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EuroLabNews

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In this issue

EFLM Connects National Societies of Clinical Chemistry and Laboratory Medicine and Creates a Platform for all European "Specialists in Laboratory Medicine"

HOT TOPICS IN LABORATORY MEDICINE

How Artificial Intelligence can aid in the development of laboratory medicine

by Janne Cadamuro, Department of Laboratory Medicine, Paracelsus Medical University Salzburg, Salzburg, Austria

For decades laboratory medicine has evolved in terms of accuracy, quality, speed and spectrum. These achievements were possible only by continuous improvements within the analytical phase. Similarly to the availability of food in correlation with population obesity, the availability of laboratory diagnostics has led to an overuse of this resource[1]. Two of the main drivers of this phenomenon, apart from the availability, are the fear of legal consequences (defensive medicine) and the uncertainty of clinicians in test-ordering and interpretation, the core expertise of laboratory specialists[2]. In order to overcome this issue, we as a profession need to proactively engage with clinicians, providing aid in the form of our vast expertise. However, as there are usually only few laboratory specialists, providing service for hundreds of clinicians and far more patients, a one-to-one counselling will not be feasible. Therefore, a semi-automated system is needed, carrying the main workload.

To be continued on page 2

Foreword

by Harjit Pal Bhattoa, Editor EFLM EuroLabNews

The current summer issue of the EuroLabNews commences with the Hot Topic column where Janne Cadamuro presents How Artificial Intelligence can aid in the development of laboratory medicine. Ana-Maria Šimundić, EFLM President reports on a list of receipients who will be presented with various EFLM awards at the EuroMedLab Conference 2021. Furthermore, the EFLM President, Ana-Maria Šimundić also introduces her new regular column "Interviews with past EFLM Presidents and past EFLM officers" where she interviews Prof. Mauro Panteghini, the fifth EFLM President (2014-2016) and the Scientific Coordinator of the Research Center for Metrological Traceability in Laboratory Medicine (CIRME) of the University of Milan. The coffee with the President features interviews with Anna Carobene, Daria Pašalić, Dalius Vitkus and Jorge Díaz-Garzón, all of whom are prominent EFLM officers. Berrak Guven reports on the EFLMLabX: the experience of an applicant. Lejla Alić presents the latests EFLM publication with her signature infographics. Present and Past EFLM events have been highlighted. The Spanish Society of Laboratory Medicine report their latest activities. Under its regular column, the IFCC corner presents global perspectives in Laboratory Medicine. The Calendar of Events lists all major happenings with its usual and unfortunate COVID-19 alert. Even though we are embracing for another wave of COVID-19 infections, I wish you all the same exemplary resilience as laboratory professionals as you always have during this pandemia.

These algorithms could then be implemented into the laboratory information system (LIS), automatically processing the orders, including reflex testing and interpretational suggestions, subsequently validated by a laboratory specialist[3]. Two of the major drawbacks of this solution are that most LISs are not flexible enough to run complex algorithms and that these pathways need to be revised on a regular basis, in order to adapt to changes in evidence. Creating only one pathway (e.g. anaemia root cause investigation) may take up to a year and revising it requires the author to repeatedly sift all available evidence and make according changes. Considering the sheer endless symptoms, suspected diagnoses or laboratory findings such algorithms may be based on, this scenario seems more feasible than the one-to-one counselling, but still not feasible enough.

This is where artificial intelligence (AI) could step in, a technology that was not easily accessible until recently, as the needed computational power was limited to selected centres. AI is an umbrella-term for various models all aiming to mimic the human brain. The most used models for medical AI applications are probably machine learning (ML) algorithms. These models are fed with input data of the respective task and "learns" how to process this data in order to come to a conclusion, alongside a probability of correctness. Depending on if the model is trained with or without provision of the expected outcome (labelled data), these models can be subdivided into supervised or unsupervised learning models. Another sub-category are reinforcement learning models, of which deep learning (DL) algorithms are probably the most known. DL models are breaking up complex tasks, aiming to identify patterns within the data by using so-called artificial neural networks. As this network consists of an input layer and an output layer and several "hidden" layers within, DL algorithms may be referred to as black boxes, since the user is unable of backward engineering. In medicine, however, every algorithm, leading to a medical outcome has to be transparently traceable, just like the measurement of laboratory tests. As this circumstance is not given in DL models, legal requirements such as the FDA 21 CFR Part 11 are currently prohibiting the use thereof to prevent loss of accuracy[4].

