Opinion Paper

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Laboratory Medicine for Society

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Abstract: This collective opinion paper, based on presentations delivered during the two-day European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)

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Strategic Conference 2026, *"Laboratory Medicine for Society"* (Prague, Czech Republic, 24–25 April 2026) offers a forward-looking overview of the Federation's strategic priorities, ongoing initiatives, and future projects aimed at enhancing the value, visibility, and societal contribution of laboratory medicine, thereby ensuring a bright and sustainable future for the profession. By generating actionable information that supports clinical decision-making across the entire continuum of care, laboratory medicine contributes substantially to improving patient outcomes, enhancing healthcare efficiency, and promoting population health.

Keywords: EFLM; laboratory medicine; technological developments; value-based laboratory medicine; actionable visions

Introduction

The EFLM Strategic Conferences, initiated with the first edition held in Milan in 2014, are organized by the EFLM President and Executive Board with the objective of moving beyond traditional lecture-based meetings and fostering the development of actionable visions, strategies, and projects for the future of laboratory medicine. These conferences provide a unique forum that brings together leading experts in laboratory medicine, representatives of national societies, delegates from clinical scientific societies, healthcare stakeholders, and members of the diagnostic industry. Since their inception, the conferences have been hosted in different European cities, including Mannheim, Padova, and most recently Prague, reflecting the pan-European mission of EFLM. The meetings are designed not only to provide updates on emerging scientific and technological developments, but also to stimulate discussion on the evolving role of laboratory medicine within modern healthcare systems. Through multidisciplinary dialogue and strategic planning, the EFLM Strategic Conferences aim to identify priorities, address current challenges, and promote innovative initiatives that will strengthen the value, visibility, and impact of laboratory medicine for patients and society. The 2026 EFLM Strategic Conference was entitled *"Laboratory Medicine for Society"* to emphasize the increasingly central role of laboratory medicine in modern healthcare systems. The title reflects the recognition that laboratory medicine extends far beyond its traditional diagnostic function, serving as a cornerstone of preventive, predictive, personalized, and value-based healthcare. By generating actionable information that supports clinical decision-making across the entire continuum of care, laboratory medicine contributes substantially to improving patient outcomes, enhancing healthcare efficiency, and promoting population health. The conference therefore focused on how the discipline can further strengthen its scientific, clinical, educational, and societal impact, ensuring that laboratory medicine continues to meet the evolving needs of patients, healthcare professionals, and society at large.

Value-based laboratory medicine – moving forward

Mario Plebani

Accumulating evidence underscores a discordance between the intrinsic value of laboratory medicine in modern healthcare and its under-recognition and limited perception among clinicians and patients. For this reason, laboratory medicine has frequently been described as "the hidden science that saves lives". The promotion of value-based laboratory medicine (VBLM) seeks to increase the visibility of laboratory services while enhancing value, defined as the ratio of clinical outcomes to costs. This proposal is not entirely new; however, its novelty lies in translating the concept of value-based laboratory medicine (VBLM) into routine practice. This transition is inherently complex and requires an architectural redesign grounded on four fundamental pillars: science, practical tools, health economics, and the regulatory framework. The scientific pillar represents the foundation of this transformation and necessitates the effective translation of major advancements in laboratory medicine into clinical practice. This includes the adoption of evidence-based analytical performance specifications [1], robust standardization and harmonization processes, objective criteria for data interpretation [2], and the systematic measurement of processes and clinical outcomes. The value-based score represents a key practical tool to translate the concept of VBLM into routine practice. It is structured around six core domains: 1) Traceability in the total testing process (TTP)**; 2)** Level of automation, 3) Quality indicators; 4) Laboratory information management**,** 5) Interaction with clinicians, and 6) Innovation and research [3]. The proposed value-based score is currently undergoing evaluation and validation in 12 clinical laboratories at the European level. Health economics and the regulatory framework represent additional fundamental pillars of the architectural redesign required to shift clinical laboratories from a transactional model to a more proactive role. Finally, the effective implementation of VBLM into routine practice mandates robust collaboration and strategic partnerships among scientific organizations, alongside the active engagement of all relevant stakeholders, including clinicians and patients [4-5].

Harmonization of the different phases in the "brain to brain loop" – what is possible and who has the responsibility?

Sverre Sandberg

The aim of Section 1 during this Strategic Conference is to give a short overview of current harmonization initiatives in laboratory medicine, and to propose a strategy for identifying which activities EFLM should prioritise. The session will also explore how to establish an appropriate structure to support these activities and how to engage the IVD-industry. Harmonization of the different phases in the total testing process is an important factor to ensure high quality laboratory testing and thus potentially improve patient outcome. Harmonization must be made in all the phases of the total testing process, from test requesting to communication of laboratory test results to the users, and in the final step, its consequences to the patient. To be able to harmonise, three things are important: the professional content of the harmonization (what to harmonise and how), the responsibility for the harmonization process, and the structure to be used for harmonization. It will always be a question about what level of harmonization is possible at the various steps of the total testing process. It is important to define who should be responsible for facilitating and monitoring the effects of harmonization, and to identify the likely barriers to achieve harmonization [6]. Harmonization can be achieved at local, national and international levels, and will be most challenging when it involves more than one profession as e.g. in the extra-analytical phases where interactions with clinicians is crucial [7]. Important factors that must be considered which can both act as facilitators and barriers, can be professional associations, regulatory bodies, accreditation systems, reimbursement systems or other economic factors, opinion leaders and manufacturers. A challenge is to try to turn potential barriers into facilitators. Harmonization effects can in many settings be monitored by external quality assurance organisations provided that schemes are expanded to cover all relevant steps and phases [8]. We must combine our efforts, both within our profession as well as in cooperation with other stakeholders, to achieve harmonization of the total testing process, in the best interests of the patient. EFLM has initiated many harmonization activities in all phases of the examination process dealing with both the scientific and educational aspects of harmonization, with the intention of disseminating best practice in laboratory medicine throughout Europe. Some examples in the references [9–12]

What is the present role of EFLM in the harmonization work

Martina Zaninotto

Harmonization of laboratory reports is a continuous challenge for laboratory professionals. The harmonization of measurement units, reference intervals, and nomenclature/terminology, the three key factors characterizing laboratory reports, must be achieved by sharing and adopting the recommendations as well as by following the suggestions by guidelines of the National and International Societies [13]. A recently published survey on the harmonization of measurement units, reference intervals, and terminology conducted in EU countries in 2023 from Committee: Harmonization (C:H, EFLM) [14], demonstrates, in comparison to a similar survey performed in 2016, only minor progress toward harmonization – particularly regarding the use of recommended SI measurement units in laboratory reports (+13 %), due to persistent use of non-SI units in specific countries/regions – despite continuous efforts by professional organizations in this field. Such findings raised several concerns about patient safety, especially in the context of implementing the European Health Data Space (EHDS) project [15]. The EFLM is strongly supporting the activities of C:H to raise awareness of the urgent need to implement recommended SI measurement units among all stakeholders, primarily institutions (international/national agencies and societies), accreditation bodies, EQA providers, IVD manufacturers, as well as editors of scientific journals and members of scientific committees through meetings between the relevant committees as well as networking among international working groups dedicated to harmonizing laboratory result reports. The ensuing discussion focuses on the development of recommendations for the optimal use of SI units in specific settings, that should be adopted not only by laboratory professionals but also by IT specialists who develop coding systems tailored for the safe and reliable transfer of unambiguous laboratory data within the Electronic Health Data Space (EHDS). Furthermore, the lack of harmonization in reporting results raises relevant ethical problems that should be clearly defined and properly addressed by ethical committees of the laboratory medicine societies (EFLM, IFCC). Moreover, from practical point-of-view, the application of well-defined and detailed rules regarding the appropriate and scientifically sound use of measurement units in specific settings, will enable acceptance by all partners involved in the harmonization process [12]. This approach is currently being refined through the collaboration with experts, representatives of the laboratory international societies, all stakeholders involved and the discussion with the IFCC Task force on Laboratory Medicine Guidelines, to share the

strategy aiming to prepare by C:H and to approve by EFLM a recommendation, drafted considering a sustainable and widely acceptable approach towards full implementation.

Applying ISO 17511:2020 to test harmonization: scientific guidance from IFCC SD and envisioned European implementation with EFLM

Christa Cobbaert

Harmonization of laboratory test results is essential to ensure comparability of measurements across analytical methods, manufacturers, and geographical regions, thereby supporting safe clinical decision-making, guideline implementation, and longitudinal patient monitoring. ISO 17511:2020 provides a contemporary framework for establishing metrological traceability of values assigned to calibrators and control materials for *in vitro* diagnostic (IVD) medical devices. Within this framework, the IFCC Scientific Division (SD) has a central responsibility to provide global scientific leadership on establishing reference systems, traceability concepts, and harmonization strategies. The descriptive ISO 17511:2020 represents a significant evolution from the earlier prescriptive 17511:2003 edition by explicitly recognizing that different measurands require different traceability solutions. Rather than mandating a single calibration hierarchy, the standard describes multiple legitimate traceability pathways, including traceability to SI units, traceability to conventional reference systems, and harmonization based on IVD-manufacturer-assigned or consensus values when higher-order reference systems are unavailable. The IFCC SD supports this flexible, analyte-specific approach and emphasizes that harmonization strategies must be scientifically feasible, clinically appropriate, and transparently documented. Where reference measurement procedures and commutable reference materials exist, the IFCC SD advocates full standardization with SI traceability as the preferred approach. However, for many clinically important measurands – such as hemoglobin A1c, enzymes, hormones, autoantibodies and tumor markers – SI traceability is not (yet) technically achievable or clinically meaningful. In such cases, the IFCC SD endorses conventional reference systems or robust harmonization approaches that ensure global comparability, long-term stability, and preservation of clinical interpretation. The IFCC HbA_{1c} reference measurement system exemplifies successful conventional standardization within the ISO 17511:2020 framework. The IFCC SD further emphasizes that harmonization is fundamentally a clinical requirement and metrology serves as a means to that end. Harmonization is embraced to improve clinical care whereas metrology serves that purpose but should not override it. Calibration strategies should therefore be evaluated in relation to intended use, clinical risk, and continuity of patient results over time. Inappropriate pursuit of higher-order traceability without demonstrable clinical benefit may disrupt established decision limits and increase patient risk and does not represent optimal application of ISO 17511:2020. Effective harmonization also requires translation of scientific principles into routine practice. In this context, collaboration between the IFCC SD and the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) offers substantial added value. While the IFCC SD provides global scientific authority on reference systems and traceability, EFLM contributes regional expertise in implementation, education, and interaction with European regulators, accreditation bodies, and professional societies. Such complementarity enables consistent interpretation of ISO 17511:2020, supports risk-based and clinically driven application under regulatory frameworks such as the EU IVDR, and facilitates harmonized uptake across routine laboratories. Through joint scientific guidance, educational initiatives, and coordinated communication with stakeholders, IFCC and EFLM collaboration can strengthen harmonization strategies that are scientifically sound, clinically meaningful, and consistently applied. By promoting analyte-specific harmonization within the ISO 17511:2020 framework, the IFCC SD – working in partnership with EFLM – aims to ensure reliable and comparable laboratory results worldwide, ultimately improving patient care.

