Editorial

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SMART and GREEN LABORATORIES. How to implement IVDR, emerging technologies and sustainable practices in medical laboratories?

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This special issue of *Clinical Chemistry and Laboratory Medicine (CCLM)* is dedicated to the lectures and contributions presented at the 3rd Strategic Conference of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) entitled *"SMART and GREEN LABORATORIES. How to implement IVDR, emerging technologies and sustainable practices in medical laboratories?"* that was held from 25th to 27th May 2022.

The 3rd EFLM Strategic Conference was a unique opportunity for all stakeholders to learn, to understand, and question the direction of Laboratory Medicine in Europe and worldwide, and to contribute. The Conference program was designed to be interactive allowing sufficient time for discussions. More in the spirit of strategic thinking: what are the problems now, what should we strive for in the future, where should our focus be, how can we achieve this, and how can we to implement revolutionary ideas to take us forward. More than 1,000 scientists registered for the Conference and listened to 60 Speakers and Session Chairs. All presentations, discussions, networking, and the exhibition were found to be rewarding and valuable by the participants.

The Scientific Program covered a wide range of important topics such as fundamental concepts, advanced diagnostics and techniques used in laboratory medicine. Outstanding expert speakers, and global opinion leaders from the fields of laboratory medicine, the *in vitro* diagnostics (IVD) industry, digital health, medical devices and representatives from the MedTech Europe attended the conference to present the latest innovations in laboratory medicine, in healthcare, diagnostic technologies and scientific advances in all disciplines relevant to laboratory medicine.

A panel of experts discussed what is needed to succeed in this changing environment and the role of collaboration between industry, public, private, and academic drivers of innovation. Their feedback, participation, and engagement during the open discussion platform at the Strategic Conference was important and will be considered to advance laboratory medicine and to shape the future of our profession.

In all sessions, speakers from the IVD industry were included in the program to emphasize the importance of the partnership model with the IVD Industry for the efficient integration and adoption of innovations and emerging technologies in the IVD landscape in medical laboratories, and to implement revolutionary ideas to move us forward, to develop a strategic vision for cost-efficient and clinically effective laboratory services, that add value, to develop an efficient collaboration with MedTech Europe for European IVD Regulations, transitioning medical laboratories to sustainable and green labs, digital twins, novel technologies and clinical research to enable precise, predictive, preventive and personalised medicine, direct-to-consumer testing, trends, opportunities, and challenges.

Session 1: Where is the MedLab industry headed in the next decade? Partnership model for efficient integration and adoption of emerging technologies and innovations (artificial intelligence, machine learning, advanced and integrative diagnostics) in the IVD landscape into medical laboratories.

In their opinion paper, Carobene and colleagues suggest that laboratory specialists should develop tools, standards, and experimental approaches to improve the assessment of safety, efficacy, quality and performance of ML/AI models used in patient care, with a focus on AI in laboratory medicine in real-world scenarios, including IT and IVD professionals [1].

In the paper by Lennerz et al., the authors discuss a conceptual framework for diagnostic quality with the specific goal of evaluating AI/ML implementations at the test, procedure, laboratory, or healthcare ecosystem level. They conclude that a diagnostic quality model is essential to navigate the complexity of clinical AI/ML implementations to specify and communicate the key implications of AI/ML solutions in laboratory diagnostics [2].

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Cadamuro describes how AI algorithms assist laboratory professionals in test selection and result interpretation to improve laboratory efficiency and medical quality [3].

Session 2: Digital transformation towards the laboratory of the future. Perspectives for the next decade.

In their opinion paper Jovičić and Vitkus describe that the changing landscape of the healthcare industry and the increasing number of data produced are forcing healthcare services to digital transformation [4].

In her paper, Gungoren presents the strategies for a successful digital transformation in the context of clinical laboratory settings [5].

In their opinion paper, Lange and Busco-Cortes answer fundamental questions from the perspective of diagnostics companies by looking at the key trends and challenges in healthcare and the opportunities for digital health and its role in the healthcare of the future and propose digital health solutions (DHS) to create a roadmap for labs and diagnostics companies to impact the diagnosis cycle [6].

Session 3: Big data and how to utilize it to improve service, quality and patient outcomes. Training the next generation to collect/analyze and use lab data in a more efficient manner with more focus on post-analytics than analytics.

The article by Hulsen and colleagues summarizes the lectures given during this session. The authors mention the crucial role of laboratory medicine as the largest producer of structured data for the efficient and safe implementation of big data [7].

The review entitled "Clinical lipidomics in the era of the big data" provides an overview of the large-scale clinical lipidomics studies that are evolving from the current clinical concept of a "single-lipid marker" to a "multi-analyte-lipid panel" [8].