In day-to-day life we are getting more and more used to the omnipresence of AI. Google, Amazon, Netflix, Spotify etc. use such models to predict our preferences, smart home assistants understand what we are saying and respond to it, and so on. In medicine the process of AI implementation is far slower, as the consequences of erroneous conclusions are far worse than Alexa putting ham instead of jam on the shopping list. Currently there are few FDA approved models available, all of which only making suggestions with a mandatory final approval by a specialist. Most models currently in use are based on image recognition technology (Pattern recognition in images). Hence, medical disciplines with image interpretation during the diagnostic process like radiology, pathology, dermatology, ophthalmology, cardiology, and others are the main target of these systems[5].

In laboratory medicine things are more complex, as several pieces of information like test result including preceding results, physical examination, medical history, current symptoms, etc. have to be gathered, clustered and interpreted cohesively. The reduction in accuracy of such complex settings, compared to "simple" image recognition, can be observed in the evaluation of on-line symptom checkers, with a correctness of the primary diagnosis in about 34% of cases, probably doing more harm than good[6]. Nevertheless, several models have been published for various steps in the laboratory total testing process, like recommendations in test selection, prediction of test results, generating test results and result interpretation[5].

Although the outlook seems very promising, there are several obstacles and pitfalls to be considered. First of all it has to be acknowledged that the quality of each model depends on the ground-truth or input data (quality in – quality out). The dataset needs to be well structured (and correctly labelled in supervised learning models) and as complete as possible, without major gaps[7]. If the documented diagnosis is incorrect or the clinical data is missing, as so often when ordering laboratory tests, the quality of the respective model will reduce drastically. For most models a huge amount of such data is needed in order to retrieve an acceptable quality. An example of what happens, if too little data are being used to develop an AI model, can be seen in the steep fall of the IBM Watson software, a 62 million USD project, aimed at providing treatment recommendations for cancer patients[8]. Additionally, it has be acknowledged that the afore-mentioned publications are solely of retrospective nature and actually implemented models are scarce.

Overall, AI is a disruptive technology that will forever change how laboratories will provide not only test results but also interpretation thereof, aiding clinicians in daily life and helping our profession become an intrinsic part of every healthcare setting.

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EFLM EXECUTIVE BOARD INFORMS

EFLM Awards 2021 on occasion of the EuroMedLab 2021

Reported by Ana-Maria Simundic, EFLM President

On behalf of the EFLM Executive Board, I am pleased to announce the EFLM Awards 2021 which will be presented in Munich on occasion of the EuroMedLab Congress 2021.

EFLM Award for Scientific Achievements in Laboratory Medicine - sponsored by Roche

This EFLM award has been created to honor an individual who has made important scientific contributions and innovations within the field of Clinical Chemistry and Laboratory Medicine. The EFLM award is granted for excellent work in basic, translational or clinical research within Laboratory Medicine to advance the field in biochemical and molecular analytics and methods, digitalization, new diagnostic strategies, health technology assessment etc. The award amounts to EUR 5.000 to be used by the winner for further educational activities.

The award 2021 goes to **Prof. Sverre Sandberg**, an accomplished scientist that never stops to communicate and share his scientific insights inspiring many young colleagues. His generous personal character and his tireless knowledge-seeking spirit, make him one of the most inspiring scientific personalities in Europe.

EFLM Award for Achievements in Advancing Laboratory Medicine in Europe - sponsored by Roche

This EFLM award has been created to recognize an individual who has made important contributions to advance the profession of Clinical Chemistry and Laboratory Medicine in Europe and to enhance the visibility of the discipline within diagnostic and therapeutic medicine (including e.g. the promotion of interoperable programs between EFLM member societies, professional development, dissemination and teaching, increasing the visibility of LM, etc). The award amounts to EUR 5.000 to be used by the winner for further educational activities.

