Guidelines and Recommendations

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Strategy of Laboratory Medicine – EFLM Vision

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Abstract: The strategic direction of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) is guided by global healthcare trends, rapid technological advancements, and the evolving role of laboratory professionals in modern medicine. The aim is to position laboratory medicine as a leader in precision diagnostics, digital healthcare transformation and integrated diagnostics, ensuring timely, accurate, and cost-effective medical testing that improves patient outcomes. EFLM reaffirms that every innovation in laboratory medicine must ultimately serve the patient – ensuring equitable access to high-quality diagnostics, enhancing patient understanding, and strengthening trust in laboratory-generated data. In a world deeply reshaped by technological, economic, and geopolitical forces, EFLM must act as both a scientific authority and a societal compass, guiding the transformation of diagnostics into patient-centered, data-driven, and resilient care models. EFLM's strategy focuses on integrating laboratory innovation and value-based laboratory medicine, strengthening workforce competencies, promoting sustainability and clinical outcomes improvement, and addressing key challenges in patient-centered healthcare. The following strategic priorities reflect the Federation's commitment to improving the impact of laboratory medicine on clinical care, public health, and scientific advancement.

Keywords: value-based laboratory medicine; education; advocacy; data structuring and interoperability; global healthcare; technological advancements

The Strategy

A fundamental goal is to move the clinical laboratory outside the "black box" to achieve full integration with the health care system and clinical pathways, promoting the value-based laboratory medicine and the value-based score [1, 2]. Foster the development of integrated diagnostic pathways combining laboratory, pathology, imaging, and clinical data [3, 4].

Promote innovation and the sustainable adoption of advanced diagnostics such as genomics, transcriptomics, proteomics, metabolomics, exposomics and integrated digital technologies.

Harmonization of measurements units, reference intervals and decision limits at least of test which are clinically impactful to avoid patient harms [5, 6]. Promote the identification and adoption of objective criteria for the interpretation of laboratory data using personalized reference intervals, personalized decision limits, and reference change values and interpretative comments [7].

Create the necessary foundations for the ethical and effective deployment of artificial intelligence in laboratory medicine.

Modernize education and training programs to equip professionals with skills for new technologies and evolving healthcare demands, update the EFLM Syllabus to reflect current scientific and professional standards and implemented new technological tools including AI to EFLM Academy [1].

Build partnerships with other scientific organizations (e.g., BioMed Alliance, EQALM), public health institutions (e.g., WHO, CDC), and regulatory bodies (e.g., ISO, EA, JCTLM, EU Commission).

Strengthen EFLM's engagement with European institutions to promote a regulatory and policy environment that supports public health and advances laboratory medicine and establish EFLM Policy Officer to keep pace with the

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legislations that affect lab medicine and effectively communicate with EU and regulatory institutions [8].

Deepen cooperation/collaboration with the IVD manufacturers on the level of Medtech-Europe and EQA providers, including regulatory engagement.

Strategic Priority 1: Advancing Value-Based Laboratory Medicine – Precision, Personalization and Clinical Integration

(1) Promote innovation and the sustainable adoption of advanced diagnostics such as genomics, transcriptomics, proteomics, metabolomics, exposomics and integrated digital technologies.
(2) Identify and validate novel biomarkers for early detection and targeted treatment, especially in complex diseases (e.g., neurodegenerative disorders) to promote personalized medicine and the concept of "companion diagnostics", i.e. the use of diagnostic biomarkers to define patient eligibility for innovative treatments as well as the consequent patient follow-up in drug treatment.
(3) Enable precision diagnostics to support individualized diagnoses and therapies. Expand precision medicine, particularly in e.g. oncology, cardiology and neurodegenerative diseases to include non-invasive and longitudinal monitoring (e.g. liquid biopsy technologies).
(4) Address emerging clinical needs, including decentralized testing, point-of-care testing (POCT), mobile health technologies, near-patient testing, wearables and patient empowerment.
(5) Promote information and recommendations of Direct-to-Consumer testing, avoiding commoditization and patient harms. Integrate home-based testing, wearables, and direct-to-consumer services into safe and value-based care.
(6) Ensure that digital transformation remains patient-centric, balancing automation and human expertise to strengthen empathy, understanding, and communication of laboratory results.
(7) Foster the development of integrated diagnostic pathways combining laboratory, pathology, imaging, and clinical data.
(8) Integrate automation and robotics to enhance lab efficiency and reduce human error.
(9) Advance digital interoperability with electronic health records (EHRs) and support innovative laboratory information systems, telemedicine and remote diagnostics.
(10) Expand the use of artificial intelligence, machine learning, and big data for predictive diagnostics, AI-assisted test selection, test interpretation suggestions and clinical decision support and establish a reference framework for clinical validation of AI in laboratory medicine, positioning EFLM as the standard-setter for Europe and beyond.
(11) Introduce and/or support the notion of control and development of the digitalization of laboratory data.
(12) Implement evidence-based laboratory practices to maximize clinical value.
(13) Deliver access to quality assessed biological variation data alongside the promotion of user knowledge and understanding of the concepts and nature of biological variation and of the utility and limitations of applications of published data.
(14) Harmonization of measurements units and reference intervals at least of test which are clinically impactful to avoid patient harms. Promote the identification and adoption of objective criteria for the interpretation of laboratory data using personalized reference intervals, personalized decision limits, Reference change values and interpretative comments.
(15) Promote the performance and use of data simulation as means EFLM Milan1b indirect outcome studies to determine analytical performance specifications based on acceptable variation in clinical classification.
(16) Transition from volume-based to value-based testing, where laboratory results demonstrably enhance patient care, and adoption of a value-based score to increase visibility and understanding among all stakeholders. This score assures an objective evaluation of quality in the total testing process, to accomplish an effective program of benchmark between clinical laboratories.
(17) Encourage appropriate test utilization and promote clinical laboratory stewardship and provide guidance in clinical recommendation of tests fit for purpose between laboratory and requesting clinicians in order to choose the test with the correct analytical performance specification to meet the required clinical performance specifications.

