as the Chair of the BMA Task Force on IVD. Representatives of BMA participated at the EFLM Strategic Conference 2024 in Padova and it was agreed that a joint session be included into the Scientific Program of EuroMedLab 2025 in Brussels. In addition, MoU was signed between EFLM and Federation of European Biochemical Societies (FEBS) where it is agreed for both federations to participate in each other's congresses. Furthermore, EFLM signed a MoU with the Chinese Society of Laboratory Medicine (CSLM) for 2025-2027.

During 2024, EFLM's CPECS® - Continuing Professional Education Credit System was used for accrediting major educational events in 2024 – IFCC WorldLab 2024 in Dubai and EFLM Strategic Conference in Padova.

Also in 2024, 11 National societies applied for the program "Invite an Executive Board Member at Your National Society Congress". The applications of seven NSs which had received minimum support in the

previous 10 years were accepted. The EFLM EB members attended NSs meetings in Romania, Lithuania, Serbia, Bulgaria, Slovak, Turkiye and Ireland.

EFLM Academy continued to grow, surpassing the number of 10000 members by the end of 2024. All the benefits for Academy members were continued.

In 2024, EFLM continued with the EFLM Scholarship program in memory of Prof. Vic Blaton related to bursaries for meetings and conferences organized by EFLM. Also, the EFLMLabX professional exchanging program has been active and opened for applications.

## **COMMITTEES**

### **Committee – Communication (C-C)**

C-C has one working group (WG Promotion & Publications, WG-PP) and two task groups (TG European Laboratory Day, TG-ELD, and TG Young Scientists, TG-YS). In 2024, C-C EFLM initiated a comprehensive redesign, rebranding, and user experience upgrade of the EFLM website.

The WG-PP oversees the Federation's primary communication channels, including the website, the bimonthly newsletter "EuroLabNews," social media, the EFLM section in the IFCC e-Newsletter, the EFLM mailing list, and regular updates to National Societies (NSs). "EuroLabNews" features key sections such as The EFLM Executive Board Informs, EFLM Office Informs, Vacancies in EFLM Functional Units, YS Corner, News from the EFLM Functional Units, Updates on EFLM Publications, EFLM Events, and IFCC News.

In 2024, the TG-YS focused on supporting young professionals by holding a meeting at the EFLM Strategic Conference in Padova, expanding membership to over 120 individuals (with 60 members in a dedicated WhatsApp group), and conducting monthly meetings with active participation. Meeting recordings are available as unlisted YouTube videos. The TG-YS has also established criteria and selected a committee for the EFLM Young Laboratory Medicine Professional Award.

The TG-ELD is responsible for promoting public awareness of laboratory medicine, primarily through the annual European Laboratory Day on November 5. In 2024, the event engaged participants from more than 15 countries and generated nearly 38,000 social media impressions, more than 190 pieces of news coverage, and a total reach of 138 million. Social media impressions and engagement rose significantly compared with 2023, and email outreach for the event achieved a 49% open rate.

### **Committee – Education and Training (C-ET)**

*Working group on congresses and postgraduate education (WG-CPE).* WG-CPE was involved in recruiting new and "old" teams for postgraduate courses. Accordingly, two PGC on Statistics in laboratory medicine was held in Tbilisi (Georgia), 12-13 Sept, and Helsinki (Finland), 16-17 May with Matteo Vidali as a lecturer. PGC course on *how to write a good scientific and professional article* was held in Dublin, Ireland, 2 Feb 2024, with Ana Bronic and Daria Pasalis as lecturers.

WG-CPE granted 31 auspices for different educational events in 2024. WG was also involved in the organization of the EFLM course "Meet the expert" and realized four online lessons in Feb, May, Nov and

Dec (Analysis and interpretation of tests for antiphospholipid syndrome, Analysis and interpretation of cardiac markers and deciphering of hs-troponin, M-protein diagnostics: analysis and interpretation of protein electrophoresis of serum, urine and cerebrospinal fluid, Interpretation of laboratory results of kidney function). For 2024, WG-CPE also prepared and planned to establish a new channel on the online platform for "educational interactive contents." This new channel should be used for interactive educational courses as well as for presenting and solving interactive clinical cases.

*Working Group on Laboratory Medicine Credit Points (WG-LMCP).* To institute an EFLM credit system, the WG-LMCP finalised a development of "Provider Application and Manual for EFLM Accreditation of Educational Programs" in conjunction with an administrative system called the Continuing Professional Education Credit System (CPECS). CPECS® accreditation was established for the XXVI IFCC WorldLab Congress, jointly hosted by the IFCC, the Arab Federation of Clinical Biochemistry, the Saudi Society of Clinical Chemistry, and the UAE Genetics Association, May 26–30, 2024. The completed materials, which include a manual for providers, a manual for speakers, and different forms and documents, were uploaded to the EFLM website.

*Working group on Distance Education (WG-DE).* In cooperation with PCO (professional congress organizers), WG members were involved in planning and organization of 21 webinars in 2024. They already prepared a list of 22 new webinars for 2025.

In 2024, C-ET members were involved in EFLM bursary evaluation for the Strategic Conference Padova 2024. In addition, chairs of the C-ET and Science committees evaluated research grants that were previously established by the Executive Board. Two applications were granted, one for an applicant coming from a country enjoying the "Vic Blaton" scholarship program and the other for an applicant coming from any other country in Europe.

### **Committee – Profession (C-P)**

The C-P activity in 2023 focused mainly in six objectives:

1. Progress with achieving recognition of Specialists in Laboratory Medicine
2. Growing the EFLM Register (EuSpLM)
3. Growing the EFLM Academy
4. EFLMLabX
5. TG: EFLM Syllabus Courses
6. Ethical issues: WG - Ethics (New)

According to the demand of Directive 2013/55/EC (Recognition of Professional Qualifications), our profession Laboratory Medicine fulfills and established all formal requirements for given profession to become automatic regulated and recognised on EU level, to move from General System (Chapter I and II) to Automatic System (Chapter III) recognition through prepared Common Training Framework for Specialists in Laboratory Medicine (CTF):

- Common name of profession: Laboratory medicine
- Common name of specialist: European Specialist of Laboratory Medicine (EuSpLM)

- Common education program: Syllabus and training (defined competences)(EoS)
- Common Training framework: CTF- confirmed by EFLM/EU NS members
- Common register: EFLM register (EuSpLM)
- Code of Conduct

In order to continue the process of achieving EuSpLM recognition, on September 29, 2023, we had an online meeting with the European Commission officer Olivier Lano, responsible for this directive and professional regulation, where we also presented our progress and the actual situation. Unfortunately, the meeting was not successful, because despite the facts presented, the EU commissioner did not recognize our coordination process and current situation as suitable for automatic regulation. Despite the disappointment, we have decided to continue our efforts to achieve our important goal and plan to find new connections and meet the EC again in person, together with the EFLM President.