The award 2021 goes to **Prof. Mauro Panteghini**, one of the most accomplished Laboratory Specialists not only in Europe known for his many original contributions generated from distinctive and authentic innovation. His far-reaching scientific achievements have greatly helped Laboratory Medicine to gain visibility within the international medical arena and thereby particularly have helped to support the role of our profession in medicine.

EFLM Award for Excellence in Outcomes Research in Laboratory Medicine - sponsored by Abbott Diagnostics

This EFLM award is given to the best published paper, as judged by an independent panel of experts, which demonstrates improved clinical and/or economic outcomes of an in vitro diagnostic test or better management of laboratory/test data. The award amounts to Eur 5.000 and is presented to the first author, who is responsible for division among his/her co-authors.

The award 2021 goes to **Prof. Abdurrahman Coskun**, as First Author of the paper:

Personalized Reference Intervals in Laboratory Medicine: A New Model Based on Within-Subject Biological Variation.
Abdurrahman Coşkun, Sverre Sandberg, Ibrahim Unsal, Coşkun Cavuşoglu, Mustafa Serteser, Meltem Kilercik, Aasne Karine Aarsand.
Clin Chem 2021,30;67:374-84

EFLM Award for Excellence in Performance Specifications Research - sponsored by Abbott Diagnostics

This EFLM award is given to the best published paper, as judged by an independent panel of experts, which demonstrates an important and novel contribution to the theory or practical application of performance specifications. The award amounts to Eur 5.000 and is presented to the first author, who is responsible for division among his/her co-authors.

The award 2021 goes to **Prof. Etienne Cavalier**, as First Author of the paper:

Analytical Performance Specifications for 25-Hydroxyvitamin D Examinations
Cavalier E, Fraser CG, Bhattoa HP, Heijboer AC, Makris K, Ulmer CZ, Vesper HW, Vasikaran S, Lukas P, Delanaye P, Carobene A, on behalf of the IFCC-IOF Committee for Bone Metabolism.
Nutrients 2021,28;13:431

EFLM Cardiac Marker Award - sponsored by HyTest

This EFLM award is given to the best published paper, as judged by an independent panel of experts, which demonstrates a remarkable scientific work in the field of cardiovascular diseases. This award is addressed to young scientists under 40 years of age. The award amounts to Eur 5.000 and is presented to the first author, who is responsible for division among his/her co-authors.

The award 2021 goes to **Dr. Jorge Diaz-Garzon**, as First Author of the paper:

Biological Variation of Cardiac Troponins in Health and Disease: A Systematic Review and Meta-analysis
Diaz-Garzon J, Fernandez-Calle P, Sandberg S , Ozcurumez M, Bartlett WA, Coskun A, Carobene A, Perich C , Simon M, Marques F, Boned b, Gonzalez-Lao E, Braga F, Aarsand AK, EFLM WG on Biological Variation and TG for the Biological Variation Database - Clin Chem 2021,67,1:256-64

In accordance with the EFLM Transparency Policy, all award applicants' names, evaluation ranking and reasons for that ranking were made available to every EFLM National Society submitting the application or to the award applicant in case of individual application.

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INTERVIEWS WITH PAST EFLM PRESIDENTS AND PAST EFLM OFFICERS

Reported by Ana-Maria Šimundić, EFLM President

We are happy to introduce a new section in the EFLM newsletter – Interviews with past EFLM Presidents and senior EFLM officers. It is a way to show our appreciation and gratitude to our predecessors and colleagues who have contributed significantly to developing and promoting the Clinical Chemistry and Laboratory Medicine profession and EFLM. We want to get to know the people who have been leaders, inspiration and role models for many years and even decades. Additionally, this section has been included in the EFLM Action plan for 2021, in order respond to the needs and expectations of all EFLM members and national societies, expressed in the survey conducted in 2020. We are very much looking forward to all the interviews, and we hope you enjoy them too.

In this edition, we publish an interview with Prof. **Mauro Panteghini**, the fifth EFLM President (2014-2016) and the Scientific Coordinator of the Research Center for Metrological Traceability in Laboratory Medicine (CIRME) of the University of Milan. This year, Prof. Panteghini is a recipient of the "EFLM Award for Achievements in Advancing Laboratory Medicine in Europe - sponsored by Roche". This is a major award of the EFLM, which honors individuals who have made substantial contributions to advancing the profession of Clinical Chemistry and Laboratory Medicine in Europe and enhancing the visibility of the discipline within diagnostic and therapeutic medicine. The Award has been granted to Prof. Panteghini as a recognition for his leadership and extensive expertise in metrological traceability, standardization, and the assessment of analytical uncertainty. It will be awarded to Prof. Panteghini during the Opening Ceremony of the 24th IFCC-EFLM EuroMedLab Congress in Munich on November 28, 2021.

