

Opinion Paper

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Science, Quality and Value of Laboratory Medicine

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Abstract: The *Meeting on Science, Quality and Value of Laboratory Medicine* was held on 11 December 2025 in Padua, immediately preceding the 7th European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Conference on the Preanalytical Phase. For organizational reasons, the meeting was structured in two parts, with the first held in December 2025 and the second scheduled for early 2026. The initiative, designed to better steer and promote the activities of all EFLM Committees and

Divisions, represents a pivotal step toward overcoming fragmentation and silo-based cultures. By fostering a holistic vision that captures interactions among all EFLM Functional Units, the meeting supported the translation of value-based laboratory medicine principles into real-world practice. This collective opinion paper summarizes the lectures presented at the meeting, providing an overview of ongoing EFLM projects and future developments in value-based laboratory medicine. Importantly, the meeting also generated significant opportunities for collaboration and shared project development, underscoring the transition from isolated activities to a collaborative, value-driven approach.

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Introduction

One year after the reorganization of all the Functional Units of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM), the EFLM President, together with the Chair of the Division of Science, initiated the organization of the *Meeting on Science, Quality and Value of Laboratory Medicine*, which was held on 11 December 2025 in Padua, immediately preceding the 7th EFLM Conference on the Preanalytical Phase. For organizational reasons, related to the duration of the meeting and the availability of the chairs of the various Committees and Divisions, the meeting was structured into two parts, with the first held in December 2025 and the second scheduled for the early months of 2026. This initiative, aimed at more effectively steering and promoting the activities of all EFLM Committees and Divisions, represents a pivotal step toward overcoming fragmentation and the silo-based culture that often characterizes scientific organizations. Furthermore, it promotes a holistic vision capable of capturing the interactions and interconnections among the various Functional Units, thereby enabling the translation of the principles of value-based laboratory medicine into real-world practice in their most comprehensive interpretation.

This collective opinion paper, which summarizes the abstracts of lectures delivered at the Meeting provides a comprehensive overview of the projects and programs of the Functional Units of the EFLM and offers some important insights into further developments in value-based laboratory medicine (Table 1). However, the most significant outcomes of the meeting were undoubtedly the numerous opportunities for collaboration, interaction, and the sharing of project initiatives that emerged, highlighting how the transition from a silo-based culture to a collaborative approach represents a crucial step forward in terms of both growth and improvement.

EFLM Committee “Preanalytical Phase”, Chair: Alexander von Meyer

To raise the standard and safety of laboratory medicine throughout Europe, the EFLM Committee on Preanalytical Phase (C-PRE) is working on a number of related projects. Important projects include extensive surveys, such as those on venous access device (VAD) blood sampling procedures, as well as other surveys to record variability, difficulties, and best practices for standardized standards. By combining the current “Diagnostic quality of the sample” database with fresh data produced in accordance with CRESS standards, C-PRE is

concurrently planning to create an extensive stability database with the goal of implementing stability equations and electronic interfaces with laboratory information systems in the future. Further efforts emphasize industry-laboratory cooperation to improve patient safety by reviving the HIL (hemolysis, icterus, lipemia) project in conjunction with manufacturers. Lastly, the committee is working on a project on the use of laboratory tests, initially focusing on acute coronary syndrome and myocardial infarction, in order to better understand underutilization and overutilization and to investigate collaborations with the AI committee in order to convert knowledge into practical modifications in clinical pathways.

The pre- and postanalytical working group at EQALM is one of the planned partnerships, which will promote cooperative improvements in quality assurance. C-PRE is a potential key player in lowering preanalytical mistakes and standardizing procedures across the continent thanks to these diverse initiatives.

EFLM Committee “Post-analytical Phase”, Chair: Pieter Vermeersch

The ultimate goal of value-based laboratory medicine is to maximize the effectiveness of laboratory tests to improve patient outcome [1]. The postanalytical phase is a key element to achieve this goal. Key strategies for the next years to achieve this goal include improving the clinical utilization of laboratory tests, improving the effectiveness communication of critical and significantly abnormal results, and combining the results of different laboratories in electronic health record systems.