Disclaimer

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EQALM perspectives on how EQALM and EFLM can cooperate regarding harmonization

Gro Gidske

Medical laboratory test results play an important role in diagnosing and monitoring disease. Test results are often compared with previous results, reference intervals, or decision limits, and ensuring accurate and equivalent results

across time and location is therefore crucial. This requires continuous assessment and improvement of the total testing process, from test request and sample collection to analysis, interpretation, and follow-up. External quality assurance (EQA) is a key tool for monitoring and improving quality throughout these steps, and EQA data provide valuable insight into the current level of harmonization across laboratories. The European Organisation for External Quality Assurance in Laboratory Medicine (EQALM) [16] is the umbrella organisation for European EQA providers in laboratory medicine, offering a forum for cooperation and exchange of knowledge and representing EQA providers at European level vis-à-vis political, professional, and scientific bodies. The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) and EQALM operate under a Memorandum of Understanding and recognise the added value of working together to strengthen coordination and collaboration on issues of common interest and to improve the quality of laboratory medicine in Europe. Close coordination between EFLM committees and EQALM working groups, with early joint planning of projects, surveys, recommendations and other publications, is essential for achieving this goal. Collaboration is already well established through reciprocal representation in the EQALM Working Group and the EFLM committees on preanalytical and postanalytical Phases, providing a strong foundation for coordinated harmonization activities. Collaboration is further developed through reciprocal representation in the EQALM working group Performance Specifications and those EFLM committees which develop guidance on all elements related to the clinical equivalence, including harmonization, clinical and analytical performance specifications, measurement uncertainty, laboratory data exchange, and ISO/CEN standards and accreditation. In this interaction, the role of the EQALM working group Performance Specifications is in all cases to provide guidance to EQA organisers on how their EQA schemes can be fit for purpose within the EFLM ecosystem of recommendations that relate to safe data exchange of equivalent results within clinically relevant tolerances.

We also see a clear advantage in fostering closer collaboration between the EFLM committees and EQALM's other working groups: Emerging Technologies, EQA for point-of-care testing (POCT), EQALM Central Database, Frequency, Haematology, Haemostasis, Immunohaematology, Immunology, Infection diagnostics, and ISO standards. Both organisations provide important platforms for cooperation through their symposia and meetings, which can be more actively used to present joint projects. EFLM and EQALM have agreed to share communication channels and professional networks to promote each other's projects and activities, an opportunity for mutual support that we believe could be utilised more widely. A recent example is EQALM encouraging its members to participate in an EFLM harmonization initiative recommending the use of SI units in laboratory reporting. This and other harmonization promotion can ensure broader engagement and implementation of important activities across Europe.

Reference interval harmonization in Canada: a strategic national framework for standardized laboratory reporting

Khosrow Adeli

Reference intervals (RIs) are essential for the interpretation of laboratory results and remain one of the most frequently used tools supporting clinical decision-making. However, persistent variation in RI limits across laboratories continues to undermine consistency in test interpretation, create potential inequities in patient care, and limit the comparability of results across institutions and jurisdictions. In Canada, a national survey [17] conducted by the Canadian Society of Clinical Chemists (CSCC) Working Group on Reference Interval Harmonization demonstrated marked variability in both adult and pediatric RIs used by clinical laboratories, including laboratories using comparable analytical platforms. These findings highlighted RI variation as not only a technical issue, but also a health system standardization challenge requiring coordinated national action. Canada's response has been to build a coordinated, evidence-based harmonization strategy that aligns laboratory medicine with broader goals of quality, standardization, and equitable care. A major strength of the Canadian model has been the integration of pediatric and adult initiatives. The CALIPER program [18] established a robust pediatric RI framework based on healthy community populations, with age- and sex-specific intervals and validated processes for transference across platforms. This provided an important proof of concept that nationally coordinated RI programs can support standardized interpretation while remaining scientifically rigorous and operationally feasible. For adult testing, the CSCC harmonization initiative [19] adopted a policy-relevant multi-step strategy combining indirect data mining from large provincial laboratory databases, comparison with direct studies in healthy populations, assessment of assay traceability and analytical equivalence, and multicenter verification across major manufacturers. This approach reflects an important strategic shift: harmonization is not pursued as a

purely statistical exercise, but as a structured national quality initiative grounded in evidence, implementation feasibility, and stakeholder consensus. The recent Canadian best practice guideline [20] marks an important milestone by recommending harmonized RIs for 13 common chemistry analytes, including creatinine, calcium, chloride, magnesium, phosphate, potassium in serum, total protein, alanine aminotransferase, alkaline phosphatase, total carbon dioxide, lactate dehydrogenase, thyroid-stimulating hormone, and albumin measured by bromocresol green methodology. From a policy perspective, these recommendations provide a national framework that laboratories can adopt to reduce unwarranted reporting differences, improve interpretive consistency, and strengthen continuity of care across regions. The Canadian experience demonstrates that RI harmonization should be recognized as a strategic priority in laboratory medicine. Successful implementation depends on national professional leadership, access to high-quality population data, assay standardization, external quality assessment, and mechanisms for verification and local adoption. Importantly, harmonization supports not only better laboratory practice, but also system-level goals of standardization, interoperability, and patient safety. As health systems increasingly emphasize integrated care and comparable diagnostic information, the Canadian initiative offers a scalable model for other countries seeking to embed RI harmonization within national laboratory quality strategies.

Making the standardization benefits achievable through structured post-market surveillance and application of suitable performance specifications

Mauro Panteghini

Nowadays, we are facing major changes in the landscape of laboratory test harmonization, which are asking stakeholders for a dedicated effort to obtain the expected benefits in terms of standardization of laboratory results. There are at least four important developments that should be considered [21, 22]. First, the new IVD Regulation 2017/746 of the European Union has reiterated the requirement of metrological traceability of laboratory test results to standards of higher metrological order. Second, the ISO 17511:2020 standard has described in detail a set of technical conditions that should be fulfilled to meet the requirements on metrological traceability of the mentioned Regulation. Third, the work of the Joint Committee on Traceability in Laboratory Medicine, offering a quality-assured database of higher-order reference materials, reference measurement procedures (RMP), and accredited reference measurement services, has become highly relevant. Finally, the idea that IVD-MD and individual laboratory performance should be judged against performance specifications (PS) defining the quality required for laboratory results to satisfy clinical needs has been consolidated. However, having traceability tools in place does not automatically mean that metrological traceability is correctly implemented [23]. As interventions that are poorly implemented do not produce expected benefits, it is time to move from just discussing the effectiveness of traceability theory to how correctly implement it and effectively monitor its effects. In particular, considering the implementation outcomes, there is still a limited knowledge about the actual harmonization status of laboratory test results. We need to increase the information about the expected outcome by assessing result uniformity across different IVD-MDs through a structured approach providing an ongoing robust evidence of standardization effectiveness. External Quality Assessment (EQA) programs have an irreplaceable role in this IVD traceability surveillance providing that they fulfill specific requirements. i.e., the use of commutable materials with target values assigned by RMP or strictly controlled procedures, if RMP does not exist, and with validation of results in relation to fit-for-purpose PS [24]. If adequately structured, EQA programs can create evidence about intrinsic standardization status and equivalence of the examined IVD-MDs, serving as management tool for the medical laboratory and IVD manufacturers, and forcing them to investigate and eventually fix the identified problems. In this way, major stumbling blocks opposing the correct implementation of metrological traceability and the obtaining of harmonized laboratory results can be identified and removed.

IVD-industry perspective on harmonization aspects

Dušanka Kasapić

In the evolving landscape of clinical diagnostics, the harmonization of laboratory results remains a cornerstone for patient safety and global healthcare standardization. However, the *In Vitro* Diagnostic (IVD) industry faces a complex web of logistical and regulatory barriers that impede the transition from theoretical harmonization to practical implementation. This abstract outlines the industry perspective on the hurdles and the collaborative solutions required to align diagnostic outcomes. Successful rollout of

harmonization activities is frequently hindered by significant financial and administrative hurdles. Key obstacles include: a) High development costs for manufacturers and a perceived lack of clinical demand; b) Administrative complexities regarding the acquisition of clinical specimens; c) Fragmented global regulatory frameworks; any assay modification necessitating re-registration acts as a major hurdle and d) The absence of synchronized implementation across manufacturers, which risks temporarily increasing result variability.

Strategic priorities for harmonization

To overcome these barriers, a multi-faceted approach is proposed: Reference Range Studies: There is a critical need for a harmonized approach to reference range studies that exceeds current CLSI standards. This includes establishing uniform inclusion/exclusion criteria for specific populations (neonates, pediatrics, pregnancy) and exploring Real-World Data (RWD) through indirect methods, such as the refine R algorithm.

External Quality Assessment (EQA): Ideally, the EQA framework should prioritize the commutability of materials, with target value assignments linked to Reference Measurement Procedures (RMP) or traceable to commutable Certified Reference Materials (CRM).

Clinical Practice Guidelines: Medical decision limits must be re-evaluated in light of harmonized data, necessitating full transparency in the documentation and disclosure of methods used to establish these points.

The role of collaboration and education

The industry advocates for a joint collaboration model involving the EFLM and IFCC to drive a “globalized” regulatory framework and oversee cross-manufacturer studies. Furthermore, the transition requires a robust educational strategy. Industry scientists are equipped to provide the necessary materials to prepare laboratories, clinicians, and patients for shifts in reported values, ensuring that changes occur in a timely, synchronized manner to mitigate clinical risk. In conclusion, harmonization is not merely a technical adjustment but a systemic evolution [25, 26]. By addressing regulatory fragmentation and leveraging new data-driven methodologies, the IVD industry and professional bodies can ensure that laboratory results are consistent, comparable, and clinically actionable worldwide

Advances in mass spectrometry: automation and integration

Pieter Vermeersch

Liquid chromatography-mass spectrometry (LC-MSMS) offers the advantage of better sensitivity and specificity compared to immunoassay. In-house LC-MSMS assays are, however, more laborious and traditionally performed in a batch-wise mode by dedicated laboratory technicians. The integration of LC-MSMS into clinical laboratories is also challenging due to the technical complexity, lack of automation, need for time-consuming manual sample and reagent preparation, and extensive data review.