(18) Promote accreditation and adherence to international quality standards (e.g., ISO 15189).
(19) Ensure ethical use of AI and laboratory testing (particularly genetics).
(20) Strengthen preparedness and responsiveness to global health threats (e.g., pandemics, emerging infections, biosecurity) and cyberattacks.
(21) Minimize the environmental footprint of laboratory operations and their sustainability.

Strategic Priority 2: Strengthening Education, Cooperation and Promotion

(1) Advocate and make visible the role of laboratory medicine in personalized, predictive, and preventive healthcare and society.
(2) Enhance the involvement of laboratory professionals in diagnostic decision-making for improved interdisciplinary care.
(3) Modernize education and training programs to equip professionals with skills for new technologies and evolving healthcare demands.
(4) Support early-career professionals through research and education initiatives and a pan-European mentorship program fostering interdisciplinary leadership.
(5) Foster new educational pathways addressing digital health, AI ethics, and mobile diagnostics literacy for both professionals and patients.
(6) Create a modern communication ecosystem: podcasts, short videos, infographics, and multilingual platforms to reach clinicians, policymakers, and the public.
(7) Evolve educational offerings by integrating AI-powered learning tools beyond traditional formats such as webinars.
(8) AI-powered learning ecosystems: Beyond webinars, create adaptive, personalized digital platforms with simulations, case-based learning, and interactive modules.
(9) Build partnerships with other scientific organizations (e.g., BioMed Alliance, EQALM), public health institutions (e.g., WHO, CDC), and regulatory bodies (e.g., ISO, EA, JCTLM, EU Commission).
(10) Reinforce European competitiveness through talent development, leadership training, and knowledge transfer within a rapidly changing global innovation landscape.
(11) Encourage cross-sectoral leadership – clinicians, laboratorians, policymakers, and patients – to co-create new diagnostic models that are inclusive, understandable, and trust-based.
(12) Enhance synergies with IFCC and regional federations through joint activities, best practices, and guideline development.
(13) Improve internal and external communication within the EFLM ecosystem.
(14) Deepen cooperation/collaboration with the IVD manufacturers on the level of Medtech-Europe and EQA providers, including regulatory engagement.

Strategic Priority 3: Advocacy – Shaping European Health Policy For Laboratory Medicine

(1) Strengthen EFLM's engagement with European institutions to promote a regulatory and policy environment that supports public health and advances laboratory medicine.
(2) Strengthen EFLM's leadership role as the voice of laboratory medicine within the European health ecosystem, capable of anticipating policy shifts, regulatory transitions, and global disruptions.
(3) Act as the main interface between laboratory professionals and EU institutions (EHDS, AI Act, EMA, ECDC), complementing IFCC's global reach. Implement cooperation with MedTech Europe to promote a better visibility of IVD and laboratory medicine.
(4) Advocate for equitable and sustainable access to advanced diagnostic technologies across Europe, aiming to reduce regional disparities in patient care in cooperation with the Lancet Diagnostics Commission.
(5) Promote the integration of laboratory data into European health data initiatives (e.g., EHDS, EHR systems).
(6) Support awareness campaigns that highlight the clinical, economic, and societal impact of laboratory medicine.
(7) Position EFLM as a key stakeholder in European health programs focused on chronic diseases, prevention, diagnostic performance, and integrated care pathways.
(8) Establish EFLM Policy Officer to keep pace with the legislations that affect lab medicine and effectively communicate with EU and regulatory institutions.

(9) Develop a European "Diagnostic Competitiveness Index" to benchmark laboratory medicine innovation, accessibility, and patient impact across member countries.

Strategic Priority 4: Data Structuring and Interoperability – Enabling Intelligent and Sustainable Health Systems

(1) Promote the standardization and structured formatting of laboratory data to enhance interoperability. Raise awareness of the need for data equivalence to ensure safe and reliable exchange, including identifying root causes of inequivalence – such as differences in metrological traceability and selectivity.
(2) Facilitate the use of laboratory data in translational research, disease registries, and real-time public health monitoring.
(3) Support the creation of a patient-centered data architecture where laboratory data, wearable data, and mobile health inputs converge into actionable insights for clinicians and patients.
(4) Build a federated infrastructure to share laboratory data securely across borders for clinical care, research, and crisis monitoring (Pan-European laboratory data network).
(5) Ensure seamless integration of laboratory information with electronic health records and clinical systems for faster, more contextualized diagnostics.
(6) Ensure harmonization principles to guide AI model training and validation, so that algorithms built on laboratory data are reliable, reproducible, and transferable across healthcare settings.
(7) Create the necessary foundations for the ethical and effective deployment of artificial intelligence in laboratory medicine.

Summary

EFLM should continue its essential mission: to place the patient at the heart of every innovation in laboratory medicine and healthcare, strengthen the link between science, technology, and humanity, and promote a European laboratory model that stands for excellence, ethics, and sustainability.

A fundamental goal is to move the clinical laboratory outside the "black box" to promote full integration with the health care system and clinical pathways.

By guiding the transformation of laboratory medicine toward an integrated, connected, and predictive approach, EFLM contributes to shaping a future where health is more accessible, personalized, and resilient to technological, economic, and geopolitical changes.

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