While reflex and reflective testing and minimal retesting intervals have been used to improve clinical utilization of laboratory tests for more than 20 years, there is significant variation in current practice among European laboratories. The EFLM Committee Postanalytical Phase (C-POST) is preparing a critical appraisal of current practice based on a number of surveys.

The impact of laboratory errors on patient safety and patient outcomes is underscored by the fact that failure or delay in ordering a diagnostic test and misinterpretation of diagnostic test results are among the top five causes of diagnostic errors resulting in serious patient harm [2]. Effective communication of critical and clinically significant results is important to improve patient safety and the effectiveness of laboratory test results [3]. Advanced IT tools can provide new ways of communication and enable

Table 1: Program of the EFLM Meeting of Science, Quality & Value in Laboratory Medicine.

Thursday December 11th 2025

Session 1: Total Testing Cycle Harmonization and Digitalisation

Chairs: M. Plebani, M. Langlois

- EFLM Committee “Preanalytical Phase”, Chair Alexander von Meyer
- EFLM Committee “Post-analytical Phase”, Chair Pieter Vermeersch
- EFLM Committee “Harmonisation”, Chair Martina Zaninotto
- EFLM Committee “Exchange of Laboratory Data”, Chair Ruben Smeets
- EFLM Committee “Digitalisation and Artificial Intelligence”, Chair Andrea Padoan
- EFLM Committee “Laboratory Error Database”, Chair Hickmet Can Cubukcu

Session 2: How to Translate Science into Quality of Laboratory Medicine

Chairs: P. Fernandez-Calle, T. Trenti

- EFLM Committee “Value-Score for Clinical Laboratory”, Chair Mario Plebani
 - EFLM Committee “Clinical and Analytical Performance Specifications”, Chair Phillip J. Monaghan
 - EFLM Committee “Practical Guide to Implement Measurement Uncertainty”, Chair Abdurrahman Coskun
 - EFLM Committee “Direct-to-Consumer Lab Testing & Patient Empowerment”, Chair Matthias Orth
 - EFLM Division “Quality, Standards and Regulations”, Chair Marc Thelen
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customization taking into account individual patient characteristics. Combining structured clinical information and results from different clinical laboratories in clinical decision support systems could help reduce inadequate and clinically inconsistent alerts and improve patient outcome. C-POST is preparing an opinion paper on “the best-in-class solution” for defining and communicating critical and clinically significant results.

EFLM Committee “Harmonisation”, Chair: 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. The widespread acceptance of this approach is imperative, not only because harmonization of nomenclature and measurement units allow to minimize risk to patient safety but also considering the future “European Health Data Space” which will entail mandatory the accessibility and exchange of healthcare data. However, the results of a recent survey carried out from EFLM Committee “Harmonisation” [4] demonstrated that the community of the laboratory professional seriously underestimates the problem: some countries in Europe expressed little interest in this specific topic and 25 % of the countries failing to participate. In addition, the data showed an overall and progressive, albeit slow, improvement in harmonization of reports in comparison to the results of previous survey dating back to 2016: currently, about 80 % of the European countries adopt SI units in reporting results, but 7.7 % use obsolete units (mEq/L) for electrolytes reports and 91 % use “seconds” (and largely discouraged measurements units from all scientific societies) in coagulation test panels. Considering different areas of the laboratory diagnostic, some interesting points may be highlight and in particular: -Hematology, a satisfactory harmonization for hemoglobin reports, 60 % adopting g/L and a significant harmonization for blood count leukocytes, 90 % of the responders use the recommended unit (10^9 g/L); -Endocrinology, a significant adoption of SI units from 90 % (for fT4) to 70 % for progesterone; but up to four different measurement units for reporting fT4 results (pmol/L recommended, ng/dL, ng/L, pg/mL), three for prolactin (mIU/L recommended, ng/mL, mg/L) and three for progesterone (mmol/L recommended, ng/mL, mg/L) are currently