Efforts have been made to automate LC-MS/MS methods, with a view to minimizing manual involvement of the user, reducing turnaround times, and rendering LC-MS/MS more suitable for high – throughput use by non-specialist staff in routine clinical environments. The Cascadion SM Clinical Analyzer (Thermo Fisher Scientific, Vantaa, Finland) launched in 2017 was the first fully automated LC-MS/MS instrument. The Cascadion was an automated LC-MSMS with multiplexing of 2 LC streams coupled to a single MSMS. An interlaboratory comparison study showed excellent comparability between laboratories for immunosuppressants, demonstrating that a fully automated LC-MSMS platform could allow a new level of harmonization of results [27]. Only 2 assays were ever approved (immunosuppressants and 25-OH vitamin D) and Cascadion was discontinued in 2023. In 2025 the company Roche (Roche Diagnostics, Rotkreuz, Switzerland) launched the cobas i 601 automated LC-MSMS analyzer. Notable improvements compared to the Cascadion are the more extensive online sample preparation using magnetics beads, automatic onboard mixing of mobile phases rather than assay-specific mobile phase, and the inclusion of three high-performance LC columns in addition to five rapid LC columns. This allowed the development of a broad assay menu with more than 60 analytes under development. The analyzer can be operated in random access without impacting the precision by non-expert staff and calibration is only required every few weeks [28]. A workflow analysis at multiple laboratories showed that the i 601 analyzer substantially reduced turnaround and hands-on times for

common analytes [29]. In the near future it will be possible to connect the cobas i 601 to a track, allowing integration into a 24/7 core laboratory. The introduction of automated random-access LC-MSMS into the routine clinical laboratory marks a new phase in laboratory medicine and will improve access to mass spectrometry testing.

Multi-omics revolution: from data to tailored therapies

David Friedecký

Patients with the same diagnosis and treated with the same drug may experience markedly different outcomes. This variability reflects differences in the genome, epigenome, transcriptome, proteome, metabolome, microbiome and environmental exposures that are not captured by conventional phenotype-driven diagnostic pathways. Multi-omics integrates these molecular layers into a clinically interpretable patient portrait and is rapidly moving from a research concept toward decision support in routine laboratory medicine. In oncology, integrated tumor profiling, liquid biopsy, and artificial intelligence-based models support patient stratification, treatment selection, and monitoring of resistance [30]. In metabolic disease and diabetes, combined metabolomic, microbiome, and clinical data can identify treatment responders and reveal new therapeutic targets [31]. In sepsis and critical care, transcriptomic and metabolic signatures may enable earlier diagnosis, molecular subtyping, and risk prediction in time-critical settings. The translation of multi-omics into clinical practice, however, depends less on data volume than on laboratory quality. Metabolomics and lipidomics illustrate the challenge: pre-analytical variables, platform-dependent measurement, incomplete annotation, inconsistent nomenclature, and limited reference materials can generate substantial inter-laboratory variability. Machine learning models trained on such data may learn batch effects rather than biology. In contrast, diagnostics of inherited metabolic disorders demonstrate a more mature path to implementation. Complementary validated liquid chromatography-tandem mass spectrometry platforms can combine orthogonal separations, multianalyte interpretation, age-stratified robust standardized values, and network visualization to deliver rapid, clinically actionable metabolic profiles [32]. The next step is to extend this philosophy to the broader omics ecosystem. Laboratory medicine must lead pre-analytical standardization, inter-laboratory harmonization, external quality assessment, clinical validation, and education. The future clinical laboratory will not only measure analytes; it will integrate molecular information into reliable, patient-specific decisions.

How laboratory medicine will change in the near future: integrating artificial intelligence, automation, and human expertise in laboratory medicine: an Industry 5.0 perspective

Janne Cadamuro, Cornelia Mrazek, Sylvia Mink

The field of laboratory medicine is facing its most disruptive transformation so far. The integration of Artificial Intelligence (AI) and advanced automation are changing the laboratory diagnostic process from a technology-centered approach of Industry 4.0 to a more human-focused one in Industry 5.0 [33].

Laboratories have always been aiming for the highest quality of test results while maintaining low turn-around times. This has led to highly automated “number factories”. This development was fueled by an ever increasing availability of diagnostic testing (e.g. by implementation of electronic order/entry systems or total lab automations) and the according demand from clinicians. As the increasing amount of data and information ultimately must overwhelm human capabilities in terms of information chaos, new ways of processing this information become necessary [34]. The strategic integration of AI and machine learning (ML) into the diagnostic process is inevitable to turn numbers into actionable information. This may suggest that ML models and AI will replace humans in the lab. Although the future is uncertain, we believe that Industry 5.0 will combine advanced technology with human expertise. The goal is not to replace professionals but to support them, allowing technology to handle repetitive or predictable tasks while lab specialists in collaboration with clinicians focus on interpretation, judgement, and clinical decision-making. A key element of this development will be the introduction of collaborative robots (“cobots”). Unlike traditional laboratory robotic systems, which were the foundation of total lab automations, cobots are designed to assist and interact with lab personnel. They offer consistency and precision of automation while leaving space for human reasoning and experience. As a result, the role of laboratory physicians is changing. Rather than primarily validating routine results, they can focus on more complex cases and diagnostic stewardship. Amidst all enthusiasm, the challenges of reliable

data and regulatory frameworks need to be addressed. These are essential to safely use machine-learning systems in clinical practice. Another concern is the risk that excessive reliance on AI assistance might lead to reduced opportunities to learn from diagnostic errors or to develop new insights, ultimately reducing the need of critical thinking, so-called automation bias or AI-induced deskilling [35]. Considering all of the mentioned pros and cons, the introduction of these technologies requires careful planning and interdisciplinary collaboration. If implemented well, the principles of Industry 5.0 could reshape laboratory medicine into a highly specialized consultative service. In such a model, laboratories would change from being a "number factory" to being an indispensable partner in patient care.

Safe and sound: implementing AI with confidence and governance

Andrea Padoan

Artificial intelligence (AI) and machine learning (ML) are increasingly recognized as transformative tools in laboratory medicine, supporting predictive diagnostics, clinical decision-making and workload reduction. Despite the exponential growth of scientific literature, a substantial gap remains between research and real-world implementation. This discrepancy is driven not only by regulatory and organizational barriers, but also by intrinsic challenges related to data quality, analytical variability, and model validation and maintainance.

Laboratory data present unique complexities, including method dependency, analyte-specific variation, and sensitivity to pre-analytical and analytical conditions. These factors, if not accounted in machine learning (ML) models, can significantly influence AI performance and limit the generalizability of models across settings. Evidence from recent studies highlights that even analytically acceptable bias may result in clinically relevant shifts in outputs, potentially leading to patient misclassification. Furthermore, most AI applications in laboratory medicine lack robust external validation and auditability, and their adoption in routine workflows remains limited across key use cases. To ensure safe and trustworthy AI implementation, adherence to rigorous data governance principles is essential. Key elements include the integration of metadata and peridata [36], ensuring that data are compliant with FAIR standards. Standardization, continuous performance monitoring, and context-aware validation strategies are critical to guarantee reliability and reproducibility. Bridging the implementation gap will be pivotal to fully leverage AI in laboratory medicine, enabling more efficient, accurate, and patient-centered diagnostic pathways, while paving the way for future innovations such as digital twins and agentic AI systems – technologies that are already being applied in other areas of medicine.

Shaping the future: AI, data-driven innovation and emerging technologies in diagnostics

Damien Gruson

The rapid evolution of artificial intelligence (AI), multi-omics, and advanced diagnostic technologies is profoundly reshaping laboratory medicine. During the session 2 of the EFLM Strategic Conference 2025, experts from academia, healthcare institutions, and the IVD industry explored how these innovations are redefining diagnostics, clinical decision-making, and patient-centered care. A major theme throughout the session was the transition toward an "Industry 5.0" paradigm, where intelligent systems collaborate with healthcare professionals rather than replacing them. AI applications are already supporting laboratory workflows through automated quality control, reflex testing algorithms, and decision-support systems. However, speakers emphasized that human expertise and clinical accountability remain essential to ensure safe and meaningful implementation. Another central topic was the growing role of multi-omics integration in precision medicine. Combining genomics, proteomics, metabolomics, and lipidomics enables unprecedented characterization of disease mechanisms and patient stratification. Yet, despite technological advances, interoperability, harmonized data standards, and bioinformatics infrastructure remain significant barriers to large-scale clinical implementation. Laboratories are therefore expected to evolve into multidisciplinary data-science hubs capable of integrating analytical, computational, and clinical expertise. Mass spectrometry (MS) also emerged as a transformative technology moving rapidly from specialized research laboratories into routine clinical practice. Advances in automation, workflow integration, and AI-assisted spectral interpretation are reducing analytical variability and enabling high-throughput testing. Emerging applications include automated monoclonal protein detection and highly sensitive minimal residual disease monitoring, potentially replacing traditional electrophoretic methods in some clinical settings.

The conference further highlighted the importance of governance and regulatory preparedness. Several contributors stressed that AI tools in diagnostics must undergo

rigorous analytical validation, clinical utility assessment, and continuous post-market surveillance, similarly to conventional *in vitro* diagnostic devices. Transparency, explainability, and bias mitigation were repeatedly identified as mandatory requirements for trustworthy AI deployment. Participants also emphasized the urgent need for proactive governance frameworks aligned with evolving European regulations, including the EU AI Act and IVDR.

Beyond central laboratories, innovation is increasingly expanding toward decentralized and preventive healthcare models. Smartphone-connected biosensors, point-of-care devices, and liquid biopsy approaches are bringing precision diagnostics closer to patients and underserved populations. Such technologies could significantly improve early detection of chronic diseases, including type 2 diabetes, hypertension, and pancreatic cancer.

Importantly, the session underscored that technological progress alone is insufficient. Education, digital literacy, multidisciplinary collaboration, and equitable access must accompany innovation to avoid widening healthcare disparities. The discussions concluded with several calls to action for the laboratory medicine community, including the development of AI governance frameworks, reinforcement of digital competencies, and stronger collaboration between scientific societies, regulators, healthcare providers, and industry partners. Overall, this session illustrated that laboratory medicine is entering a new era (Figure 1) where AI, omics technologies, and advanced diagnostics will not only improve analytical performance but also fundamentally redefine the role of laboratories within future healthcare systems.