You have recently been awarded by the "EFLM Award for Achievements in Advancing Laboratory Medicine in Europe - sponsored by Roche". This is a major award of our Federation which has been created to recognize an individual who has made important contributions to advance the profession of Clinical Chemistry and Laboratory Medicine in Europe and to enhance the visibility of the discipline within diagnostic and therapeutic medicine. The award was motivated by your leading role and extensive expertise in metrological traceability, standardization, and the assessment of analytical uncertainty. Could you name some major achievements and milestones in that area?

In 1990's, experts on both Atlantic sides started to debate the impact that poor comparability of laboratory results may have in clouding clinicians' interpretation of reported data, potentially creating a substantive problem for patient safety. They identified the lack of metrological traceability of assay calibration to suitable standards as one of the main causes. Establishing metrological traceability of IVD measuring systems depends on some basic requirements being fulfilled. First, it is essential to establish a calibration hierarchy starting from the unequivocal definition of the measurand as the quantity subject to measurement. The assay selectivity (formerly mentioned as 'specificity') for the measurand at each level of the traceability chain is a crucial aspect and in a standardization project correlation studies should preliminarily be performed to test the relationship among commercial methods and to demonstrate the harmonization potential. Elimination of measurement bias by the applied implementation strategy enables the reliable transfer of the measurement trueness from the highest level of the metrological hierarchy to commercial calibrator values, thereby leading to unbiased results on clinical samples. Finally, an adequate estimation of all sources of measurement uncertainty (MU) should be performed.

The **first milestone** starting the "traceability era" was the publication at end of **1998** of *The In Vitro Diagnostic (IVD) Medical Devices Directive 98/79/EC*, transposed into national laws within the European Union (EU) by the end of 1999. With the aim to improve equivalence of measurement results through more structured and understood approaches for standardization, the Directive, supported by two ISO standards (17511 and 18153) describing metrological principles, asked IVD manufacturers to ensure metrological traceability of their measuring systems to higher-order references. Only IVD devices providing the CE ("Communautés Européennes") marking, indicating the compliance with the EU Directive, may be distributed on the Community market. For the first time, a directive introduced a legal background for the use of metrologically correct measuring systems in Laboratory Medicine and gave to our profession a unique role in promoting and applying these concepts to the medical setting. We should therefore recognize the remarkable role of the European Parliament in providing the basis to obtain more comparability of laboratory results and ensuring that IVDs do not compromise the health and safety of patients.

Someway unexpectedly, this new European legislation, given the globality of IVD market, had immediately a worldwide impact and an international consensus and agreement on how to implement metrological traceability was urged by all players in the field. This was the reason for the creation in **2002** of the Joint Committee on Traceability in Laboratory Medicine (JCTLM), representing the **second milestone** in the history of metrological traceability in Laboratory Medicine. In the last twenty years, the main objective of JCTLM has been to identify, through a transparent review process, reference materials and reference measurement procedures that fulfil the definition of "higher order", and laboratories offering a reference service, and made this information publicly available on a database (https://www.bipm.org/jctlm/).

In the meantime, other concepts such as commutability of calibration materials, estimate of MU, and definition of analytical performance specifications (APS) that permit to provide test results that are clinically suitable, have emerged, all contributing to correctly implementing metrological traceability. EFLM made a landmark contribution by organizing in **2014** its first Strategic Conference in which a consensus was reached in defining models for establishing APS. We can consider the Conference as the **third milestone** as it originated several important outcomes contributing to the improvement of traceability implementation.
The concept of MU in medical laboratories has also achieved a central role, moving from being considered just as a 'foe', because its calculation is requested to comply laboratory accreditation requirements, to become a 'friend', because it can be used to describe both the performance of an IVD measuring system and the laboratory itself, assuming the role of a key quality indicator. The ISO Technical Specification 20914, released in **2019**, providing a practical guidance to be applied in medical laboratory settings for the purpose of estimating MU of values produced by measuring systems, can be therefore considered the **fourth milestone** in the standardization activity.