used in Europe. In order to accelerate the harmonization activities, some key partners that play essential roles in the harmonization process, may be identified and in particular: Institutional Bodies, EQA providers, Manufacturers of reagents and quality control materials, Editors of the international journals [5]. The first step might consist in strongly encouraging EQA scheme providers to force laboratories to adopt SI units only in entering results and to evaluate the performance for the results being expressed in SI units only: EQA performance represent a fundamental prerequisite for ISO 15189 accreditation, and, according to the proposed strategy, laboratories should adopt the SI units to evaluate their analytical performance through the EQA scheme. Furthermore, at institutional level, the national accreditation bodies should evaluate the compliance with the requirement to report the results in SI units, as part of the assessment in the accreditation process A further step might be to oblige manufacturers (within the IVDR regulation) to exclusively include in their Instructions For Use (IFU), the SI units in their product description, in declaring the specific analytical performance and in reporting the proposed reference intervals. Currently, in IFU of the main manufacturers of reagents and systems, SI units are reported in brackets or named as “alternative” to the traditional units, the latter being identified as principal or “standard” units, and the “liter” is never reported as “unit of volume”. Finally, for the Editors of the scientific international journal, the action point should be to force the use of SI units in instructions for author and in the publication of the papers in “peer review” journals. In order to address this issue promptly, EFLM working groups and the official bodies managing the *in vitro* diagnostic medical device regulation requirements, are working together to plan the joint strategic activities to propose a pragmatic and sustainable approach enabling the rapid achievement of the harmonization of the three key issues in reporting results: measurements units, reference intervals, and nomenclature.

EFLM Committee “Exchange of Laboratory Data”, Chair: Ruben Smeets

“Technical exchange of diagnostic data does not equate to the provision of correct information or its appropriate interpretation in primary medical care.” This statement sets the direction for the establishment of a new EFLM committee on laboratory data exchange, marking a transition into a new era of cross-enterprise diagnostic data sharing. Medical institutions, healthcare professionals, and governmental

bodies increasingly recognize the critical importance of exchanging medical information at both national and international levels. The European Health Data Space (EHDS) initiative further underscores this ambition by aiming to facilitate and structure cross-border health data exchange within Europe.

Moreover, the growing need to reuse diagnostic information in primary care and secondary research contexts highlights the necessity of addressing key requirements related to exchangeability, interoperability, and interpretability of laboratory data. This development calls for active involvement of diagnostic laboratory specialists to ensure that not only laboratory tests meet established quality standards, but that results documented in laboratory information systems (LIS), exchange information systems (XIS), and electronic health records (EHRs) – including associated diagnostic data and metadata – are of sufficient quality to support accurate exchange and correct interpretation by receiving parties.

The traditional boundaries of medical laboratories and care pathways have shifted from intramural settings towards trans-mural and multi-institutional care models. This evolution necessitates targeted action and the development of standards to safeguard this emerging form of post-analytical quality assurance.

To address these challenges, the committee has defined the following initial objectives:

- To define the minimum dataset required for national and international exchange of laboratory data for clinical purposes within Europe.
- To define the optimal dataset, including relevant metadata, to be coded for standardized exchange of laboratory test results across Europe.
- To coordinate issues related to laboratory data exchange with the European Union, particularly in the context of the European Health Data Space, and to liaise with relevant stakeholders.

Additional objectives and future perspectives include:

- Establishing robust laboratory data governance frameworks, including standardization and interoperability.
- Developing collaborations to assemble, curate, and share well-structured laboratory datasets effectively and at scale.
- Scaling activities towards national organizations and an international professional community.
- Defining implementation standards and best practices for EHR and LIS configuration, as well as for the development of data exchange platforms.
- Promoting public and clinical engagement.

- Supporting education and training of laboratory specialists in the fundamentals of laboratory informatics, standardized system configuration, and business analytics, with consideration for high-, middle-, and low-income country settings.