In support of this process, the launch of the EFLM Academy, which is open to anyone (not just EFLM members) interested in laboratory medicine, proved successful. EFLM Academy offers a lot of benefits to its members, including free access to important Journals, free access to CLSI documents (for block enrolled members), free access to EFLM Syllabus Courses with more than 350 lectures on all Syllabus topics, free access to EFLM webinars and much more. There are a few differences in the additional benefits of membership of the EFLM compared to non-EFLM Academy membership: enrollment in the EFLM EuSpLM register, which will only be possible by applying to the EFLM Academy and eligibility for EFLM grant applicants. All information about the Academy and its benefits is available on the EFLM website: <https://www.eflm.eu/site/eflm-academy> . Therefore, the number of Academy and EuSpLM register members is constantly growing, especially through block-enrolled NS. The number of registrants for the Academy increased steadily until the end of 2024 (+27% compared to 2023). The total number of members of the Academy is 9980 (with and without EuSpLM): through NS block enrollment (maximum share of registrants) (Total: 9164 (92%)) members, without EuSpLM certificate: 5140 (56%) members from total 9980; individual registration (Total: 621 (8%), without EuSpLM registration: 583). The total number of members of the Academy without EuSpLM, joined by both channels, moves from 4580 to 5140. In 2024 we got additionally 4 block enrolled NSs (Cyprus, Luxembourg, Sweden, Ukraine), together is now 40 block enrolled NSs members.

The WG-Register confirmed 800 more applications for EuSpLM Register in 2024 than in 2023 (total 4058), mainly achieved by block entry 4024 (99%) and 28 (1%) from individual applications.

By the end of 2024, a Memorandum of Understanding (MoU) for Academy/EuspLM register group enrollment had been signed with 44/48 EFLM national societies (4 new in 2024: Poland, Denmark, Bulgaria and Switzerland, Cyprus).

In 2024, all registration (**block enrollment** and **individual registration**) for the Academy and EuSpLM register have been successfully managed through this platform, where all applicants can retrieve their certificates.

The EFLM Committee on Professions conducts **an occasional audit to check that submitted individuals for the EuSpLM** certificate by the National Society meet the EFLM Equivalence of Standards. In 2024, WG-Register also evaluated random check and ran the evaluation process of compliance of EuSpLM certificated candidates who have applied through NSs block enrollment way. For each NS with block

enrollment, at the closure of the renewal process for 2023 (within Dec 10), the system automatically sends an e-mail with the name of the applicant for which the accurate personal documentation should be sent to WG-R for evaluation. 36 out Academy block enrolled NSs (EU Countries) in January 2024 were with applied EuSpLM members and were involved in this first evaluation process (one candidate from each NS). 34 out of 36 randomly checked EuSpLM individuals complied with EuSpLM criteria.

The EFLMLabX practice exchange project continues with many new applications for the practices. The rising interest in the project, especially from young scientists, has shown the need for its growth. TG-EFLMLabX is taking care of support and development on the project activities. One of the most critical tasks is to attract more institutions/laboratories as the offerers of new practices. In 2024 3, new institutions joined the project as offerers (CHU de Liege . Prof. Cavalier, France (January 2024) - no new practice created, Tel Aviv Medical Centre, Israel (tertiar hospital) – application, Lile Hospital University , Grzych, France (January 2024). We have now 27 active practices form 13 countries and 25 institutions. This year, 10 practices were implemented (in Spain, Germany, Greece, Belgium, Slovenia). The project achieved significant support through the introduction of an EFLM Bursaries programme. We got 12 applications, and 10 of them have been confirmed and received the bursary. We have been taking care for promotion of EFLMLabX activities through publications within EFLM e-news (through EFLMLabX corner), where we presented experiences of previous practices and new institutions as new offerers of the EFLMLabX project.

In 2024, the TG: *EFLM Syllabus Courses* continued the project of Syllabus Courses. Courses are available on the EFLM Academy website as a part of the new e-learning platform for Academy members only. In 2024, 6 modules (Biological variation, Vitamines and trace elements, General microbiology, Mycology, AI, Post-analytical phase) were finished and added on a platform.

Ethics Working Group address several questions and topics on ethics in laboratory medicine (in clinical settings, research and experimental medicine) in accordance with the EFLM Code of Conduct in Laboratory Medicine. In 2024 they published two papers in CCLM: 1. Clin Chem Lab Med. 2024 May 8;62(12):2388-2392. doi: 10.1515/cclm-2024-0525. Print 2024 Nov 26., 2 Clin Chem Lab Med. 2024 Sep 13;62(12):2373-2387. doi: 10.1515/cclm-2024-1022. Print 2024 Nov 26. They also have presentation on Ethics topic at NS Conference SiBIOC, Strategic Conference Padova 2024.

C-P updated the site accordingly with any changes.

### **Committee – Quality and Regulations (C-QR)**

**The committee operates with one active working group: accreditation and ISO standards (WG-A/ISO)**

Activities can be summarized along 3 main objectives:

Objective 1: The EU IVDR and the new ISO15189:2022

Together with the EFLM Task Force on European Regulatory Affairs, the Working Group Accreditation and ISO/CEN standards earlier has published on ISO15189 sufficiency for the IVDR-conform validation of the production and the putting to use of laboratory developed tests meant for in-house use. In 2024 this work was updated by the preparation of a publication on the impact of the 2022 revision of ISO15189. In this document also references made to ISO 15189 in th publications below are updated to the 2022 revision.