What is the role of IVD industry in method standardization?
The EU Directive (and now the EU Regulation 2017/746) has asked IVD manufacturers to ensure metrological traceability of their measuring systems to higher-order references. Thus, the primary onus is on the manufacturers to drive traceability. Manufacturers are responsible for implementing suitable commercial systems that fulfil this requirement and individual medical laboratories should therefore rely on the manufacturers who must ensure metrological traceability of their measuring systems to the highest available hierarchical level. Better said, IVD manufacturers should define a calibration hierarchy to assign traceable values to their system calibrators and to fulfil during this process uncertainty limits, which represent a proportion of the uncertainty budget allowed for medical laboratory results. IVD manufacturers are asked to provide end-users with technical documentation, instructions for use, and a QC material suitable for post-market surveillance of the measuring system performance, when working according to the manufacturer's indications. End-users must strictly observe these indications, as only operating in conformity with them the intended purpose of the CE marketed measurement system can be warranted, including the performance declared in terms of metrological traceability. This requires a paradigm shift in the thinking that many stakeholders, including laboratory professionals and many manufacturers, have still not perceived. If, according to the EU legislation, the manufacturer should assume total responsibility for supplying products of acceptable quality in terms of metrological traceability and MU of the measuring systems, it is no longer possible to consider separately the components of each measuring system (i.e., platform, reagents, calibrators, and control materials), which in terms of performance can only be guaranteed and certified by the manufacturer as a whole set. Any change introduced by users or third parties (for instance, the use of reagents, calibrators, or control materials from other suppliers) may significantly alter the quality of the measuring system performance, removing any responsibility from the manufacturer and depriving the system (and, consequently, the produced results) of the certification originally provided through CE marking. Particularly, IVD manufacturers are requested to provide QC materials as a qualified part of the measuring system; these materials, representing what I call the internal QC component I, should be designed by the manufacturer for daily monitoring of the measuring system alignment, with appropriate target values and acceptability range, which defines the tolerance of value deviation from the target, permitting the suitable application of test results in clinical setting. This relies on the concept that, if the metrological traceability of the measuring system to higher-order references must be granted by the manufacturer, QC materials, which are part of the whole system, should be a suitable surrogate of the employed (and declared) reference to permit routine checking of the correctness of system alignment to such reference. In practice, however, manufacturers of measuring systems commonly derive mean values of their QC materials just from replicates performed by independent laboratories using the same measuring system, with no explicitly certified quality, and frequently provide them as approximate targets, only for convenience, with no trueness claims regarding assigned values. On the other hand, information reported on QC data sheets shows that the acceptability range provided by manufacturers is usually based on the statistical dispersion of data obtained by *n* laboratories (e.g., ±2SD or ±20% of the mean value), with no relationship with clinically suitable APS.
Sometimes data from interlaboratory programs are used in the determination of validation range, with the risk to include results from laboratories working under biased analytical conditions, and quite often both mean QC values and ranges are provided only "as guide", with the recommendation that each laboratory should establish its own acceptability limits [sic]. You may easily understand the high vulnerability of this approach, adopted by manufacturers to assign QC values and define acceptability ranges, in terms of metrological traceability. Unfortunately, taking care of the metrological quality of the assigned values to offered QC materials is still not an issue for manufacturers, with very few exceptions.