EFLM Committee “Digitalisation and Artificial Intelligence”, Chair: Andrea Padoan

Artificial intelligence (AI) and machine learning (ML) are increasingly recognized as transformative technologies; however, their integration into clinical laboratory routine practice remains limited compared with other medical disciplines. A significant barrier to effective advancement lies in the structure and governance of laboratory data, which frequently do not adhere to FAIR (Findable, Accessible, Interoperable, and Reusable) principles. Current laboratory information systems (LIS) and middleware often lack the capacity to adequately store and exchange the rich metadata and peridata required for robust AI applications. As a result, valuable information generated throughout the total testing process is only partially captured or not readily retrievable, contributing to the delayed adoption of AI and ML tools in clinical laboratories. Laboratory data present unique methodological and semantic complexities, including method dependency, analyte-specific biological variation, and strong contextual sensitivity, which are not adequately addressed by general-purpose AI frameworks. The Committee on Digitalisation and Artificial Intelligence (C-AI) of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) emphasizes that adherence to FAIR data principles, together with robust data governance, is a prerequisite for reliable, effective, and clinically meaningful AI deployment in clinical laboratories. To support this aim, C-AI has contributed to the expansion of existing AI assessment frameworks by proposing laboratory-specific extensions to the ChAMAI checklist, aiming to support transparent and methodologically sound evaluation of AI studies in laboratory medicine.

Beyond methodological aspects, regulatory developments such as the EU Artificial Intelligence Act introduce new opportunities and challenges. To address these requirements, C-AI outlines strategic priorities including enhanced education of laboratory professionals in AI and digital competencies, collaboration with international partners, responsible public-private partnerships, and targeted future initiatives dedicated to medical validation. These

efforts aim to foster a structured, responsible, and clinically relevant integration of AI into laboratory medicine.

EFLM Committee “Laboratory Error Database”, Chair: Hickmet Can Cubukcu

Laboratory errors are a substantial and under-recognized cause of diagnostic inaccuracy, with 26–30 % of reported errors adversely affecting care and up to 95 % of incident reports showing potential for harm. Despite scattered literature and manufacturer manuals, there is no sustainable, open-access resource that consolidates error types, their assay-specific effects, and potential severity of harm [6]. EFLM Committee on Laboratory Error Database (C-LED) aims to develop, implement, and maintain a continuously updated, evidence-based database covering various laboratory errors, their impact on test results, the potential severity of harm they can cause, and supporting references. C-LED will procure literature information across three pillars: (1) peer-reviewed literature, (2) IVD manufacturer data, and (3) other real-world sources (incident reports, corrective and preventive action reports, surveys, and regulation bodies' reports). Artificial intelligence (AI) assisted literature information procurement pipeline comprises two stages: Stage 1 uses a large language model (LLM) (via model context protocol-integrated access to PubMed/Crossref) for literature screening; Stage 2 performs full-text information extraction (with LLM cross-checks) to capture assay-specific, quantitative effects. Finally, expert review validates all AI-extracted outputs before inclusion to database. To demonstrate the feasibility of this approach, EFLM C-LED started a pilot study on hemolysis interference on cardiac troponins. The establishment of the EFLM C-LED represents a critical step forward in addressing the persistent challenge of laboratory errors and their impact on patient safety. By combining institutional governance, innovative AI-driven literature procurement, comprehensive metadata structures, and measurement system-specific detailed information, C-LED aims to create a sustainable, evidence-based resource that previous initiatives could not achieve. The success of C-LED depends on continued engagement with expert consultants, international, regional, and national societies, *in vitro* diagnostic manufacturers, regulatory bodies, and the broader laboratory medicine community. Through collaborative effort and sustained commitment, C-LED can transform how laboratory professionals understand, identify, and manage laboratory errors, ultimately

enhancing patient safety and diagnostic accuracy across healthcare systems globally.