The future of AI-driven medicine

Ema Popova

Healthcare is entering a period of "frontier transformation," in which artificial intelligence (AI) is shifting from isolated pilots to an enterprise operating capability. Medicine sits at the centre of this shift: more than 95 % of health data is unstructured and multimodal – spanning structured laboratory results, pathology, radiology, genomics, and free-text clinical notes – and effective AI requires that these data streams be unified, harmonized, and reasoned over in clinical context. This presentation outlines a framework for AI-enabled medicine built on four pillars: empowering the workforce, personalizing patient experiences, unlocking value from clinical and operational data, and accelerating research and discovery. The framework is grounded in interoperable data foundations using FHIR and DICOM, multimodal medical foundation models (e.g., MedImageInsight, MedImageParse, CXRReportGen), and orchestrated specialized agents – including patient-history, pathology, radiology, clinical-guidelines, and clinical-trials agents – coordinated by a healthcare agent orchestrator and governed by clinical safeguards (hallucination and omission detection, clinical provenance, code validation, semantic validation, and conflict detection). Realizing AI-driven

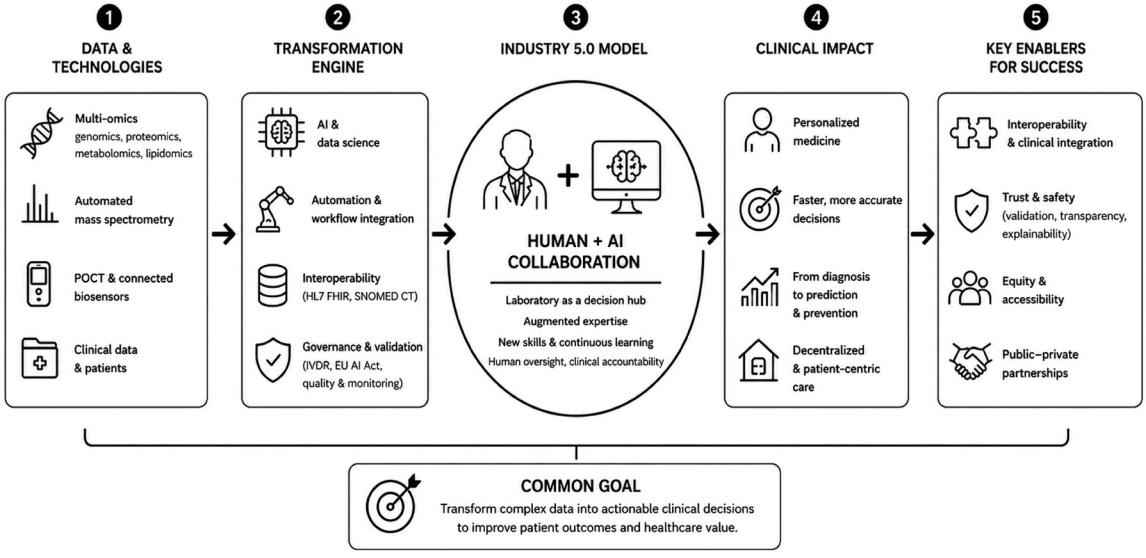

Figure 1: Conceptual overview of the future laboratory ecosystem integrating artificial intelligence, multi-omics, automation, interoperability, and emerging diagnostic technologies within an Industry 5.0 framework. The model highlights how human–AI collaboration, governance, and connected diagnostics may transform laboratory medicine from reactive testing toward predictive, personalized, and patient-centered healthcare.

medicine requires laboratory professionals to lead on data quality, interoperability, and validation. Responsible, multimodal, agentic AI – anchored in trusted laboratory data – is becoming a prerequisite for safe, scalable precision medicine.

The MedTech Europe perspective

Martin Fuhrer

At the EFLM Strategic Conference 2026 in Prague, Martin Fuhrer – Board Member of MedTech Europe & Siemens Healthineers, Executive Vice President – Global Head of Specialty Lab Solutions – reflected the perspective of MedTech Europe and the *in vitro* diagnostics (IVD) industry as committed partners in advancing laboratory medicine as a public good. Building on the conference theme "Laboratory Medicine for Society", his intervention highlighted the increasing importance of diagnostics in prevention, precision medicine, and optimized patient pathways across Europe. The EFLM Strategy 2026–2027 is a timely and ambitious framework, emphasizing patient-centered care, integration of diagnostics across disciplines, and the responsible use of innovation, including data and artificial intelligence. It calls for moving laboratory medicine out of the "black box" toward greater visibility, clinical impact, and societal value. In this context, the partnership between EFLM and MedTech Europe – formalized through a memorandum of understanding in April 2024 – is highlighted as a key enabler of progress. Cooperation focuses on critical areas such as IVD regulation, clinical evidence generation, accreditation, digital health, sustainability, value promotion and ethical business practices, all of which directly influence patient access to innovation and quality care outcomes. I also acknowledged the rapid transformation of the sector, driven by advances in AI, data interoperability, and decentralized testing models. He highlighted the importance of innovation for improving quality, trust, and clinical value, while preserving the central role of laboratory professionals. The IVD sector positions itself as a co-developer of healthcare solutions, a long-term partner to laboratories, and a driver of clinically meaningful and sustainable innovation. My intervention to the EFLM strategic Conference reinforces MedTech Europe's commitment to collaboration with EFLM, IFCC, and the broader laboratory community to ensure that scientific excellence in laboratory medicine translates into tangible benefits for patients and society. In this context, the appointment of Pierre-Yves Brevet as MedTech Europe Liaison Manager for EFLM further strengthens the collaboration between the two organisations and supports the continued alignment of their strategic priorities.

The next generation of M-protein analysis

James Last

Quantitative immunoprecipitation mass spectrometry (QIP-MS) using matrix-assisted laser desorption/ionization time-of-flight (MALDI-TOF) has become an increasingly valuable method for monitoring monoclonal proteins in plasma cell disorders such as multiple myeloma. Conventional diagnostic techniques, including serum protein electrophoresis (SPE) and immunofixation electrophoresis (IFE), are limited by relatively low sensitivity and challenges in distinguishing endogenous monoclonal proteins from therapeutic monoclonal antibodies [37]. By integrating selective immunoprecipitation with MALDI-TOF analysis, the EXENT® system provides a more sensitive and specific alternative. Antibodies targeting specific immunoglobulin heavy chains or light chains are used to selectively isolate monoclonal proteins from patient serum [38]. The isolated immunoglobulins are then reduced to separate heavy and light chains, enabling clearer downstream analysis. MALDI-TOF mass spectrometry is subsequently employed to analyze the mass distribution of these components. This technique allows for rapid, high-throughput analysis with minimal additional sample preparation. The resulting spectra display monoclonal proteins as distinct peaks corresponding to their molecular weights. Because each monoclonal immunoglobulin exhibits a unique mass signature – particularly in the light chain region – this approach enables precise identification and longitudinal tracking of specific clones in individual patients. Quantification of the immunoglobulins is achieved through relative comparison of peak areas as a percentage of total immunoglobulin measurement by turbidimetry on the Optilite® analyser. The reproducibility of relative measurements enables sensitive detection of changes in monoclonal protein levels, supporting evaluation of treatment response and early identification of disease relapse.

A key advantage of the EXENT system is its ability to differentiate endogenous monoclonal proteins from therapeutic antibodies, a common limitation of traditional assays, such as SPE. In addition to protein identification and quantification, MALDI-TOF IP-MS enables the detection of post-translational modifications (PTMs), which can alter the molecular mass of immunoglobulin chains [39, 40]. The ability to identify these PTMs is clinically relevant, as they may influence protein stability, disease biology, and, in some cases, pathogenicity. For example, aberrant glycosylation of light chains has been associated with certain plasma cell disorders and can be detected as distinct mass variants using

EXENT analysis. Therefore, the EXENT system represents a significant advancement in monoclonal protein monitoring and holds strong promise for improving patient management in plasma cell disorders.

When diagnosis becomes prediction: reimagining medicine through data and nanotechnologies

Bernard Gouget

Medicine is entering a new era in which biological measurements are no longer isolated results but components of large-scale data ecosystems. For more than a century, laboratory medicine has been structured around the measurement of individual biomarkers to support clinical diagnosis. This paradigm is now being challenged by the convergence of nanotechnology, large-scale biological data generation and artificial intelligence. Together, these advances are transforming the nature of biomedical information, shifting the focus from single measurements to integrated data interpretation and progressively redefining the role of laboratory medicine within data-driven healthcare systems. Nanotechnologies are rapidly expanding the analytical frontier of diagnostics. Nano-biosensors, multiplex molecular platforms and miniaturized lab-on-chip systems now allow the detection of biological signals at extremely low concentrations and with unprecedented temporal resolution. Beyond improving analytical sensitivity, these technologies enable the capture of high-density molecular signatures reflecting the dynamic state of biological systems, opening new perspectives for precision diagnostics and personalized medicine [41]. At the same time, advances in genomics and other omics technologies are generating vast volumes of heterogeneous biological data. When combined with electronic health records, imaging data and real-world health information, these datasets form complex biomedical ecosystems that require new approaches for interpretation. Artificial intelligence and machine learning are increasingly capable of identifying weak signals and multidimensional biomarker interactions within these data environments, enabling earlier detection of biological deviations associated with disease onset and progression [42, 43]. The convergence between nano-scale diagnostics and AI-driven analytics therefore opens the possibility of a transition from episodic diagnostics toward predictive and anticipatory medicine. Emerging concepts such as digital twins, computational representations of individual patients integrating biological, clinical and environmental data, may allow simulation of disease trajectories and support more personalized therapeutic strategies [44]. In such a framework, biological measurements become part of dynamic biological data streams interpreted by advanced analytical models rather than isolated diagnostic values. However, the scientific value of these innovations will depend on our ability to structure, annotate and integrate biomedical data at scale. High-quality laboratory data, interoperable information systems and transparent analytical models will be essential to transform massive biological datasets into clinically actionable knowledge. Looking toward the next decades, the convergence of nanotechnology, big data and artificial intelligence may progressively transform healthcare from a reactive system centered on disease detection into a predictive model capable of anticipating biological risk and guiding personalized interventions. The next revolution in laboratory medicine will not be defined by not only by new biomarkers, but by our capacity to transform biological data into predictive knowledge.

Lipidomic screening for pancreatic cancer: from pilot evidence to multicentric clinical validation

Karolína Kašparová

Pancreatic cancer remains one of the most aggressive malignancies, with persistently high mortality rates primarily driven by late diagnosis and limited opportunities for early detection. Since prognosis strongly depends on disease stage at diagnosis, there is an urgent need for innovative analytical approaches capable of improving risk stratification and supporting earlier clinical intervention [45, 46].