**ISO 15189 is a sufficient instrument to guarantee high-quality manufacture of laboratory developed tests for in-house-use conform requirements of the European In-Vitro-Diagnostics Regulation. Joint opinion of EFLM TF-ERA and WG-A/ISO**

*Vanstapel F.J.L.A, Orth M, Streichert T., Capoluongo E.D, Oosterhuis W.P, Can Çubukçu H, Bernabeu-Andreu F.A, Thelen M, Jacobs L.H.J, Linko S, Pal Bhattoa H, Bossuyt P.M.M, Meško Brguljan P, Boursier G, Cobbaert C.M and Neumaier M.* Clin Chem Lab Med 2023. <https://doi.org/10.1515/cclm-2023-0045>

**In-house diagnostic devices under the EU IVDR and unwanted side-effects of intentional transparency**

*Vanstapel F.J.L.A., Boursier G., Cobbaert C.M., on behalf of the EFLM Task Force on European Regulatory Affairs and the EFLM Quality and Regulations Committee.* Clin Chem Lab Med 2023. <https://doi.org/10.1515/cclm-2023-0750>

Objective 2: Auditable and defensible implementation of ISO-15189 requirements

The WG-A/ISO has published guidance on retention times of laboratory registrations:

**EFLM Working Group Accreditation and ISO/CEN standards on dealing with ISO 15189 demands for retention of documents and examination objects**, Adv Lab Med. 2024 Jan 30;5(2):103-108.

<https://doi.org/10.1515/almed-2023-0053>

In 2024 the WG-A/ISO has worked on:

- guidance on the impact of ISO15189 revision on laboratory Quality management systems including impact on published EFLM guidance on previous versions of ISO15189. The work has been accepted for publication in CCLM.
- guidance on quality control policies to monitor that Analytical performance characteristics remain within analytical performance specifications, including guidance on the use of real time patient result based QC. This work will be continued to be presented as a manuscript for publication in 2025.
- guidance on how to evaluate performance of AI/ML-enabled medical devices in the light of IVDR, ISO 15189:2022 and ISO 23053:2022 documents: a laboratory medicine perspective. This work will be continued to be presented as a manuscript for publication in 2025.
- A follow up on guidance on method validation and verification of IVDs including a practical web-based tool (Verify My Lab) for calculation of method comparison as in CLSI EP9, precision, trueness as in CLSI EP15A3, LoD, and LoQ, etc. This work will be continued to be presented as a manuscript for publication in 2025.

Objective 3: The future of the Committee and WG

The 2023 Committee chair (cc) asked to be relieved of his task, and prepared the transfer of tasks to the newly (2024) appointed CC (Marc Thelen) and transfer of the European Accreditation Health Care group liaison activity to the WG ISO/A chair (Guilaine Boursier).

Together with all other EFLM bodies C-QR with WG-ISO/A has given input to the EFLM executive board to the new EFLM strategic plan. In this plan the committee is transformed into the division quality, standards and regulation (D-QSR) with the WG-ISO/A transformend into the committee accreditation and quality management systems (C-ISO). The terms of reference of division and committee are to produce guidance on implementation on the ISO and CEN standards on laboratory medicine and to stimulate the correct accreditation of such implementation. The division and committee also collaborate with other EFLM bodies in their work that affects implementation of such standards. The to be installed executive committee of the D-QSR will be asked to take a role in liaisoning with the committees of the EFLM science division working on topics related to the ISO15189 standard. At the level of ISO and CEN, the D-QSR and C-ISO gave input to the development of standards. The complete terms of reference can be found on the EFLM website along with the current staffing of the D-QSR and C-ISO.

### **Committee – Science (C-S)**

In 2024 large part of the Science Committee's activities was dedicated to the transition of the new Division: Science in the reorganization of the EFLM functional units. Despite this restructuring dominating the functional units' agendas and memberships, the scientific outcome was again impressive in 2024 and comprises 22 EFLM papers published (including the European Urinalysis Guideline) or accepted, 32 papers submitted or in preparation, 5 surveys conducted, and 39 invited lectures in webinars and symposia including IFCC WorldLab Dubai, EFLM Strategic Conference in Padua, SEQC-ML Quality Symposium in Barcelona, NFKK Nordic Congress Clinical Chemistry in Stockholm, and other congresses in 2024. New and updated biological variation data were published in the EFLM Biological Variation Database: [www.biologicalvariation.eu](http://www.biologicalvariation.eu). New collaborations and joint projects with clinical specialists' Societies are in the pipeline or initiated, including the European Society of Radiology and Working Groups of the European Renal Association and the International Osteoporosis Foundation. The Science Committee adds to strategic objectives and actions documented in the EFLM Strategic Plan 2024-2025: [EFLM-Strategic-Plan-2024-25-FINAL.pdf](#).

The Terms of Reference (ToR) were updated. The new Division "Science: Value-based Laboratory Medicine" is responsible for scientific matters within the EFLM and projects which advance the scientific development and practice of Clinical Chemistry and Laboratory Medicine and improve patient outcomes through the appropriate use and applications of in vitro diagnostic (IVD) data in health services and medical practice.

The Division initiates and manages the scientific projects through its functional units, Committees (C) and a Technical Committee (TC). These functional units are classified in 3 main areas of work:

- AREA 1: Total Testing Cycle Harmonization
- AREA 2: Integrative Diagnostics
- AREA 3: Emerging Perspectives

The Division: Science will deliver the following specific objectives to achieve the goals of EFLM to promote science and value-based laboratory medicine: inside and outside the clinical laboratory:

- Identify scientific and technological areas of relevance to Clinical Chemistry and Laboratory Medicine and facilitate the translation of research evidence to the profession.
- Identify new and emerging IVD biomarkers and technological innovations, appraise evidence of their analytical and clinical performance, and provide recommendations and guidelines on how to implement them in clinical laboratory practice and integrative diagnostic strategies.
- Establish safety and quality standards to be met in delivering value to patients, clinicians, public health agencies and authorities through better test utilization, test-assisted clinical decision, integrated diagnostics, personalized (precision) diagnostics, and patient empowerment through remote monitoring, Direct-to-Consumer Testing (DTCT) and patient self-tests (PST).
- Promote harmonisation of the total testing process, through the production of guidance documents stating best practice in pre-analytical, analytical and post-analytical areas including (but not limited to) measurement units, reference intervals and decision limits, across the full continuum of the brain-to-brain loop of requesting, performing, reporting and using laboratory tests and test-based calculations for diagnosis and treatments through the full patient journey in the clinical pathway.
- Practical guidance to implement clinical and analytical test performance specifications, measurement uncertainty, and biological variation estimates in clinical laboratory practice. Deliver biological variation data to the global laboratory community.
- Facilitate digital transformation, Artificial Intelligence (A.I.) applications and standardized health data coding to enable novel approaches in the exchange and use of diagnostic data being shared between laboratories, healthcare professionals, healthcare providers and patients.
- Organize and participate in international collaborative projects between scientific and professional organizations within and outside Europe, and engage in guideline development in co-operation with relevant clinical specialists' scientific societies and multidisciplinary consensus initiatives. Maintain direct link to the Scientific Division of IFCC.
- Respond to scientific, clinical and technical needs, opportunities, or (pandemic) emergencies by translating expert scientific and clinical evidence into advice for EFLM Member Societies, IVD Industry, European Regulatory and other key stakeholders to ensure the clinical benefit and safety of IVD tests on the market, and education of patients/consumers to ensure safe use of DTCT and appropriate interpretation of self-tests.
- Produce criteria and recommendations to implement sustainable practices in the medical laboratories by decreasing their deleterious environmental impact without compromising patient safety.