EFLM Committee “Value-Score for Clinical Laboratory”, Chair: Mario Plebani

The concept of Value-Based Laboratory Medicine (VBLM) is attracting increasing interest as an effective strategy to enhance the visibility, relevance, and clinical impact of laboratory services. However, translating the principles of VBLM into routine clinical practice requires substantial efforts, including the development of new and enhanced professional competencies, as well as practical tools capable of supporting interlaboratory comparisons based on meaningful and outcome-oriented indicators. Following the dissemination of a 10-point manifesto for the implementation of VBLM [7], the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) launched a novel initiative aimed at developing a value-based score (VS) for clinical laboratories [8]. The main objectives of the value-based score can be summarized as follows: (a) to identify fundamental requirements that enable a comprehensive understanding of the true quality of clinical laboratory services; (b) to achieve an objective evaluation of quality across the total testing process (TTP); (c) to develop a value-based score grounded in these requirements, relying on information that is readily available and preferably automatically collected, in line with the goal of increasing automation; and (d) to establish an effective benchmarking program among clinical laboratories. The initial proposal of the value-based score was based on the following core domains: (1) traceability throughout the total testing process; (2) level of automation, assessed by the extent of manual procedures; (3) laboratory performance as measured by quality indicators; (4) data management and the quality of laboratory information; and (5) interaction with clinicians and participation in multidisciplinary initiatives. A newly established EFLM Committee, launched following the 2024 Strategic Conference, has subsequently worked to further refine the value-based score by introducing an additional domain, “Innovation and research,” and by clearly defining the qualifying elements for each category. To assess both the acceptance and the practical feasibility of the proposed framework, the Committee has decided to initiate a Pilot study involving at least 10 clinical laboratories of varying size and from different geographical regions. The aim is to collect feedback, suggestions, and critical insights, thereby facilitating the refinement of the value-based score and supporting its

effective implementation in real-world clinical laboratory practice. We have recently identified 12 clinical laboratories that have agreed to evaluate the value-based score and are expected to provide their feedback by February 2026.

EFLM Committee “Clinical and Analytical Performance Specifications”, Chair: Phillip J. Monaghan

The Milan consensus proposed the now widely accepted approach to derive analytical performance specifications (APS) based on three non-hierarchical models; Model 1 – Outcomes (model 1a – direct outcome studies, model 1b – indirect outcome studies), Model 2 – Biological Variation, and Model 3 – the State of the Art. APS is defined as “criteria that specify (in numerical terms) the quality required for analytical performance in order to deliver laboratory test information that would satisfy clinical needs for improving health outcomes” [9]. If we take Model 1 for deriving outcome-based performance specifications, APS in this regard quite simply refers to “how good the analytical performance of a test needs to be to do more good than harm to the patient” [10].

The REGULATION (EU) 2017/746 on *in vitro* diagnostic (IVD) medical devices, defines clinical performance as “the ability of a device to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended user”. Hence, as test results are linked indirectly to health outcomes through the clinical decision-making process, clinical performance requirements must first be set in order to define APS appropriate to medical needs.

The EFLM Committee for Clinical and Analytical Performance Specifications (C-CAPS) represents collaboration between experts in evidence-based laboratory medicine, evidence-based diagnosis and epidemiology, and research and development of IVD industrial partners. C-CAPS aims to develop and progress the principles and key elements required for setting Model 1b APS. Critical in this context is how the test is used in the clinical pathway and what the consequences of testing are. The C-CAPS convened a 2025 Workshop on Model 1b APS, with collaboration across a number of Committees within the EFLM Division of Science – Value-based Laboratory Medicine, including the Committee on Biological Variation, Committee on Laboratory Error Database, and Committee on Practical Guide to Implement Measurement Uncertainty, as well as the EFLM

Division Quality, Standards and Regulations. Furthermore, the establishment of the EFLM C-CAPS enables deliverables across three key areas: (1) development of conceptual frameworks and methods for defining clinical and analytical performance specifications for measurands based on intended purpose of tests, (2) development of practical tools which support the design, conduct and appraisal of clinical trials that provide high quality evidence for the clinical and analytical performance of biomarker and IVD medical devices, (3) providing methodological support for the evaluation of the clinical and analytical performance of biomarkers and IVD medical devices both at the pre-market assessment and post-market surveillance phase of the test evaluation cycle. Ultimately, the success of the C-CAPS rests in the continued collaboration across EFLM Committees, with the IVD industry, regulatory and other key stakeholders, whilst looking outward at the future synergistic collaborative opportunities through cooperation with clinical and professional societies (for example, to deliver harmonised APS for the laboratory community), and to work with aligned key partners including the European Organisation for External Quality Assurance Providers in Laboratory Medicine (EQALM) Working Group for Performance Specifications. Collectively we need to ensure that laboratory tests on the market are fit for intended use to address unmet clinical needs [11].