You are the Scientific Coordinator of the Research Center for Metrological Traceability in Laboratory Medicine (CIRME) of the University of Milan. What are the activities of the Center?
CIRME was created in 2006 with the scope to promote standardization in the field of the Laboratory Medicine through the application of the metrological traceability concepts, with the main objective of improving the clinical value of laboratory information and permitting a common global approach to diseases. The *'CIRME traceability revolution manifesto'*, launched in 2014 (available in https://sites.unimi.it/cirme/public/UploadAttach/Pubblications%202018/Foreword.pdf), well summarizes the main points that are object of attention by CIRME.
CIRME offers activities related to reference measurement services (including six enzymes, glucose, and HbA1c) contributing to the characterization and certification of reference materials and assessment of their commutability, validation of metrological traceability of commercial IVD measuring systems, and value targeting of EQAS materials. CIRME also organizes international conferences on the topic of metrological traceability and standardization in Laboratory Medicine and works actively for promoting the related concepts to the laboratory professional and IVD manufacturer audience.
I like to remember here that some of the proposals elaborated by CIRME scientists in the last 15 years have become points of reference in the following scientific discussions. I refer to: the image of the 'Temple of laboratory standardization' (2014), describing the pillars of the metrological traceability; the concepts behind the 'Rethinking of QC (internal and external) in the traceability era' (2010), more recently consolidated in a whole theoretical approach; the recommendation of limits for combined uncertainty budget (expressed as percentage of total MU budget goal) in metrological traceability implementation (2015); the update of the approaches to be used for generation of data on biological variation (2016); the utility of MU measurement in medical laboratories (2017); and, quite recently, the definition of APS for MU of common biochemical measurands (2021). One can find the most important contributions displayed as *'CIRME cardinal points for implementing traceability in Laboratory Medicine'* in the CIRME website homepage (https://sites.unimi.it/cirme/).
Finally, I would like to mention that, in collaboration with the Clinical Pathology Unit of the 'Luigi Sacco' academic hospital, one of the two Italian reference centers for infectious diseases, CIRME has supervised studies on hospitalized COVID-19 patients to evaluate the role of laboratory tests as clinical

predictors of disease severity. Optimum biomarker cut-offs were specifically selected to have a high ability in detecting patients at risk of in-hospital death and in identifying patients at very low risk of ICU admission. One of the major strengths of the published results is represented by the use of methodologies for which standardization and metrological traceability had been verified and validated, enabling the universal application of results obtained in our clinical studies and permitting their unambiguous interpretation, providing institutions implementing them also use standardized assays. This work provides an excellent example showing that the implementation of assay standardization is an absolute priority for optimizing healthcare. Only the use of assays providing standardized results allows the application of common decision limits, as those defined in our COVID-19 studies, worldwide and the comparability of clinical studies performed in different institutions. Related papers are available on the 'CIRME COVID-19 page' (https://sites.unimi.it/cirme/the-cirme-covid-19-page/).

You have served in many leading roles both nationally and internationally *(among others: EFLM President, IFCC Scientific Division Chair, JCTLM Executive Board Member, 20th EuroMedLab President).* What is your greatest motivation? Was it difficult for you to allocate time for these tasks?
Driving motivations have been always the same: providing medical dignity to our profession and promoting the visibility of the role of laboratory professionals to guarantee optimal care for patients. If you want to play a significant role in medical science, you should dedicate all your time and efforts to justify the existence of Laboratory Medicine as a medical discipline and as a vocation. In my working life, I have been prepared to accept only tasks that in principle permitted me to promote Laboratory Medicine as the science that underpins Medicine. Using activities just to promote myself (as often happens, not only in our world) have never interested me. If you believe on the need to do something, you should find time for it: usually, a good working organization and a proper selection of coworkers permit to obtain the expected results.

You were the fifth EFLM President. Your term of office was during 2014-2016. What were the greatest challenges during your Presidency? Did you achieve your goals?
When I started my involvement in this apical position in the Federation, I noted there were some basic issues still unsolved, probably because, at that time, EFLM was a quite recent entity with just a brief history. There were no financial and administrative autonomy, poor international (and even regional) recognition, and an organization fully based on voluntary dedication. My previous experience in the IFCC, where I covered for a decade management positions in the Scientific Division, working with outstanding persons like Profs Mathias Mueller and Jean-Claude Forest, helped me to find alternatives and propose solutions. For example, for the first time, an EFLM Procedure Manual was released (and you may remember well this because you covered the EFLM Secretary position at that time), the numbering system for classifying different items to be discussed introduced, and a policy for EFLM publications finalized. Thanks to a good relationship with the IFCC top officers, I was able to obtain a full-time person dedicated to the EFLM office and to negotiate a new memorandum of understanding with the International Federation, also including a more remunerative agreement for the EuroMedLab organization. I am not in the position to say if I have achieved or not important goals, but, just recently, a valued person (I cannot disclose the name for privacy reasons) has confirmed to me that I remain her favorite EFLM President and, after years, it is surely a positive signal.