Lipids play essential roles in cellular processes, and alterations in lipid profiles have been observed in various cancers, including pancreatic cancer [47]. Mass spectrometry-based lipidomics demonstrated the potential of lipidomic profiling to distinguish between healthy controls and pancreatic ductal adenocarcinoma patients with high sensitivity and specificity [48]. A pilot study investigating a blood-based screening method for pancreatic cancer using lipidomic profiling of plasma or serum was recently published [49]. In a prospective cohort of 488 participants, the method demonstrated high diagnostic accuracy (>95 %), including early-stage disease, outperforming CA 19-9 by approximately 30 % in this dataset. In high-risk individuals, the method achieved specificity exceeding 96 %, comparable to established imaging-based surveillance approaches. The analytical workflow is based on ultra-high performance supercritical

fluid chromatography coupled with high-resolution mass spectrometry (UHPSFC/HRMS), enabling efficient separation of lipid classes and high-throughput lipidomic profiling. The UHPSFC approach provides enhanced resolution of complex lipid mixtures and supports robust quantification across a broad range of lipid species. Data processing and interpretation are performed using proprietary software Lipidica integrating multivariate statistical analysis, including principal component analysis (PCA) and orthogonal projections to latent structures discriminant analysis (OPLS-DA), to translate complex lipidomic data into clinically interpretable classification output. Importantly, the presented approach illustrates the translational potential of combining advanced separation technique, high-resolution mass spectrometry, and multivariate data analysis for clinically relevant biomarker development. Beyond analytical performance, successful implementation of emerging omics technologies in laboratory medicine requires prospective validation, standardization, quality assurance strategies, and integration into existing clinical pathways. The methodology is currently being evaluated in an ongoing prospective multicenter clinical performance study (NCT06549725), designed to assess its diagnostic accuracy in newly diagnosed patients with resectable pancreatic cancer and in high-risk individuals under real-world surveillance conditions. The study represents a critical step toward translation of lipidomics-based diagnostics into routine clinical practice and reflects the broader movement toward data-driven and precision laboratory medicine.

Certified contactless AI assessment of health indicators using remote photoplethysmography BioScan

Jiří Pecina

The growing demand for accessible, rapid, and non-invasive healthcare solutions has accelerated the development of digital diagnostic technologies capable of remote physiological assessment. MEDDI hub a.s. has co – developed a certified contactless artificial intelligence (AI) solution based on remote photoplethysmography (rPPG), enabling the assessment of selected health indicators through a standard smartphone camera without the need for physical contact [50, 51]. The technology represents a new generation of borderless medicine, designed to increase healthcare accessibility, improve triage efficiency, and support preventive care in both clinical and remote environments [52]. The presented systém BioScan is compliant with MDR (EU) 2017/745 requirements and certified as a Class I medical device [53]. Using advanced AI algorithms and optical signal analysis, the platform evaluates physiological changes captured from facial microvascular blood flow during a short examination lasting approximately 1 min. The solution currently enables the assessment of selected physiological and laboratory-related health indicators, including blood pressure, heart rate, respiratory rate, hemoglobin, and glycated hemoglobin, in a completely non-invasive manner. The examination requires only a smartphone or computer camera and internet connectivity, eliminating the need for specialized hardware or wearable sensors. Remote photoplethysmography offers significant potential for modern telemedicine and emergency triage workflows. Prior to a remote consultation, physicians may obtain immediate insight into the patient's physiological condition while the patient is waiting to be examined. This approach may contribute to earlier identification of risk conditions, optimization of healthcare resources, and improved patient comfort. The technology is particularly valuable for underserved regions, elderly populations, and situations where rapid screening or repeated measurements are required. In addition to its clinical implications, contactless AI diagnostics may represent an important step toward scalable preventive medicine and personalized healthcare [54]. The integration of AI-driven health assessment into commonly available consumer devices creates opportunities for continuous monitoring, population-level screening, and broader adoption of digital health services. Ongoing development focuses on expanding the portfolio of measurable biomarkers and validating the technology in larger clinical datasets. The lecture will present the technological principles of rPPG, regulatory and certification aspects, practical implementation within telemedicine ecosystems, and future perspectives of smartphone-based contactless diagnostics.

Holistic approach to the diagnosis of heart failure: laboratory methods are essential!

Petar M. Seferović

Biomarkers can be defined as a biological substances produced by normal pathophisiological or pathogenic processes, as well as pharmacologic responses to the therapeutic interventions. Cardiac biomarkers are essential in diagnosis, risk stratification, and treatment guidance in heart failure. They can be devided into three groups: a) myocardial insult (NT-proBNP, BNP); b) neurohumoral activation (renin, angiotensin II, copeptin, ET-1); c) remodeling (galectin-3, soluble ST2). NT-proBNP and BNP are essential part of the diagnostic algorhytm for heart failure in both, chronic and

acute heart failure. They lead to earlier and more accurate diagnosis, as well as to the more accurate treatment of heart failure. In addition, they are essential in monitoring congestion status in HfrEF patients, as well as to the better diagnosis in HFpEF patients. High NT-proBNP levels correlates with the risk of rehospitalization, but also with mortality and cardiovascular events in patients with heart failure. The field of biomarkers is developing rapidly, and they are four biomarkers readily used in the cardiology practise: troponin, galectin-3, procalcitonin and ST-2. Troponin can predict with the great precision in-hospital and late CV mortality in patients with acute heart failure. Galectin-3 may also be independent predictor of late CV mortality and rehospitalization in heart failure. Procalcitonin provides a differential diagnosis of pneumonia in patients with acute heart failure, while ST-2 is sensitive mortality marker in acute heart failure.

Measurement of albuminuria or proteinuria for screening and monitoring of chronic kidney disease

Ron Gansevoort

In his presentation Ron Gansevoort, professor of Medicine at the University Medical Center Groningen in the Netherlands, addressed the developing, central role of assessing albuminuria in nephrology and cardiovascular medicine. Nowadays, many new biomarkers are being developed. Albuminuria is, however, is one of the oldest known in medicine [55]. Already in 1764 the word albumin was for the first time used in literature. At that time the urinary excretion of total protein was measured. In the 1960s a immunoassays were developed to specifically assess the urinary excretion of albumin even in trace amounts [56]. Since, it has become clear that albuminuria is the strongest risk factor for kidney disease progression and among the strongest risk factors for cardiovascular disease (CVD) [56]. As such it has become, besides kidney function (eGFR), the key variable to diagnose and stage chronic kidney disease (CKD) [56]. Moreover, equations to predict CVD risk such as the SCORE2 algorithm now incorporate information on eGFR and albuminuria to come to more precise risk prediction [57].

Beyond the use for risk prediction, albuminuria is now also used for the early diagnosis of CKD in clinical practice by screening subjects at risk to develop CKD. For instance, subjects with diabetes type 2 should be screened once every year for albuminuria, because when albuminuria is increased renoprotective treatment should be started. Unfortunately, such opportunistic screening of high risk subjects is implemented poorly [58]. A step towards better CKD screening could be population screening. Urine can be collected at home in a special device, a so called PeeSpot and be sent via regular surface mail to a central laboratory where albuminuria is measured with a gold standard methodology. When an increased value is measured, people are invited to a central screening facility for in-detail assessment of cardiovascular and renal risk factors. Thereafter people are referred to their general practitioner for treatment. Such a screening has been shown to be well accepted by the general population with a high participation rate of around 60 % [59]. Moreover, modelling of the results suggests that population screening for albuminuria may also be cost-effective to reduce the global increasing burden of the CKD and CVD. Formal prospective cost-effectiveness studies have recently started [60]. For these clinical developments it is essential that albuminuria is measured exactly. In this respect it is of interest that the U.S. National Institute of Diabetes and Digestive and Kidney Diseases and the International Federation of Clinical Chemistry and Laboratory Medicine have developed certified reference agents and a reference measurement procedure for urinary albumin [61]. This standardization that will be rolled out in 2026/27 will improve comparability of urinary albumin results within laboratories over time as well as across laboratories worldwide.

Laboratory measurement of protein glycation in the era of precision medicine – biomarkers of metabolic dysfunction and health decline

Naila Rabbani, and Paul J Thornalley

Quantitation of protein glycation provides clinically established biomarkers of glycemic control used in diagnosis and therapeutic monitoring of clinical diabetes. Glycated hemoglobin, HbA 1c, (A1C) is measured for the diagnosis of diabetes and prediabetes and assessment of medium-term glycemic control in patients with established diabetes [62]. It is early-stage fructosamine glycation adducts of hemoglobin with glucose. The level of A1C in healthy human subjects is <5.7 % Hb (<39 mmol/mol Hb), increasing in prediabetes and diabetes. A1C is influenced by glycemic control over 90–120 days prior to sampling, by deglycation of glycation adducts by fructosamine 3-kinase and red blood cell lifespan.

Validity of A1C for glycemic control is impaired in renal failure, unstable hemoglobin variants and dysregulated iron and red blood cell metabolism. Glycated albumin (GA) is increasingly preferred where interferences in A1C apply. The extent of albumin glycation in healthy human subjects is 11–16 %, increasing 2–3 fold in patients with diabetes. GA provides a report on glucose control over 14–20 days prior to blood sampling. Validity of GA for glycemic control is impaired by change of albumin transcapillary escape rate in hypertension, acute inflammatory disease and peripheral artery disease, decreased albumin synthesis and catabolism in patients with cirrhosis and change of leakage of albumin through the renal glomerular filter by renoprotective drugs. Serum fructosamine is a related measure of total serum protein glycation by glucose. Both serum fructosamine and GA correlate positively with A1C. Advanced glycation end-products (AGEs) have been explored for clinical utility as markers of glycemic control and risk of hyperglycemia-linked health impairments. Arginine-derived hydroimidazolone MG-H1 formed from methylglyoxal (MG) has the highest levels clinically; ca. 2 mol% albumin in plasma, increasing in diabetes. Plasma AGE free adducts, glycated amino acids, are formed from proteolysis of AGE-modified proteins. Plasma levels and fractional excretion of AGE free adducts, particularly combined in diagnostic algorithms, are promising markers of renal function and risk predictors of renal function decline. Other applications include screening for autism and osteoarthritis. Robust measurement is made by stable isotopic dilution analysis liquid chromatography-tandem mass spectrometry. Recent advances in studies of the pathogenesis of hyperglycemia indicate that the normal control of flux of cellular glucose metabolism by hexokinases is subverted by sustained high cellular glucose concentration for hexokinase-2 and glucokinase [63]. This produces abnormally high levels of glycolytic intermediates and cell dysfunction. A metabolic state called “glycolytic overload”. Glycolytic overload contributes to the pathogenesis of hyperglycemia leading to the development of hepatic, peripheral and central insulin resistance, impaired incretin effect, beta-cell glucotoxicity, metabolic dysfunction-associated steatotic liver disease (MASLD), type 2 diabetes and vascular complications of diabetes [64, 65]. High calorie, sugar and fat-rich diets and impaired fasting glucose favor glycolytic overload. Increased MG and MG-modified proteins are glycolytic overload biomarkers. Further study holds the prospect of improved risk prediction for development and progression of MASLD, type 2 diabetes and vascular complications of diabetes and improved prediction and assessment of therapeutic responsiveness and monitoring.