EFLM Committee “Practical Guide to Implement Measurement Uncertainty”, Chair: Abdurrahman Coskun

The committee aims to (1) develop practical approaches for calculating measurement uncertainty (MU) in medical laboratories for single and multiple instruments and laboratory settings; (2) promote the use of MU as a tool to support laboratory harmonization; (3) establish procedures to estimate MU across the full measurement interval of analytical methods using patient samples; and (4) clarify and standardize MU-related concepts for medical laboratory professionals. The committee has developed a pragmatic algorithm for estimating MU for a conglomerate of laboratories using data collected under reproducibility conditions [12]. The approach is based on combining long-term data (a minimum of two months for hematology parameters and three months for other parameters) from all instruments and laboratories measuring the same measurand and treating these data as a single pooled dataset. The standard

MU is calculated from this dataset. The estimated MU should be lower than the maximum acceptable MU, defined as $2 \times 0.5 \times CV_1$ for the desirable performance level [13]. The committee has proposed the use of MU as a basis for harmonization within conglomerate laboratory networks and has applied this approach to hematology parameters [14]. If the MU of the combined laboratories is lower than the maximum acceptable MU, the laboratories can be considered harmonized. Conversely, if the MU exceeds this threshold, it indicates that at least one laboratory is measuring the measurand differently from the others.

Challenges, obstacles and redefinition of measurement uncertainty

Over the past decade, transformative advances have occurred in the fields of metrology and MU. A historic milestone was the redefinition of the SI units, whereby several base units – including the kilogram, ampere, kelvin, and mole – were redefined in terms of fixed numerical values of fundamental natural constants rather than material artefacts [15–17]. Previously, some SI units relied on physical reference objects that were susceptible to surface degradation, contamination, and environmental influences, thereby introducing instability and increasing MU. By anchoring these units to immutable constants – such as the Planck constant (h) via the Kibble balance for the kilogram, the elementary charge (e) for the ampere, the Boltzmann constant (k) for the kelvin, and the Avogadro constant (N_A) for the mole – metrology has achieved unprecedented long-term stability, consistency, and international harmonization across measurement systems. These developments have substantially contributed to reducing uncertainties in scientific, industrial, and medical measurements.

In parallel, MU has been conceptually refined as “the doubt about the true value of the measurand that remains after a measurement,” quantitatively expressed through one or more parameters that are often associated with a probability distribution of values reasonably attributable to the measurand [18]. Despite these advances, the implementation of MU in medical laboratories continues to face resistance, largely due to reliance on outdated concepts that are incorrectly presented as alternatives to MU. To ensure accurate and globally harmonized reporting, MU should be actively promoted as the appropriate framework for characterizing the quality and reliability of laboratory measurement results. Concepts not defined within the International Vocabulary of Metrology (VIM) or ISO standards should not be proposed as substitutes. In particular, the continued use of Total Allowable Error (TEA) as a surrogate for MU should be

avoided and ultimately abandoned. MU represents the internationally accepted, scientifically robust approach for expressing and interpreting uncertainty in medical laboratory measurements, and its systematic adoption is essential for advancing patient-centered, evidence-based laboratory practice.

Future perspectives and desirable cooperation with key stakeholders

From a forward-looking perspective, MU should encompass the entire measurement interval of the measurand and be estimated continuously, thereby enabling the timely detection of erroneous results irrespective of when they occur. Beyond the measurand itself, MU should also be assessed using Bayesian and patient-centered analytical frameworks. Moreover, acceptable MU limits should be defined according to their potential impact on clinical decision-making, including disease diagnosis, patient monitoring, and therapeutic management. To support the effective implementation of MU in medical laboratories, close collaboration with leading professional and scientific organizations is essential. In particular, establishing strategic partnerships with EURACHEM; the EFLM Committees on Harmonization, Biological Variation, and Clinical and Analytical Performance Specifications; and the IFCC Working Groups on Commutability in Metrological Traceability and Method Evaluation will facilitate methodological alignment, enhance the harmonization of practice, and promote the broader adoption of MU-based approaches within laboratory medicine.