To align the functional units with the ToR, the Division is restructured accordingly:

AREA 1: Total Testing Cycle Harmonization.

- C-BV: Biological Variation. Chair: Sverre Sandberg, Norway.
- TC-BVD: Biological Variation Database. Chair: Aasne Aarsand, Norway.
- C-H: Harmonisation. Chair: Martina Zaninotto, Italy.
- C-PRE: Preanalytical Phase. Chair: Alexander von Meyer, Germany.
- C-POST: Postanalytical Phase. Chair: Pieter Vermeersch, Belgium.
- C-PGIMU: Practical Guide to Implement Measurement Uncertainty. Chair: Abdurrahman Coskun, Turkey.
- C-CAPS: Clinical and Analytical Performance Specifications. Chair: Philip Monaghan, UK. This Committee is a merging of the former Working Group: Test Evaluation and the Task Group: Performance Specifications Based on Outcome Studies (chair: Rita Horvath, Australia).

#### AREA 2: Integrated Diagnostics.

- C-ID: Integrative Diagnostics. Chair: Jochen Lennerz, USA.
- C-AT: Autoimmunity Testing. Chair: Xavier Bossuyt, Belgium.
- C-BMTBI: Biomarkers of mild Traumatic Brain Injury. Chair: Vincent Sapin, France.
- C-BNOA: Biomarkers of Nitrous Oxide Abuse. Chair: Guillaume Grzych, France.
- C-CKD: Chronic Kidney Disease. Chair: Etienne Cavalier, Belgium.
- C-VRB: Vascular Risk Biomarkers. Chair: Karl Lackner, Germany.

#### AREA 3: Emerging Perspectives.

- C-AI: Digitalisation & Artificial Intelligence. Chair: Andrea Padoan, Italy.
- C-DCLTPE: Direct-to-Consumer Testing & Patient Empowerment. Chair: Matthias Orth, Germany. This Committee is a merging of the former Working Group: Patient Focused Laboratory Medicine (chair: Snezana Jovicic, Serbia) and the EFLM Task Force: Direct-to-Consumer Testing.

Other functional units in this area are former EFLM Task Forces repositioned under the Division:

- C-PLE: Preparation of Labs for Emergencies. Chair: Giuseppe Lippi, Italy.
- C-GSL: Green & Sustainable Laboratories. Chair: Tomris Ozben, Turkey.
- C-ERA: European Regulatory Affairs. Chair: Christa Cobbaert, Netherlands.

To coordinate the above functional units' activities, a new Executive Committee (EC) of the Division: Science is established to undertake the following tasks:

- Ensure that each of its functional units are functioning under clear terms of reference together with an agreed EFLM project proposal, aligned with the major objectives of the Division.
- Monitor and evaluate scientific outcome of activities and projects of functional units (publications, guidelines, lectures and symposia) in accordance to the plans.
- Annual report to the EB of the functional units' activities and achievements. Evaluate and make proposals to close and create new ones in identified areas of interest.
- Review and approve any documents that result from the work for publication as EFLM paper in scientific journals and dissemination to the National Societies.
- Validate European laboratory practice surveys planned by the functional units.
- Evaluate the National Societies' nominations and select applicants for Full Member and Young Scientist-Full Member vacancies in the functional units, based on scientific background and

proposed contribution of the applicant, and ensuring equal gender and geographical representation in the Division.

- Evaluate and score applications for EFLM Scientific Awards and Research Grants.
- Contribute to the International Scientific Advisory Board of EuroMedLab congresses, to suggest topics for the scientific programme and evaluate submitted abstracts.

This EC is chaired by Michel LANGLOIS (Belgium) in continuation of his 2<sup>nd</sup> term of office as Chair of the former EFLM Science Committee. Following nominations by the National Societies in 2024, the EC members were selected and appointed: Olga CIEPIELA (Poland), Pilar FERNÁNDEZ-CALLE (Spain), Merve Sibel GÜNGÖREN (Turkey) and Tommaso TRENTI (Italy).

Coinciding with the EFLM reorganisation, 5 Chairs of functional units have finalized their term of office: Janne CADAMURO (Working Group: Preanalytical Phase), Rita HORVATH (Task Group: Performance Specifications Based on Outcome Studies), Snezana JOVICIC (Working Group: Patient Focused Laboratory Medicine) and Timo KOURI (Task & Finish Group: Urinalysis). The EFLM is forever grateful and indebted to their hard work and dedication, successful leadership, and important achievements for science and laboratory medicine for many years.

## **TASK FORCES**

### **Task Force - Green and Sustainable Laboratories (TF-GSL)**

Evaluation/assessment of labs applying for Green Lab certificates were started.

EFLM Green and Sustainable Lab Certificates were given to the laboratories fulfilling the EFLM Green Lab requirements from Belgium, Finland, France, Romania, Switzerland, Turkiye, Qatar (7 laboratories), Saudi Arabia and Netherlands.

IVD companies were invited to support financially EFLM Task Force–GSL and its activities. Beckman, Roche and Abbott provided a total fund of € 25 000.

Exams were performed for the Representatives of the National Societies to become Green & Sustainable Laboratory Experts and 29 of them successful at the exams became GSL experts.

Two manuscripts were published in Clinica Chimica Acta (CCA) and Clinical Chemistry and Laboratory Medicine (CCLM) in addition to the four manuscripts published one year ago.

TF-GSL Chair, Tomris Ozben attended 14 Congresses worldwide as an invited speaker to give information and promote EFLM GSL program.