How do you see the future of our profession? What are the biggest challenges and how to overcome them?
Advances in science and technology will continue to result in the introduction of more complex, expensive, and difficult-to-interpret tests. Furthermore, new diseases (COVID-19 represents the last test case) will probably appear where laboratory contribution may undoubtedly provide better care. So that, laboratory tests have for sure a brilliant future. The question is however what will happen of Laboratory Medicine? Its raison d'être can be summarized as 'to help clinicians understand diseases by making lab voices heard'. I am always convinced that Laboratory Medicine will have (or not) a future only by combining the unique talent of performing high-quality laboratory assays with knowledge of the pathophysiological rationale behind the tests. The biggest challenges are always the same. To play a central role in healthcare delivery, we need to change our own attitude, become more outward looking and innovative, and create opportunities to demonstrate the value of our profession. This needs for an excellent cultural and scientific background of laboratory professionals, starting from the postgraduate schools training new colleagues.
SARS-Cov-2 diagnostics recently offered a good example of the two sides of the coin, i.e., laboratory tests vs. Laboratory Medicine (note the use of uppercase just for the latter). From the beginning of the pandemic, plenty of papers were published, the great majority including laboratory test results. It is however embarrassing to note the extremely low number of papers that at the same time dealt with the real-life performance of employed tests. And we know that when not properly evaluated in the quality of provided results, they have indeed the potential to misdiagnose and misinform. Laboratory Medicine professionals have therefore a unique role in evaluating the preanalytical, analytical, and post-analytical quality of employed assays, fighting the battle against the poor quality that may be the bane of medical use of laboratory tests. The very good news is that in the last few years, at least in our academic center, there has been an increasing number of promising young scientists and physicians who see their future in Laboratory Medicine. Thus, the future of Laboratory Medicine may be less critical than we imagined just few years ago.

Which skills and competencies, besides professional competencies, are most important for a young individual to become a successful specialist in laboratory medicine? What advice would you give to young colleagues who have just started their professional career in the medical laboratory?
From the first moment when the young colleagues decide to pursue the Laboratory Medicine career, they should be stimulated in increasing their knowledge and improving their skills by acquiring a working methodology that is sufficiently critical and enables them to correctly evaluate the collected information. Laboratory daily tasks and applied research should be kept both active, constantly supported and improved by the study. By the way, the electronic era markedly helps, and we carry now whole libraries in our pockets with electronic librarians at our beck and call. Those newly entering the field should also be stimulated to publicly presenting their experiences and publish their observations in scientific journals, showing the ability to correctly apply methodologies to manage and solve laboratory issues as well as to promote studies for test evaluation and their appropriate utilization in clinical practice. For this, it is very important to find a mentor who can guide the individual through this still neglected task. As Director of the Post-Graduate School in Clinical Pathology and Clinical Biochemistry of the University of Milan, my final advice at the end of the first meeting with new registered graduates is always: 'love Science, never give up on studying, and don't take anything for granted'.

Is there something, outside work, that you are passionate about? What kind of music do you like?
Literature, old movies, and music (all types except rap) take up all my free time, except when I ski (in winter) or ride a bike (in good weather). But my free time is not so much because it takes a long time to get results that deserve an award and then an interview by the current EFLM President.

COFFEE WITH THE EFLM PRESIDENT

Dear EFLM friends, in this issue of the EFLM Newsletter, I present you a new edition of the "Coffee with the President" - interviews with four EFLM officers: Anna Carobene, Daria Pašalić, Dalius Vitkus and Jorge Díaz-Garzón.

These and many other people make EFLM what it is today: a respectable and indispensable organization for Clinical Chemistry and Laboratory Medicine profession throughout Europe. Therefore, these interviews are an excellent opportunity to acknowledge their unfailing and genuine efforts, to get to know who they are and what drives their tireless enthusiasm and optimism.

I hope you enjoy these interviews and I invite you to listen to our podcast here.

Ana-Maria Šimundić
EFLM President

Coffee with Anna Carobene

When did you join EFLM? What is your current role in EFLM? What are the activities of the functional unit in which you work?