EFLM Committee “Direct-to-Consumer Lab Testing & Patient Empowerment”, Chair: Matthias Orth

In Direct-to-Consumer Testing (DTCT,) consumers are not protected by the regulations valid in healthcare. This protection of the patients in healthcare is rather complex and is regulated on a national level. In healthcare, this patient protection works pretty well primarily by direct control of compliance with the national rules by the health insurances or government bodies covering the health care expenses. In DTCT, however, these checks should be performed by the payers of the tests, i.e., the consumers themselves who, obviously, are not able to make informed unbiased decisions

about the quality of the laboratory testing provided including the potential benefits and damages of DTCT.

In particular in countries with a universal coverage of healthcare expenses, confusing and misleading claims are often used to market DTCT. A characteristic of DTCT are claims that this testing is in compliance with IVDR and that the regulations of IVDR protect the consumers. Some DTCT companies claim to be accredited according to EN15189. However, IVDR does not address the testing process and the accreditation of restricted parts of the analytical process may not be confused by accreditation of the whole testing process. EN15189 specifically prohibits the claim of processes which are not accredited. In particular, EN15189 demands advice on the selection of tests, clinical indications and limitations of examination methods, and the frequency of requesting the examination. The accredited laboratories are also in charge of an effective utilization of laboratory examinations, which clearly contradicts many marketing efforts in DTCT.

DTCT is often regarded as a reagent and is labeled with the CE mark and with certificates of the manufacturer. Some DTCT are not labeled at all since they are only regarded as sample receptacles or are regulated under MPR. For patient protection, however, DTCT must be regarded as service and should be monitored according to the national regulations. In additions, notified bodies should not accredit laboratories according to EN 15189 which are not medical laboratories and/or which do not clearly list the scope of their accreditation. Medical laboratories should not cooperate with commercial entities offering DTCT and consumers should be informed by respected, non-biased and evidence-based sources.

EFLM Division “Quality. Standards and Regulations”, Chair: Marc Thelen

The committees of both the EFLM Science and Value based laboratory medicine division (D-Science) and the division for quality, standards and regulations (D-QSR) produce guidance for stakeholders on how to address certain topics in laboratory medicine in order to optimize their implementation with regard to the quality of outcome.

A possible difference between approaches by projects from the two division is the starting point. The D-Science committees work from a scientific topic as starting point and then identify how requirements in ISO standards should be translated into topic specific requirements. This is needed because ISO standards try to prevent overprescription which would conflict a risk based approach and therefore ISO

requirements are limited to the ‘what’ with in some cases explanations from the ‘why’ and leave prescription on the ‘how’ to the guidelines by scientific societies. The committee on accreditation and ISO/CEN standards (C-A/ISO) of the D-QSR takes not a topic, but the standard as starting point and provides how certain requirements should be applied to certain processes or techniques. Typically such guidance is written on requirements around a scoped scientific theme in the standard. With that it is for outsiders hard to distinguish whether a certain EFLM guidance document has been written by either the D-science and D-QSR when only the content is taken into account. Recommendations on the same topics and related to the same ISO standard requirements could be the either the product of D-Science or D-QSR.

Examples of recent topics addressed by D-QSR which also could have been the output of the D-Science are metrological traceability [19] performance specifications [20] allowable lot-lot variation [21] and Artificial Intelligence [21, 22]. In the same light several recommendations by D-Science committees could have easily been the output of the D-QSR, such as the harmonisation of measurement units [4, 5] by the harmonisation committee and recommendations on sample collection by the committee on pre-analysis [23].

Independent of which EFLM body takes initiative in developing guidance of recognised need for such guidance, opportunities must be recognised which other EFLM could contribute to optimise the content by the addition of different angles of expertise. In addition, EFLM stakeholder organisations must be involved in an early stage to allow them to organise input in standard development and later in dissemination and implementation. Stakeholders are not only the national scientific societies representing the laboratory specialists. Also IVD-industry represented by Medtech-Europe and EQA organisations, represented by EQALM, as well laboratory service users, represented by the biomed alliance, are considered stakeholder and are individually addressed in several guidance documents. When it comes to interaction with these stakeholders the QSR sees a role for the umbrella organisations of all types of stakeholders. During guideline development they can identify parties for valuable contributions to the recommendations. Later, in the dissemination phase they can aid in communication and implementation.

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