It was decided to organize a GSL workshop in November 2025, in Antalya, Turkiye. Preparations are on-going.

### **Task Force - European Regulatory Affairs (TF-ERA)**

The Task Force ERA holds 10 members, 8 regular members and 2 corporate members. Four out of the 8 regular members are also EFLM observers in either the MDCG IVD WG respectively in the MDCG Emerging Technology WG. On behalf of Medtech Europe both the CEO and another Medtech Representative participate. Regular two-monthly zoom meetings and one live meeting (organized during the strategic EFLM conference in Padua, Italy in September 2024) have taken place.

In 2024 the ***strategic positioning of EFLM in BioMed Alliance in Europe*** was strengthened. To accomplish this, Prof. Michael Neumaier became the chair of the IVD Task Force in BioMed Alliance in Europe (BMA), encompassing also other diagnostic disciplines such as EHA and ESHG. Michael Neumaier is still consultant in the EFLM committee on ERA. Christa Cobbaert became the official liaison between EFLM and BMA.

In 2024 the EFLM Task Force ERA ***contributed to the joint application for an EU-horizon call entitled "HORIZON-HLTH-2024-IND-06-08"*** with clinicians and laboratorians in an EU consortium led by BMA, named MUSE. The overall objective of MUSE was to develop specifications and frameworks for the evaluation of scientific evidence, based upon regulatory, clinical and scientific expertise, to improve clinical performance evaluation, to augment the predictability of clinical evidence requirements for health technology developers, and to increase patient trust and safety and support innovation. The TF-ERA acted as sounding board whereas the chair focused on recruiting Work Package leads for clinical evidence generation work package respectively for the Post Market Surveillance work package of medical tests. Periodic alignment on the content of the call and work packages was scheduled with the BioMed Alliance Principal Investigator, Board and IVD Work Package leads. The application was submitted in time. Yet, in August 2024 the message was received that BMA was not awarded the EU-call nor the funding, which was unexpected for the BMA board and EFLM. BMA will look for another EU- call/opportunity.

In 2024 EFLM TF ERA chair and members gave exposure and shared their IVDR activities and knowledge by lecturing or taking part in panel discussions at the following occasions:

#### **A. MedTech Summit 2024, 10-14 June 2024, Brussels**

Multi-Stakeholder Perspective: How IVDR is impacting Innovation & Industry & Lab Professionals.

#### **B. IFCC Worldlab Symposium, Dubai, UAE, May 2024**

Title: Thoughts on maintaining innovation and availability of medical tests or how to meet regulatory challenges for Lab-Developed-Tests?

Chairs: Michael Neumaier, Alexander Haliassos

1. Regulatory considerations for Laboratory-Developed Tests from an international perspective: Opportunities and risks for patient care, Folker Spitzenberger
2. Impact of diagnostic regulations on laboratory developed tests in the US, Tina Lockwood
3. Off-label Diagnostics - an analogy to individualized therapeutic medicine: the oncology case  
Michael Neumaier, Ralf Hofheinz

#### **C. Regulatory Symposium on LDTs at ADLM, Chicago, USA, August 2024**

Session overview: ***International regulatory considerations for laboratory-developed tests: opportunities and risks for patient care***

1. The session highlighted the international role of lab medicine experts in diagnostic test regulation, including laboratory-developed tests. Faculty experts from the European Union described the EU's In Vitro Diagnostic Medical Device Regulation (IVDR) launch and its impact on clinical laboratories. Policymakers and regulatory agencies cannot maintain pace with the ever-increasing complexity of laboratory medicine and specialty testing. Understanding diagnostic innovations, emerging issues that impact lab operations, and advocating for lab medicine are critical aspects of laboratory medicine practice.
2. Faculty discussed how policies as proposed in the IVDR and US FDA regulations are likely to affect laboratories' day-to-day resources, management, and operations. The session included an interactive panel discussion that provided attendees with practical knowledge of the effect of policies on lab operations, and how to be involved to ensure their labs function optimally within the confines of said regulations to provide the highest quality patient care.
3. A notification d.d. 22 November 2024 was received from the ADLM senior director on education (Dennis Harris): this session was chosen to be a key part of a new online course titled "*Navigating FDA Oversight of LDTs: Insights and Implications from ADLM 2024*," which will be available starting December 16, 2024.

**D. ISMD conference in Graz, Austria, June 2024:**

Critical implications of the IVDR for continuation of essential tests and for innovation in diagnostics

**E. SKML conference in Ede, the Netherlands, 4th June 2024:**

Does the EU IVDR 2017/746 present a suitable framework for safe and effective medical tests?

**F. EFLM strategic conference in Padua, September 2024:**

The In-Vitro Diagnostic Regulation 2017/746: time to scrutinize!?

**G. RBSLM annual conference, Dolce la Hulpe, Brussels, 15 November 2024:**

The In-Vitro Diagnostic Regulation 2017/746: time to scrutinize!

**H. VDPH congress, Frankfurt, Germany, 27-28 November 2024: Auf dem Weg zur IVDR 2.0?**

IVDR aus Anwendersicht. Beyond Analytics: Impact der IVDR auf die Gesamtprozesskette des Laborbefundes.

In 2024 quarterly update **meetings took place with Medtech Europe** as well as numerous stakeholder meetings with the **European Commission** were attended. E.g. a phlebotomy in healthy individuals is seen as surgical intervention!

In 2024 the European Commission started several **TARGETED IVDR VALUATIONS** among all stakeholders and evaluated the IVDR fitness-for-purpose as well as the opportunities for improvement.

There are undistinguished problems with the knowledge level of the Notified Bodies and the IVD-industry, especially SMEs and newcomers, regarding clinical evidence generation and clinical study designs for

medical tests! Transversal collaborations between EFLM WG TE and TF-ERA to mutually work on this are key. Other opportunities for collaboration have to be explored:

1. Likely also a role for EFLM C-accreditation to give insight at the European level into which tests are suboptimal;
2. Collaboration with IFCC SD is also key and for sure complementary.

### **Need for IVDR reform!?**

A white paper with recommendations was put together with BMA in the lead, to provide input to EC on topics demanding IVDR reform.

### **Education and training!?**

Regulatory science should be structurally embedded in the education of trainees.