Fluid biomarkers for Alzheimer’s disease in the era of disease-modifying therapies

Kristian Steen Frederiksen

With the approval of new disease-modifying therapies for Alzheimer’s disease (AD) and an outlook with more therapies to come, the patient pathways through which patients are diagnosed and followed are on a cusp of a fundamental transition. The currently recently approved drugs are monoclonal antibodies targeting different amyloid species and are approved for treatment of early AD. In this new landscape of AD diagnosis and management, fluid biomarkers are positioned to play a pivotal role in several ways. This includes earlier diagnosis at the mild cognitive impairment or even asymptomatic stage of the disease where treatments may be more effective [66]. Case-finding at the primary care level will be an important step in earlier diagnosis. In order to free up capacity in specialized centers, more patients in advanced stages may have to be diagnosed and treated outside these centers. For both instances, blood-based biomarkers will be instrumental to achieve this offering accurate, low-cost and scalable tools. While these are unlikely to be stand-alone tools for diagnosis, they will be a key piece in the diagnostic tool kit [67]. New drugs may also target other pathologies other than amyloid which will require more granular biological staging. Here, fluid markers of e.g. microglia activation and other aspects of neuroinflammation may become essential if drugs targeting these will show to be efficacious [66]. At present, various hyperphosphorylated tau species measured in blood have shown the largest promise as diagnostic markers. Specifically, tau phosphorylated at residue 217 (ptau217) is often reported as having the highest accuracy but with relatively modest outperformances of other phosphorylated tau species [68]. Due to low fold change between AD patients and controls and other factors, direct measurement of pathological species of amyloid, is less attractive as a diagnostic marker for AD. Ptau217 and other markers are highly specific for cerebral amyloid and to a lesser degree to neurofibrillary tangles containing tau. Instead, microtubule-binding region tau 243 may have specificity for tau deposition and thus a possible staging marker as symptom and progression is more closely tied to the spread of tau tangles. There is still a lack of prognostic and disease and treatment tracking fluid biomarkers as well as markers of microglia activity, but promising markers include glial fibrillary acid protein, neurofilament light and TREM-2 [69].

Driving health care pathways through integrative diagnostic medicine

Michael Neumaier and Stefan O. Schönberg

Modern Health Care is rapidly becoming more complex based on our increasing understanding of disease mechanisms and a progress in therapeutic options. In today's medicine, the primary key for clinical decision-making increasingly uses knowledge generated from data and information that originate from different fields in diagnostic medicine contributing *in-vivo* and *in-vitro* biomarkers of their respective fields, but this information still resides in silos in a heavily segmented fashion. Diagnostic data complexity is overwhelming for the clinician, and its wealth of information cannot be exploited properly to support medical diagnosis. Recently, the synergistic potentials of interdisciplinary collaboration in Diagnostic Medicine is being appreciated for its potential to drive progress in health care pathways. Laboratory Medicine and Radiology have formed a strategic alliance to explore, conceptualize and design collaboration based on their unique and complementary skills and insights into disease mechanisms and – in its generic sense – biomarker fluctuations.

Specifically, while Laboratory Medicine generates highly specific and sensitive molecular information – most often in quantitative numerical formats, it has a limited topological resolution at the organ level. In contrast, Radiology (imaging) technologies have developed enormously in recent years providing highly sensitive and detailed topological information about tissue conditions, yet with very limited biomolecular information. Naturally, Laboratory Medicine and Radiology/Imaging favorably complement each other in the information they can feed into diagnostic pathways making a joint effort through systematic synergies "a marriage made in heaven". Also, it is important to emphasize that Imaging is leading Diagnostic Medicine in the field of AI integration of diagnostic data. In 2019, a strategic partnership has been signed between EFLM and the European Society of Radiology (ESR) during the 2nd EFLM Strategic Conference in Mannheim, Germany to develop integrative diagnostic concepts to support knowledge in Health Care. We will discuss the status of this endeavor presenting the concept and work conducted within the "Centre for integrative Diagnostics" (CID), which systematically approaches projects of integrative diagnostics between diagnostic and clinical units as a template for further developing Diagnostic Health Care.

Integrated diagnostics: from fragmentation to orchestrated patient care

Clemens Cyran

Integrated diagnostics is emerging as a strategic framework for improving patient-centred care through the coordinated interpretation of imaging, laboratory, pathology and clinical data. Rather than merging professional disciplines, this model aims to orchestrate complementary diagnostic expertise across the patient pathway, from referral and diagnosis to therapy monitoring and long-term follow-up. The lecture highlighted how recent advances in artificial intelligence, interoperability, digital infrastructures and precision medicine have made integrated diagnostics both feasible and increasingly necessary within European healthcare systems.

The presentation positioned integrated diagnostics as a natural extension of current priorities within the European Society of Radiology (ESR) and the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM). It aligns with ongoing efforts to improve test appropriateness, reduce duplication, strengthen evidence-based pathways and support data-driven decision making. Particular emphasis was placed on the strategic convergence between radiology and laboratory medicine in oncology, cardiology and neurodegenerative disease, where imaging findings and biomarkers increasingly require joint interpretation to optimise diagnosis, risk stratification and treatment monitoring.

The lecture also outlined practical opportunities for collaboration between ESR and EFLM. Proposed actions included joint scientific sessions, harmonization of standards and terminology, collaborative multicentre research, integrated educational programmes and coordinated policy engagement regarding the European Health Data Space (EHDS), AI governance and interoperability. In this context, the European Institute for Biomedical Imaging Research (EIBIR) was presented as an operational platform capable of supporting funded multicentre projects, FAIR data infrastructures and translational research initiatives in integrated diagnostics. A central message of the lecture was that successful implementation should begin with focused pilot pathways rather than large-scale institutional restructuring. Small, evidence-generating initiatives with shared clinical endpoints could demonstrate measurable benefits in quality of care, efficiency and patient outcomes while strengthening the collective diagnostic voice of European scientific societies. Integrated diagnostics was therefore presented not as

a theoretical concept, but as a realistic and strategically important direction for future healthcare delivery and precision medicine in Europe.

Global cooperation and sharing the best practice in laboratory medicine: the IFCC view

Tomris Özben

International cooperation and the sharing of best practices are essential drivers of quality, harmonization, and innovation in laboratory medicine. As a global federation, the IFCC plays a central role in fostering collaboration across regions, disciplines, and professional societies to support high-quality laboratory services worldwide. Through its international committees and expert working groups, the IFCC promotes coordinated scientific activities, the exchange of knowledge, and the development of strategies aimed at improving laboratory medicine practice across diverse healthcare systems. By working closely together, these groups actively support the IFCC mission, contributing to scientific advancement, strengthening education and training opportunities, and building a strong global professional network that allows the IFCC to remain a key reference point for laboratory medicine around the world. This presentation will outline the IFCC perspective on global cooperation, highlighting key mechanisms for knowledge exchange, standardization, education, and capacity building. Selected examples of IFCC initiatives and collaborations will illustrate how the sharing of expertise and best practices can contribute to improving patient care, supporting professional development, and reducing variability in laboratory medicine across different healthcare settings. Particular attention will be given to collaborative efforts aimed at developing clinical guidelines, consensus documents, and recommendations that support harmonized laboratory practices and promote evidence-based decision-making. Another important area in which IFCC continues to invest and evolve is e-learning, through the development of digital platforms, webinars, and online educational resources. These tools are increasingly recognized as essential for expanding access to education, supporting continuous professional development, and reaching laboratory professionals worldwide, including those working in regions with limited resources or reduced access to traditional training opportunities. At the same time, increasing attention is being given to the integration of digital transformation and artificial intelligence, which are emerging as key topics in contemporary laboratory medicine and hold significant potential to improve data management, diagnostics, and clinical decision support. The presentation will conclude with reflections on future opportunities for strengthened collaboration between international and regional organizations, including IFCC and EFLM, with the aim of further advancing excellence, harmonization, and sustainability in laboratory medicine worldwide.

Bridging the gap between basic research and the clinical laboratory: finding common ground

Miguel A. De la Rosa

The future of biomedical science increasingly depends on a stronger and more integrated relationship between basic research and the clinical laboratory. At the Federation of European Biochemical Societies (FEBS), we recognize that advancing human health requires closer collaboration between these two communities. FEBS is one of the largest organizations in the molecular life sciences in Europe, representing more than 35,000 researchers across 39 constituent national societies. Since its foundation in 1964, FEBS has promoted excellence in biochemistry, molecular biology, and related disciplines through a broad range of activities, including scientific meetings, advanced courses, fellowships, educational initiatives, and the publication of leading scientific journals. Beyond supporting fundamental research, FEBS is increasingly committed to strengthening the connections between discovery science, biomedical innovation, and societal well-being. The Milan Declaration on the Crucial Role of Science in Meeting Global Challenges – promoted in 2024 by FEBS together with IUBMB and the other continental federations of biochemistry – emphasizes the importance of science and research in providing coordinated solutions to global challenges. In this context, promoting closer interaction between basic research and the clinical laboratory has become an important strategic priority. Historically, basic research and clinical laboratory science have developed as largely separate spheres. Basic research focuses on uncovering the fundamental mechanisms that govern biological systems, generating knowledge about molecular pathways, cellular processes, and disease mechanisms. Clinical laboratories, by contrast, translate these discoveries into practical applications such as diagnostic tests, biomarkers, and analytical procedures that guide medical decision-making. Despite these differences, both communities ultimately pursue a common objective: improving human health. Several structural barriers, however, contribute to this divide. Basic scientists and clinical laboratory professionals

often operate within different institutional cultures and scientific languages. Their evaluation systems also differ: academic researchers are typically rewarded for publications and grants, whereas clinical laboratories prioritize accuracy, standardization, and regulatory compliance. In addition, relatively few institutional mechanisms exist to promote sustained collaboration. Historical experience illustrates the transformative potential of interdisciplinary cooperation. The Manhattan Project (1942–1946) was one of the first large-scale efforts to unite scientists, engineers, and industry in a coordinated research enterprise. Although motivated by wartime objectives, it demonstrated how integrating fundamental science with technological expertise could accelerate innovation dramatically. Thousands of researchers collaborated across multiple institutions, establishing new models of large-scale scientific organization. The project also influenced postwar science policy through Vannevar Bush's report *Science: The Endless Frontier*, which articulated the "linear model" linking fundamental research, technological development, and societal progress. While biomedical research pursues different goals, the lesson remains relevant: coordinated collaboration across disciplines can greatly enhance the impact of scientific discovery. Bridging the gap between basic research and the clinical laboratory requires deliberate strategies. Collaborative projects involving both communities from the earliest stages of research can facilitate translation into clinical practice. Interdisciplinary education and training can also prepare scientists to work across disciplinary boundaries. Finally, institutional platforms and partnerships – such as those between FEBS and the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) – can foster dialogue and sustained cooperation.