Session 4: IVD regulation and the road to May 2022 and beyond. Preparation of the profession for the new IVDR.

The new European *In Vitro* Diagnostic Regulation (IVDR) EU/2017/746, published on May 25, 2017, creates a new environment for IVD companies in terms of product development, management of product lifecycle, and commercialization approach. IVD companies need to re-register their entire IVD portfolio under the new regulation by the end of the five-year transition period extended for one year. The IVDR is applicable to all devices sold or marketed within the European Union (EU), with no distinction as to where they are marketed. New concepts for the IVDR may lead to a new infrastructure for innovation in the field of IVDs in the EU.

The opinion paper by Hallersten et al., entitled "Principles of ideal diagnostic regulation and the IVDR" contains a wealth of sensible suggestions for both manufacturers and regulatory bodies trying to find the necessary path for a smooth transition from the IVDD to the IVDR. The principles presented are global in nature and can be used both in the long term to support regulatory reform, as well as in the short term to guide interpretation and decision-making, when implementing existing regulatory frameworks [9].

The article entitled "The ISO 15189 is a sufficient instrument to guarantee high-quality manufacture of laboratory developed tests (LDTs) for in-house-use in conformity with requirements of the European In-Vitro-Diagnostics Regulation (IVDR)" is the position paper of the EFLM Task Force on European Regulatory Affairs (TF ERA) and Working Group on Accreditation and ISO/CEN standards (WG ISO/A) [10].

Session 5: Green labs for improving environmental sustainability. What are the priorities of medical laboratories under the EU green deal?

The Chair and Speakers of Session 5 prepared opinion papers and reviews on the contribution of laboratory medicine to a sustainable healthcare system and environmentally friendly laboratories that ensure resources are used efficiently from an environmental, social, and economical perspective, while providing high-quality services to patients and physicians. Sustainability practices should be a key element in the rapidly changing healthcare environment. Incorporating sustainable practices into daily laboratory routines will reduce emissions and help the European Commission European Green Deal (EGD) achieve its Climate and Sustainability Action Plan in line with the Paris Climate Agreement. EFLM and its Member Societies will lead the laboratory medicine community in the shift to carbon neutrality in line with the European Green Deal (EGD) Investment Plan, also known as the Sustainable Europe Investment Plan, which aims to make Europe the world's first climate-neutral continent. For this reason, a new Task Force was created: the EFLM Task Force "Green and Sustainable Laboratories" [11–15].

Session 6: Novel technologies and clinical research in enabling precise and personalized medicine.

In their paper, Poveda-Rogers and Morrissette review and compare the benefits and drawbacks of next-generation sequencing (NGS) technology and comprehensive genomic profiling [16].

Simmaco and colleagues describe the systematic application of integrated bioinformatics tools for routine precision medicine in multiple treated patients, the recent development, and validation of bioinformatics tools, aimed at automated evaluation and optimization of multiple therapies according to the unique individual characteristics (including genomic variability), and are poised to change the daily approach to pharmacological prescription [17].

Session 7: Strategic vision for laboratory services that add value. Cost-effective and clinically effective laboratory services–enhancing the value of laboratory testing with focus on major (acute and chronic) public health problems.

In their opinion paper, Adeli and colleagues evaluate the role of laboratory medicine in clinical outcomes [18].

In the opinion paper entitled "Improved implementation of medical tests – barriers and opportunities" St John and colleagues discuss various barriers and challenges to test implementation. They identified significant gaps in the resources and skills that would be required for better test implementation, and that professional organizations need to recognise these gaps and provide the education and training resources to generate an appropriately skilled workforce [19].

In the original article entitled "Precision QC: a dynamic model for risk-based analysis of analytical quality" Schmidt and colleagues describe the significant resources that clinical laboratories devote to quality control (QC) programs to minimize the impact of errors [20].

In their original article, entitled "Quality indicators in laboratory medicine: state-of-the-art and future strategies", Sciacovelli and colleagues describe quality indicators (QIs), developed specifically designed for laboratory medicine which are effective in the assessment and monitoring of all critical events occurring in the different phases of the total testing process (TTP), in particular, in the extra-analytical phases [21].

Session 8: Direct to consumer testing – what role should laboratory medicine have?

The paper prepared by the symposium speakers and chairs addresses the present state-of-art for direct-to-consumer testing. What are the views of regulators, consumers and the IVD industry? Should laboratory medicine become more actively involved to give input to the EFLM on the required organization's strategy in this field [22].

The paper by Hinzmann describes the benefits of direct-to-consumer-testing, but also emphasizes concerns and provides recommendations for the proper use of these tests [23].

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