### **Task Force - Preparation of Labs for Emergencies (TF-PLE)**

The EFLM Task Force – Preparation of Laboratories for Emergencies (TF-PLE) was established on January 1, 2023, as part of the EFLM Strategic Plan 2022–2023. As with other Task Forces, this functional unit will transition into a Committee (C) in 2025. Currently, its activities are paused pending the enrollment of new full members. Reflecting on its past initiatives, the Task Force aimed to foster extensive discussion and develop a series of documents to help clinical laboratories and healthcare systems in Europe prepare for critical scenarios arising from various emergencies. Chaired by Prof. Giuseppe Lippi, the new C operates in line with the structure of other EFLM functional units, retaining all former Task Force members as expert consultants. Key achievements in 2024 included conducting a specialized survey on cybersecurity, with results published in the official journal of the EFLM Clinical Chemistry and Laboratory Medicine (Clin Chem Lab Med): „Lippi G, Cadamuro J, Danese E, Favalaro EJ, Favresse J, Henry BM, Jovicic S, Ozben T, Thachil J, Plebani M. EFLM Task Force Preparation of Labs for Emergencies (TF-PLE) survey on cybersecurity. Clin Chem Lab Med. 2024 Jul 4;63(1):e1-e2. doi: 10.1515/cclm-2024-0727“. Following the survey, the Task Force organized a joint meeting to develop recommendations for preventing and managing cyberattacks in clinical laboratories. These recommendations were also published in Clin Chem Lab Med: „Lippi G, Akhvlediani S, Cadamuro J, Danese E, García de Gadiana Romualdo L, Delacour H, Favalaro EJ, Favresse J, Henry BM, Jovicic S, Kütt M, Moreno Y Banuls L, Ozben T, Peretz A, Perovic A, Thachil J, Yucel D, Plebani M. EFLM Task Force Preparation of Labs for Emergencies (TF-PLE) recommendations for reinforcing cybersecurity and managing cyber-attacks in medical laboratories. Clin Chem Lab Med. 2024 Jul 17;63(1):27-34. doi: 10.1515/cclm-2024-0803“. In addition to these publications, a special session on cybersecurity was held during the 56th National Congress of SIBioC (Italian Society of Clinical Chemistry and Laboratory Medicine; Bologna, October 8–10, 2024). Prof. Lippi also delivered a lecture titled „Task Force (Committee): Preparation of Laboratories for Emergencies (TF-PLE)“ during a webinar organized by the Ukrainian Association of Clinical Chemistry and Laboratory Medicine, Challenges in the Work of Medical Laboratories in Ukraine During the War (November 7, 2024). Further, Prof. Lippi gave an interview titled Out of Technology, but Not Options for the journal Mbiomed, detailing the Task Force’s activities (now C-PLE). Plans for new initiatives in 2025 will commence once the composition of the Committee is finalized.

## Task Force - Direct-to-Consumer Testing (TF-DTCT)

Focus of the work in 2024 was the concept of patient / consumer self empowerment and shared decision making. The framework of in vitro diagnostics was scrutinized so that patients' safety is guaranteed and their health is improved by the use of in vitro testing while loopholes trying to evade safety regulations can be closed.

The TF held seven Webex meetings and two hybrid meetings (in Dubai (May 28, 2024) and Padova (September 22, 2025)).

The work of this taskforce will continue in 2025 after the merger with WG-PFLM into the C-DCLTPE.

Invited lectures were delivered on May 28, 2024 (IFCC Worldlab, Dubai, UAE), September 5, 2025 (SSCC/SGKC, Zürich, CH), September 24, 2025 (EFLM Strategic Conference, Padova, IT), September 27, 2025 (ADLM, San Diego, US), October 4, 2025 (ÖQUASTA, Iglis, AUT) and October 8, 2025 (SIBIOC, Bologna, IT).

### Publication

Shih P, Sandberg S, Balla J, Basok BI, Brady JJ, Croal B, De Vos N, Karlsson M, Kedars P, Ozben T, Pijanovic M, Plebani M, Orth M. Direct-to-consumer testing as consumer initiated testing: compromises to the testing process and opportunities for quality improvement. Clin Chem Lab Med. 2024 Aug 14. doi: 10.1515/cclm-2024-0876. Epub ahead of print. PMID: 39141796.

## MEETINGS

These are the EFLM live events that took place in 2024:

- EFLM Postgraduate Course - Dublin (IE), 2 February 2024  
**How to write a good scientific and professional article**  
*in collaboration with the Association of Clinical Biochemists in Ireland*
- EFLM Postgraduate Course - Helsinki (FI), 16-17 May 2024  
**Biostatistics in Laboratory Medicine**  
*in collaboration with the Finnish Society of Clinical Chemistry*
- EFLM Postgraduate Course - Tbilisi (GE), 12-13 September 2024  
**Biostatistics in Laboratory Medicine**  
*in collaboration with the Georgian Laboratory Medicine Association (GLMA)*
- 4th EFLM Strategic Conference - Padova (IT), 23-24 September 2024  
**A Vision to the future: value-based laboratory medicine**

## WEBINARS

EFLM has organized several Webinars during 2024, thanks to the new EFLM e-learning platform:

- 24/01/2024 - Hunting Unicorns. Digital Pathology Transformation of the Catalan Health Institute Network of 8 Hospitals. The DigiPatICS Project (Catalonia, Spain)
- 30/01/2024 - Immunology of sepsis: diagnostic and therapeutic challenges
- 15/02/2024 - MEET THE EXPERT: Analysis and interpretation of testing for antiphospholipid syndrome
- 20/02/2024 - Current trends in transplant immunology in the global village
- 05/03/2024 - Functional biomarkers of Sepsis immunosuppression
- 12/03/2024 - Chronic Stress and Exosomes as key players in precipitation and diagnosis of Alzheimer's disease
- 26/03/2024 - Role of the Clinical laboratory in the implementation of non-invasive tests for screening and diagnosis of MASLD
- 09/04/2024 - EV associated Biomarkers in Liquid Biopsies-How to identify valid microRNA Biomarker Signatures in circulating extracellular vesicles
- 23/04/2024 - Prioritizing patients' safety by elevating standards in our laboratory processes
- 07/05/2024 - Application of proteomics in biomarker discovery
- 09/05/2024 - MEET THE EXPERT Analysis & interpretation of cardiac markers and deciphering of High sensitive troponin
- 22/05/2024 - AI and digital Pathology implications on the Pathologists and the Pathology Laboratory
- 04/06/2024 - Role of pharmacogenomics in the individual response to therapeutic drugs
- 18/06/2024 - Male and female hypogonadism - laboratory workup
- 23/07/2024 - Between analyzer and laboratory medicine professional
- 17/09/2024 - Infrared Spectroscopy in the Modern Clinical Laboratory: A spectrum of opportunities
- 03/10/2024 - Post analytical procedures
- 08/10/2024 - Global coagulation testing - Global fibrinolysis testing
- 17/10/2024 - Web based Clinical Decision support tools
- 29/10/2024 - Hydrogen and methane breath tests in the service of the Gastroenterology Laboratory
- 07/11/2024 - MEET THE EXPERT: M-Protein diagnostics: analysis and interpretation of protein electrophoresis of serum, urine and cerebrospinal fluid
- 12/11/2024 - An evaluation framework for effective and safe Laboratory Information Systems
- 19/11/2024 - The ejaculate – problems and promises from proteomics and other investigations
- 09/12/2024 - MEET THE EXPERT Interpretation of laboratory results on kidney function
- 17/12/2024 - Calprotectin: diagnostic potential, challenges in analytics and application in inflammatory disorders