Driving laboratory leadership and best practices: the EFLM–AFCC collaborative potentials

Gizachew Taddesse Akalu

The European Federation of Clinical Chemistry and Laboratory Medicine Strategic Conference 2026 – *Laboratory Medicine for Society* – convened in Prague at a critical juncture. Laboratory medicine has unequivocally evolved from an empirical support function to a cornerstone of evidence-based clinical decision-making. Yet, despite this progress, profound disparities persist between well-resourced regions and low and middle-income countries, particularly across Africa. This narrative reflection, grounded in conference deliberations and supported by global policy frameworks, outlines the collaborative potential between EFLM and the African Federation of Clinical Chemistry and Laboratory Medicine to drive laboratory leadership and best practices. The World Health Organization is actively building future generations of laboratory leaders through the Global Laboratory Leadership Program. However, unmet needs in LMICs remain stark: diagnostics must be Affordable, Sensitive, Specific, User-friendly, Rapid, Equipment-free and deliverable to the point of need that directly informs the framework highlighted at the conference. Simultaneously, current global health priorities – antimicrobial resistance, pandemics, non-communicable diseases, the One Health agenda, and health crises during conflict – demand a multidisciplinary, collaborative response. Historically, engagement between EFLM and AFCC has been fragmented. The conference made evident that a structured, strategic partnership is not merely aspirational but essential. Such collaboration can enhance knowledge sharing, promote standardization, increase resource efficiency and foster innovation. Concrete joint actions include expanding research initiatives addressing cross-continental health burdens – e.g. AMR surveillance, strengthening educational programs and training resources, and harmonizing laboratory accreditation processes to ensure quality and safety – aligning with the WHO Laboratory Leadership Competency Framework core domains. Beyond technical domains, a shared leadership framework is needed: one that establishes clear leadership models, promotes interdisciplinary teamwork, conducts regular performance evaluations, implements robust safety protocols, and fosters a culture of innovation. Strategically, this can be operationalized through structured leadership training programs, mentorship frameworks connecting experienced European laboratory leaders with emerging African professionals, and active engagement in international forums such as the GLLP. The WHO Global Research Agenda for AMR in Human Health developed in 2024 lists 40 priorities – including rapid point-of-care tests to discriminate bacterial from non-bacterial infections and optimal surveillance methods for low-resource settings – directly relevant to EFLM–AFCC collaborative research. Moreover, the World Economic Forum's *Diagnostics for Better Health* report in 2021 warns that 90 % of genomics research investment addresses only 10 % of the world's population, risking AI-driven diagnostic bias if African data are excluded. AFCC member societies need AI tools validated on local pathogen genomics, while EFLM can lead in establishing open-source AI frameworks and regulatory harmonization. Driving laboratory leadership through effective, equitable collaboration enhances best practices, promotes innovation, and ultimately leads to better patient care. The Prague conference reaffirmed that

EFLM and AFCC have both the responsibility and the opportunity to transform fragmented interactions into a sustained, bi-continental force for advancing laboratory medicine – serving society on both continents.

APFCB–EFLM collaboration to promote best laboratory practices across regions

Praveen Sharma

The collaboration between the Asia-Pacific Federation for Clinical Biochemistry and Laboratory Medicine (APFCB) and the European Federation for Laboratory Medicine (EFLM) is of immense significance in advancing laboratory medicine globally. In an era where healthcare systems are increasingly interconnected, international collaboration is essential to address disparities in research capacity, teaching standards, laboratory infrastructure, and quality practices across different regions. Strengthening the partnership between APFCB and EFLM can help harmonise laboratory standards, promote scientific excellence, and ultimately improve patient care outcomes worldwide. A major objective of this collaboration is to promote high-quality regional research. Both organisations can jointly encourage multicentre and interdisciplinary research projects that address region-specific healthcare challenges. Supporting the publication of scientific findings in peer-reviewed journals will enhance the global visibility of research conducted within member countries. In addition, sponsoring workshops, scientific symposia, and educational sessions at regional and international meetings such as the APFCB, EFLM, and AFCC congresses can foster innovation and knowledge dissemination. Scientific exchange through conferences and academic meetings represents another key area of collaboration. Joint symposia and scientific sessions can provide platforms for researchers, clinicians, academicians, and laboratory professionals to exchange ideas, discuss emerging technologies, and share best practices. Such interactions strengthen professional networks and encourage collaborative problem-solving across regions. Collaborative research initiatives are also essential for addressing common healthcare challenges such as non-communicable diseases, infectious diseases, quality assurance, and laboratory standardization. By combining expertise, infrastructure, and resources, APFCB and EFLM can undertake impactful research that contributes to evidence-based laboratory medicine and improved healthcare delivery. An equally important goal is the implementation of best laboratory practices. Harmonization of quality standards, accreditation procedures, and diagnostic protocols can improve accuracy, reliability, and consistency in laboratory services across participating countries. This will directly contribute to better clinical decision-making and enhanced patient safety.

Capacity building through digital platforms offers tremendous opportunities for continuous professional development. Webinars, virtual workshops, distance-learning modules, and structured e-learning programs can make high-quality educational resources accessible to laboratory professionals regardless of geographical limitations. Such initiatives are particularly beneficial for developing regions with limited access to advanced training opportunities. The collaboration should also focus on identifying gaps in expertise and resources within different regions and facilitating support through international cooperation. Resource sharing, mentorship programs, and technical assistance can help bridge disparities and strengthen laboratory systems globally.

Strengthening laboratory medicine worldwide: insights from the NAFCC societies

Shannon Haymond

Professional societies play an important role in advancing laboratory medicine beyond their national or regional boundaries, particularly where access to training, quality systems, and standardization resources remains unbalanced. This presentation described how societies within the North American Federation of Clinical Chemistry and Laboratory Medicine (NAFCC), Association for Diagnostics & Laboratory Medicine (ADLM) and the Canadian Society of Clinical Chemistry (CSCC), are contributing to the strengthening of laboratory medicine worldwide. The objective was to highlight practical mechanisms by which professional organizations can support capacity building, improve laboratory quality, and promote sustainable regional collaboration. The presentation outlined four complementary areas of activity by ADLM and CSCC: financial support, strategic partnerships, scientific improvement initiatives, and education. Financial aid has included support for society or federation membership fees and grants for travel and professional development. Partnership activities have involved collaboration with local universities and government agencies, in addition to international and national organizations, such as IFCC, US Centers for Disease Control and Prevention, and the International Society for Neonatal Screening [70]. Scientific initiatives have centered on areas with broad clinical relevance, including reference

interval standardization and best-practice development in newborn screening. Educational efforts have focused on virtual and onsite workshops in quality control, method validation, and related topics, often delivered in collaboration with local societies, government, industry, and regional experts. Needs assessment surveys help identify the educational priorities and region-specific challenges faced by laboratory professionals worldwide [71, 72]. ADLM's Global Lab Quality Initiative was presented as an implementation example. Since 2010, the program has supported workshops across Latin America, Africa, Asia-Pacific, and the Caribbean [73]. Its model is funded through a Wallace H. Coulter Foundation endowment, supported by operations, and delivered primarily by member volunteers through a Global Affairs Core Committee and regional subcommittees [74] The approach emphasizes collaboration with local professional societies, use of regional and native-speaking experts when possible, and a train-the-trainer model to extend the reach of educational activities. Several lessons emerged from this experience. Successful programs benefit from skilled volunteer faculty, affordability, effective local advertising, alignment with national or regional stakeholders, and partnerships that create momentum for continued improvement. Persistent challenges include limited funding for long-term sustainability, variable local regulatory and political contexts, language barriers, and differing needs for foundational vs. specialized education. External threats include political instability, shifting institutional priorities, and the risk that solutions developed in North America or Europe may not be directly transferable to other settings. In conclusion, NAFCC society activities illustrate how professional organizations can improve laboratory medicine through coordinated education, standardization, financial support, and partnership-building. Durable progress requires locally adapted programming, sustained regional leadership, multilingual engagement, and investment in networks that allow laboratory professionals to translate educational activities into lasting improvements in quality and patient care.

Laboratory-enabled best practices can catalyze change and replication

Tricia Ravalico

In the 'Cooperation and Sharing Best Practices' session led by IFCC President, Professor Tomris Özben, Tricia Ravalico delivered an invited talk on 'Laboratory-enabled best practices catalyzing change and replication'. Powerful messages were shared related to how laboratory medicine enables best practices with outcomes that have measurable benefits to patients, payers, clinicians and entire health systems. Using insights derived from the UNIVANTS of Healthcare Excellence award program, Tricia emphasized a call to action for all healthcare teams to work collaboratively across disciplines to solve gaps in care. More than half of the recognized best practices to date through the UNIVANTS of Healthcare Excellence award program have been triggered through viable process improvement initiatives that are independent of new assays and/or algorithms [75]. With nearly 100 examples now recognized through July of 2026 [76] actionable improvements across geographies and disease areas are not only possible, but imminent through 'Unifying for Something Greater'.

From shadows to spotlight: how EuLabDay reframes our profession

Tara Rolić

Laboratory Medicine (LM) is the backbone of modern healthcare, playing a central role in diagnosis, treatment and patient management, yet it remains largely invisible to patients, clinicians, and policymakers [77]. Despite the fact that approximately 70 % of clinical decisions rely on laboratory results, the expertise of laboratory medicine professionals (LMPs) is frequently underrecognized [78]. The aim is to highlight the need for greater visibility of the profession and to present the EFLM initiative EuLabDay as a strategic effort to reposition LM from a "behind-the-scenes" discipline to a proactive and engaged partner in healthcare. Particular focus is placed on strengthening communication, public engagement, and interdisciplinary collaboration as key priorities for LMPs. Traditionally, laboratories have been perceived as technical "black boxes", where samples are processed and numerical results are generated with little awareness of the scientific expertise behind them [79]. Patients rarely encounter LMPs directly, and even healthcare professionals may not fully understand their role in clinical decision-making [80]. This limited visibility has contributed to a perception of LM as purely technical rather than clinical and consultative. However, the role of LMPs extends far beyond analytical processes. Their education, expertise, and responsibility position them as key contributors to patient care, requiring active involvement in interdisciplinary communication with clinicians, patients, and health authorities [80]. To achieve this, a cultural shift is necessary from a traditionally introspective and defensive stance to one that is outward-looking, innovative, and proactive. Recognizing this need, EuLabDay is lunched, celebrated

annually on November 5th. This initiative encourages laboratory professionals across Europe to engage with the public and the broader healthcare community through activities such as open laboratory days, media appearances, social media campaigns, educational events, exhibitions, and collaborative projects [81]. EFLM supports these efforts by providing communication materials, ideas, and platforms for sharing experiences, including photos and videos that showcase the people behind laboratory results. Since its start in 2022, EuLabDay has seen growing participation across countries, reflecting increasing motivation among LMPs to step outside their comfort zones and actively promote their profession. These efforts not only enhance public awareness but also build trust, inspire future professionals, and strengthen the role of LM within healthcare systems. EuLabDay represents more than a single-day event, it is part of a broader movement to redefine the identity of LM. By fostering visibility, transparency, and engagement, it helps shift the perception of LM from a hidden service to a vital, patient-centered discipline. The future of the profession depends on sustained proactivity, effective communication, and openness to collaboration. By embracing these principles, LMPs can ensure their expertise is recognized, valued, and fully integrated into the evolving landscape of healthcare.