## **PUBLICATIONS**

### **Recommendations for European laboratories based on the KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease**

*Cavalier E, Zima T, Datta P, Makris K, Schaeffner E, Langlois M, Plebani M, Delanaye P, on behalf of the EFLM Task Group on Chronic Kidney Disease (TG-CKD)*

Clin Chem Lab Med <https://doi.org/10.1515/cclm-2024-1082>

**Systematic review and meta-analysis of biological variation data of urine albumin, albumin to creatinine ratio and other markers in urine**

*Aslan B, Carobene A, Jonker N, Galior K, Boned B, Marqués-García F, Ricos C, Bartlett W, Coskun A, Diaz-Garzon J, Fernandez-Calle P, Gonzales-Lao E, Simon M, Sandberg S, Aarsand A K, on behalf of the EFLM Task Group for the Biological Variation Database (TG-BVD)*

Clinica Chimica Acta 2024 <https://doi.org/10.1016/j.cca.2024.120032>

**A comprehensive survey of artificial intelligence adoption in European laboratory medicine: current utilization and prospects**

*Cadamuro J, Carobene A, Cabitza F, Debeljak Z, De Bruyne S, van Doorn W, Johannes E, Frans G, Özdemir H, Perez S M, Rajdl D, Tolios A, Padoan A, on behalf of the EFLM Working Group on Artificial Intelligence (WG-AI)*

Clin Chem Lab Med 2024 <https://doi.org/10.1515/cclm-2024-1016>

**Point-of-care testing, near-patient testing and patient self-testing: warning points**

*Banfi G, Božič B, Cihan M, Pašalić D, Pennestrì F, Plebani M*

Clin Chem Lab Med 2024 <https://doi.org/10.1515/cclm-2024-0525>

**Data flow in clinical laboratories: could metadata and peridata bridge the gap to new AI-based applications? An investigation on behalf of the EFLM Working Group on Artificial Intelligence (WG-AI)**

*Padoan A, Cadamuro J, Frans G, Cabitza F, Tolios A, De Bruyne S, van Doorn W, Elias J, Debeljak Z, Perez S. M, Özdemir H, Carobene A*

Clin Chem Lab Med 2024 <https://doi.org/10.1515/cclm-2024-0971>

**The final part of the CRESS trilogy – how to evaluate the quality of stability studies**

*Cornes M, Vermeersch P, Simundic AM, Von Meyer A, Salek T, Meyer B, Costelloe S, De Guire V, Gomez-Rioja R, Cadamuro J, on behalf of the EFLM Working Group for the Preanalytical Phase (WG-PRE)*

Clin Chem Lab Med 2024 <https://doi.org/10.1515/cclm-2024-0527>

**A vision to the future: value-based laboratory medicine**

*Plebani M, Cadamuro J, Vermeersch P, Jovičić S, Ozben T, Trenti T, McMillan B, Lowe C. R, Lennerz J, Macintyre E, Gabelli C, Sandberg S, Padoan A, Wiencek J. R, Banfi G, Lubin I. M, Orth M, Carobene A, Zima T, Cobbaert C. M, van Schaik R. H.N, Lippi G*

Clin Chem Lab Med 2024 <https://doi.org/10.1515/cclm-2024-1022>

**Direct-to-consumer testing as consumer initiated testing: compromises to the testing process and opportunities for quality improvement. An opinion paper from the EFLM DTCT-Taskforce**

*Shih P, Sandberg S, Balla J, Isbilen Basok B, Brady J. J, Croal B, De Vos N, Karlsson M, Kedars P, Ozben T, Pijanovic M, Plebani M, Orth M*

Clin Chem Lab Med 2024 <https://doi.org/10.1515/cclm-2024-0876>

### **Preservation of urine specimens for metabolic evaluation of recurrent urinary stone formers**

Šálek T, Musil P, Vermeersch P, Marrington R, Dikmen Z. G, Poláčková R, Kipman U, Kouri T, Cadamuro J, on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine Working Group Preanalytical Phase and Task and Finish Group Urinalysis

Clin Chem Lab Med 2024 <https://doi.org/10.1515/cclm-2024-0773>

### **EFLM Task Force Preparation of Labs for Emergencies (TF-PLE) recommendations for reinforcing cybersecurity and managing cyberattacks in medical laboratories**

Lippi G, Akhvlediani S, Cadamuro J, Danese E, de Guadiana Romualdo L. G, Delacour H, Favalaro E. J, Favresse J, Henry B. M, Jovicic S, Kutt M, Moreno y Banuls L, Ozben T, Peretz A, Perovic A, Thachil J, Yucel D, Plebani M

Clin Chem Lab Med 2024 <https://doi.org/10.1515/cclm-2024-0803>

### **The biological variation of insulin resistance markers: data from the European Biological Variation Study (EuBIVAS)**

Carobene A, Kilpatrick E, Bartlett A. W, Fernandez Calle P, Coskun A, Diaz-Garzon J, Jonker N, Locatelli M, Sandberg S, Aarsand K. A, on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine Working Group on Biological Variation

Clin Chem Lab Med 2024 <https://doi.org/10.1515/cclm-2024-0672>

### **A standard to report biological variation data studies – based on an expert opinion**

Bartlett WA, Sandberg S, Carobene A, Fernandez–Calle P, Diaz-Garzon J, Coskun A, Jonker N, Galior K, Gonzales-Lao E, Moreno-Parro I, Sufrate-Vergara B, Webster C, Itkonen O, Marques-Garcia F, Aarsand AK, on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine Task Group for the Biological Variation Database, and Biological Variation Working Group

Clin Chem Lab Med 2024 <https://doi.org/10.1515/cclm-2024-0489>

### **Outcome-based analytical performance specifications: current status and future challenges**

Horvath A. R, Bell J.L. K, Ceriotti F, Jones R.D. G, Loh Tze P, Lord S, Sandberg S, on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine Task Group Analytical Performance Specifications based on Outcomes

Clin Chem Lab Med 2024 <https://doi.org/10.1515/cclm-2024-0125>

### **Applying the Milan models to setting analytical performance specifications – considering all the information**

Jones R.D. G, Bell J.L. K, Ceriotti F, Loh T. P, Lord S, Sandberg S, Smith F. A, Horvath A. R, on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine Task Group Analytical Performance Specifications based on Outcomes

Clin Chem Lab Med 2024 <https://doi.org/10.1515/cclm-2024-0104>

### **The EFLM European Urinalysis Guideline 2023**

Kouri T, Hofmann W, Falbo R, Oyaert M, Schubert S, Gertsen J, Merens A, Pestel-Caron M, on behalf of the Task and Finish Group for Urinalysis (TFG-U), European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)

Clin Chem Lab Med 2024 <https://doi.org/10.1515/cclm-2024-0070>

**The European biological variation study (EuBIVAS): Biological variation data for testosterone, follicle stimulating hormone, prolactin, luteinizing hormone and dehydroepiandrosterone sulfate in men**

Itkonen O, Jonker N, Aarsand AK, Sandberg S, Diaz-Garzone J, Fernandez-Calle P, Coskun A, Bartlett WA, Locatelli M, Carobene A, on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine Working Group on Biological Variation

Chimica Clinica Acta 2024 <https://doi.org/10.1016/j.cca.2024.117806>

**Assessing post-analytical phase harmonization in European laboratories: a survey promoted by the EFLM Working Group on Harmonization**

Zaninotto M, Agnello L, Dukic L, Akhvlediani L, on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group on Harmonization

Clin Chem Lab Med 2024 <https://doi.org/10.1515/cclm-2024-0308>

**Recommendations for blood sampling in emergency departments from the European Society for Emergency Medicine (EUSEM), European Society for Emergency Nursing (EuSEN), and European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for the Preanalytical Phase. Executive summary**

Garcia-Castrillo L, Cadamuro J, Dodt C, Lauwaert D, Hachimi-Idrissi S, Van Der Linden C, Bergs J, Costelloe S, Grossmann F, Koca A, Palomäki A, Ruiz J.L, Stonys R, Thorsteinsdottir T.K, von Meyer A, Vermeersch P, Alvarez M.C.A, Eker P, Golea A, Kurland L, Lippi G, Zhilenkova Y, Sehmi K

Clin Chem Lab Med 2024 <https://doi.org/10.1515/cclm-2024-0059>

**Biological variation of inflammatory and iron metabolism markers in high-endurance recreational athletes; are these markers useful for athlete monitoring?**

Diaz-Garzon J, Itkonen O, Aarsand AK, Sandberg S, Coskun A, Carobene A, Jonker N, Bartlett WA, Buño A, Fernandez-Calle P, on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine Working Group on Biological Variation

Clin Chem Lab Med 2024 <https://doi.org/10.1515/cclm-2023-1071>

**Biological variation estimates of Alzheimer's disease plasma biomarkers in healthy individuals**

Brum WS, Ashton NJ, Simrén J, di Molfetta G, Karikari TK, Benedet AL, Zimmer ER, Lantero-Rodriguez J, Montoliu-Gaya L, Jeromin A, Aarsand AK, Bartlett WA, Calle PF, Coşkun A, Díaz-Garzón J, Jonker N, Zetterberg H, Sandberg S, Carobene A, Blennow K

Alzheimers Dement. 2024 <https://doi.org/10.1002/alz.13518>

**Sex-related differences in within-subject biological variation estimates for 22 essential and non-essential amino acids**

Coskun A, Carobene A, Demirelce O, Mussap M, Braga F, Sezer E, Aarsand AK, Sandberg S, Fernández Calle P, Díaz-Garzón J, Erkaya M, Coskun C, Nur Erol E, Dag H, Bartlett B, Serteser M, Jonker N, Unsal I, European Federation of Clinical Chemistry, Laboratory Medicine Working Group on Biological Variation, Task Group for the Biological Variation Database

Chimica Clinica Acta 2024 <https://doi.org/10.1016/j.cca.2023.117632>

**Analytical performance specifications based on biological variation data – considerations, strengths and limitations**

Sandberg S, Coskun A, Carobene A, Fernandez-Calle P, Diaz-Garzon J, Bartlett WA, Jonker N, Galior K, Gonzales-Lao E, Moreno-Parro I, Sufrate-Vergara B, Webster C, Aarsand AK, on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine Task Group for the Biological Variation Database

Clin Chem Lab Med 2024 <https://doi.org/10.1515/cclm-2024-0108>

**EFLM Working Group accreditation and ISO/CEN standards on dealing with ISO 15189 demands for retention of documents and examination objects**

Mesko Brguljan P, Thelen M, Bernabeu-Andreu F, Kroupis C, Boursier G, Vukasovic I, Barrett E, Brugnioni D, Lohmander M, Sprongl L, Vodnik T, Ghita I, Vanstapel F, Vaubourdolle M, Huisman W

Adv Lab Med 2024 <https://doi.org/10.1515/almed-2023-0053>

**APS calculator: a data-driven tool for setting outcome-based analytical performance specifications for measurement uncertainty using specific clinical requirements and population data**

Cubukcu HC, Vanstapel F, Thelen M, van Schrojenstein Lantman M, Bernabeu-Andreu FA, Mesko Brguljan P, Milinkovic N, Linko S, Panteghini M, Boursier G

Clin Chem Lab Med 2023 <https://doi.org/10.1515/cclm-2023-0740>

**A comprehensive review on PFAS including survey results from the EFLM Member Societies**

Ozben T, Fragão-Marques M, Tomasi A

Clin Chem Lab Med 2024 <https://doi.org/10.1515/cclm-2023-1418>

January 28<sup>th</sup>, 2025.