AI in the clinical lab – opportunity or risk?

Jakob Adler

Artificial intelligence (AI) has emerged as a pivotal theme in both scientific discourse and clinical practice. The core modalities of machine learning (ML) – supervised, unsupervised, and reinforcement learning – offer a broad spectrum of applications, ranging from diagnostic enhancement and quality management to the end-to-end automation of laboratory processes. A primary strength of ML lies in its ability to identify complex patterns and non-linear correlations within high-dimensional datasets. Such capabilities have already proven transformative in elucidating the underlying pathophysiology of chronic conditions, including diabetes mellitus [82] and multiple sclerosis [83]. However, clinical implementation requires a nuanced understanding of algorithmic variability: different models may yield divergent classifications or clusters when applied to the same dataset, depending on their underlying architecture [84]. To mitigate risks such as model drift or performance degradation, the integration of ML into laboratory routines must strictly adhere to established professional guidelines and regulatory recommendations. Furthermore, the successful deployment of these technologies cannot be regarded as ancillary projects; rather, it necessitates dedicated, interdisciplinary teams with expertise in both data science and laboratory medicine. Parallel to traditional ML, the rapid proliferation of Large and Small Language Models (LLMs and SLMs) is reshaping the diagnostic landscape. Beyond tasks such as automated data synthesis and literature review, advanced LLM-based research assistants and clinical decision support systems (CDSS) are currently undergoing rigorous evaluation [85]. Despite their transformative potential, significant challenges must be addressed, including “hallucinations”, algorithmic bias, and security vulnerabilities such as prompt injections. Moreover, the risk of human deskilling necessitates robust mitigation strategies. A promising trajectory for laboratory medicine lies in the adoption of Small Language Models (SLMs) [86]. These models can be deployed on local, cost-effective hardware, ensuring that sensitive patient data remains within the laboratory’s secure infrastructure, thereby aligning with stringent data privacy requirements.

Beyond education: experiential learning and professional identity formation in laboratory medicine

Nataliia Kozopas

Professional development in laboratory medicine is often described in terms of technical skills and professional competencies. However, professional identity is increasingly shaped through international professional exchange and engagement in professional networks, which collectively influence how laboratory professionals understand their role, responsibilities, and contribution within healthcare systems. The EFLMLabX programme represents an educational exchange initiative designed to strengthen laboratory medicine across Europe by supporting specialists and fostering cooperation. It facilitates structured practical training by linking laboratories offering training opportunities with professionals seeking targeted experience in specific areas of laboratory medicine, supporting cross-border exchange and the development of a European network of collaborating laboratories. From an educational perspective, such experiences can be understood within the framework of experiential learning, where professional growth emerges through a continuous cycle of experience, reflection, and action. Learning in this model is not limited to knowledge acquisition, but is embedded in lived professional experience and its critical interpretation, enabling the

application of new understanding in practice. This dynamic learning process is precisely what programmes like LabX are designed to facilitate. In this sense, LabX aligns with EFLM strategic priorities focused on strengthening education, cooperation, and promotion in laboratory medicine [77]. Beyond its educational structure, LabX can be seen as an "open door" into international professional exchange, offering enhanced confidence, broader perspectives, and a deeper sense of purpose in laboratory medicine. Through this process, professional growth shifts from an individual trajectory toward a shared and interactive experience. Importantly, such processes extend beyond the program itself. Professional growth in laboratory medicine is increasingly shaped within broader communities of practice, where knowledge is not only acquired, but shared, discussed, and refined through ongoing professional interaction across different laboratories and healthcare contexts. Within this framework, professional identity is not formed in isolation, but emerges through participation in a wider professional ecosystem built on shared experience, dialogue, and mutual learning. Ultimately, the value of programmes like EFLM-LabX extends beyond individual development. Such experiences shape professional identity not only through knowledge exchange, but also through human interaction and trust within a broader professional community. Therefore, laboratory medicine is not only a technical discipline but also a human-centered field defined by collaboration, openness, and mutual responsibility, which together shape its future development.

Building future leaders through education: leveraging the EFLM Academy and EFLM Syllabus Course

Lejla Alić

The rapidly evolving landscape of laboratory medicine demands professionals who integrate scientific excellence with interdisciplinary, digital, and leadership capabilities. The European Federation of Laboratory Medicine (EFLM) Academy and the EFLM Syllabus Course are pivotal in addressing these contemporary needs. The EFLM Academy functions as a dedicated digital hub designed to advance the training and provide continuous education of laboratory medicine professionals across Europe. Rather than being restricted to laboratory medicine specialists, the EFLM Academy welcomes anyone with an interest in the field through its individual membership program. This inclusive approach fosters a broad professional community while providing career advantages. EFLM Academy membership encompasses many benefits, among others, reduced registration fees for EFLM events, complimentary access to webinars, and eligibility for travel grants. Additionally, for those meeting the Equivalence of Standards requirements, the Academy provides a direct pathway to enrollment in the European Specialists in Laboratory Medicine (EuSpLM) Register. This reinforces its role as a cornerstone for professional recognition and cross-border mobility [87]. Created by the EFLM Task Group for Syllabus Course in 2021 and launched in January 2022, the EFLM Syllabus Course initiative aims to standardize postgraduate training for laboratory medicine specialists across Europe. It offers a practical curriculum filled with expert lectures designed to help participants master specific professional skills. Importantly, the course is built directly on the European Syllabus; this document serves as the foundation for the Common Training Framework for non-medical specialists, aligning with the professional qualification standards set by EU Directive 2013/55/EU [88]. Engagement with EFLM Syllabus Course initiatives directly contributes to career advancement and the achievement of professional objectives. A defining strength of the Syllabus Course is its dynamic structure, allowing for constant updates and improvement. Its long-term impact relies on active contributions from the professional community, such as practical case studies and new educational materials. These inputs are essential to keep the course relevant, comprehensive, and impactful. By leveraging these EFLM platforms, the laboratory medicine community equips the next generation of specialists to embrace innovation and lead with vision in a modern healthcare environment [89].

EFLM strategy for better future

Tomáš Zima

Laboratory medicine is undergoing a profound transformation driven by rapid technological advancements, evolving healthcare demands, and the increasing need for precision and value-based care. The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) has outlined a comprehensive strategic vision to position laboratory medicine at the centre of modern healthcare systems [77]. This strategy reflects a shift toward integrated diagnostics, digital transformation, and patient-centred care. During the Strategic Conference we received feedback and proposal for concrete action There are the key pillars of the EFLM strategy:

1) **Value-Based Laboratory Medicine**

Value-based laboratory medicine focuses on maximizing clinical outcomes rather than simply increasing test volume. Key elements include – Integration into clinical pathways, development of personalized diagnostics using multi-omics approaches, use of individualized reference intervals and decision limits.

2) **Harmonization in Laboratory Medicine**

Harmonization is essential for ensuring consistency and reliability across healthcare systems. Variability in laboratory results can lead to diagnostic errors and compromised patient safety. Key harmonization goals include standardization of measurement units, alignment of reference intervals and decision thresholds, development of analytical performance specifications. Monitoring tools such as external quality assessment (EQA), patient data analysis, and post-market surveillance are critical for evaluating harmonization efforts.

3) **Artificial Intelligence and Emerging Technologies**

Artificial intelligence (AI) is transforming laboratory medicine by enhancing efficiency, accuracy, and clinical decision-making. AI applications include quality control, automated diagnostics, and interpretation of complex datasets [90]. The integration of AI with multi-omics data enables predictive and preventive medicine by identifying disease risks before clinical manifestation. Emerging technologies such as mass spectrometry and nanotechnology further expand diagnostic capabilities.

4) **Collaboration with Clinicians, Regional federations and Stakeholders**

Collaboration between laboratory professionals and clinicians is essential for integrated diagnostics. Interdisciplinary approaches improve diagnostic accuracy and patient outcomes mainly in important areas as cardiology, diabetology, oncology, neurology and imaging with partnerships with clinical societies under the umbrella of BioMed Alliance. Strengthen EFLM's engagement with European institutions to promote a regulatory and policy environment that supports public health. Enhance synergies with IFCC and regional federations through joint events and activities, sharing best practices, and guideline development. We should make together research multicentric projects and we will prepare the action plan with APFCB. We should support some part of regions with educational materials, webinars, mentoring and leadership programmes and support quality system management and accreditation system.

5) **Collaboration with IVD Industry and EQA providers**

Strengthening collaboration with IVD manufacturers at the level of MedTech Europe and EQA providers, including active regulatory engagement, is essential to advancing laboratory medicine across Europe. This effort should go hand in hand with promoting innovation and the sustainable integration of advanced diagnostics – such as genomics, transcriptomics, proteomics, metabolomics, exposomics, and digital technologies – into routine clinical practice. Promoting the laboratory medicine profession and investing in the education of the next generation of scientists are equally important. At the same time, adopting new guidelines that incorporate novel biomarkers and technologies will enable more personalized medicine. Joint discussions across the Europe are needed to address reimbursement policies for innovative diagnostics. Finally, reducing waste through measures such as digital labelling represents an important step toward sustainability.

6) **Education and Workforce Development**

The evolving landscape of laboratory medicine requires new competencies in data science, AI, and advanced diagnostics. Education and training programs must adapt accordingly with up-date of EFLM Syllabus to reflect current scientific and professional standards, expanding digital learning platforms and promoting continuous professional development on our platform – EFLM Academy. *LabX* shapes identity, resilience, and future leaders and one step forward can inspire a lifelong commitment. These efforts ensure that laboratory professionals remain equipped to meet future healthcare challenges.

7) **Role of Young Scientists**

Young scientists are critical to sustaining innovation in laboratory medicine. Mentorship programs, international collaboration, and professional networks support their development and initiatives as research fellowships, Initiatives such as EuLabDay and structured training programs as EFLM Syllabus courses help build leadership skills, competencies and foster engagement within the scientific community.

8) **Future Organization of Laboratory Services**

Laboratory services are transitioning toward integrated networks combining central laboratories with automation

and centralization, peripheral labs, and point-of-care testing (POCT) and new trends with expansion of POCT and direct-to-consumer- testing and integration of wearable will be the challenging for the quality and our responsibility to society. Advances in molecular diagnostics, nanotechnology, and digital health are transforming laboratories into central hubs for predictive and personalized medicine [90].

Conclusions

The EFLM strategy provides a comprehensive framework for advancing laboratory medicine in Europe. By emphasizing integration, innovation, collaboration, and education, it supports the transition toward personalized, predictive, and patient-centred healthcare. Laboratory medicine is becoming a central component of healthcare systems, contributing not only diagnostic results but also actionable clinical insights. Continued investment in technology, workforce development, and collaboration will be essential to realizing our vision.

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