I joined the EFLM in March 2013 as a full member of the Working group of Biological Variation where I am still working as an expert/consultant.
My prior initiative resulted in the design, coordination, and execution of the European Biological Variation Study (EuBIVAS), a project undertaken by the working group of BV. It was aimed to deliver high-quality BV data using a multicenter approach involving five European countries. I am also a member of the Task Group Biological Variation Database: the EFLM database a never-ending job for which I am grateful to Aasne K. Aarsand for her patient and perseverance!

What do you like most about EFLM?

Working in an EFLM group has been a gift, an incredible experience in my professional and personal life. The idiom "union is strength" is absolutely true! We are much more powerful and likely to succeed when we work together for a common purpose. I love exchange ideas, and if they are from other countries, the exchanges are powerful. I still have the possibility to learn from the people I work with; during these last years I have had the opportunity to meet extraordinary people and this represents the most beautiful and attractive aspect of my job!

Last but not least, meeting people with different traditions and habits is an exciting human experience, for which I am very grateful to the scientific society.

How do you see EFLM in 10 years from today?

In my opinion, EFLM has become an international society of an incredible scientific level. Our profession is facing major challenges today and the support from our Scientific Society is necessary and decisive. Among others, I am thinking at the rapid development of the field of artificial intelligence and machine learning and at the profound impact that big data will have on laboratory medicine.

What do you like about your current job?

I work in one of the Scientific Institute for Research, Hospitalization and healthcare (IRCSS) hospital in Milan, Italy, as a responsible for the analytical quality of the laboratory. This role allows the opportunity to know several aspects of the laboratory medicine. Working in an IRCCS gives me also the opportunity to work, as a researcher, and I must admit that the fact of keeping my brain active in new knowledge is an undeserved chance! For example, in collaboration with data scientists, I have been recently involved in a project for the diagnosis of COVID-19 through the use of a machine learning approach. It has been an enthusiastic experience where I have learned a lot, and I would like to continue in this field. In my opinion, some initiatives of our society should be devoted to better understand and apply this new approach in laboratory medicine!

Do you have a role model? If you do, what makes this person so special?

Yes I have got it!!! My role model is St Philip Neri! He was an Italian saint that invented the oratory in 1500. He loved the homeless children and used to teach them everything he knew without any sort of power or publicity. During a meeting with the Pope and several cardinals, he refused a nomination as cardinal, replying to the Pope with the historical sentence "I prefer Heaven". In my professional life, I must admit that I have been very lucky! I met several masters who taught me a lot without wanting to appear, and without telling anyone. I cannot remember here all of them, but I would like to cite at least the beginning of my international experience for which I have to thank Prof Callum Fraser, which used to work as a hidden reviewer of my first papers teaching me a lot, making always detailed and constructive revisions. Prof Fraser provided this support quietly and rather behind the scenes. To be honest, in occasion of his first revision of one of my paper, he sent me it totally rewritten in a very good English! Moreover, he proposed my name a couple of times as a speaker in international congresses, instead of him; that is unbelievable!!! I cannot forget his kindness.

What are the qualities you appreciate most about people?
The goodness, the sensitivity and the depth of heart.

Do you have some hobbies? What are the things outside of your work that you are passionate about? How do you like to spend you free time?

Free time is never enough! I love walking, cycling and swimming. I love also to spend my time with my friends, enjoying Italian food and good wine. I love also visiting artistic cities that are not lacking in Italy! To be honest, I used to travel a lot some years ago... After my experience in Ethiopia, I have changed my habits. I worked in Adwa, in the Tigray region, for more than one year to set up a medicine laboratory in a missionary hospital. I was back just in time for the COVID 19 pandemic! After that, I spend most of my free time to keep in touch with my Ethiopian friends and to find anything that could support them. I have also started a collaboration with a researcher in Addis Ababa, the capital, and published a couple of papers, and others are in progress. It is nice to share what I have learned in these years.
Moreover, periodically I go to visit inmates in high-security prisons who have long sentences in maximum security. That is another experience I would recommend anyone!

What are your greatest challenges?

It is sort of an obsession of mine more than just a challenge. I do not wish to live a meaningless and a comfortable bourgeois life. It is probably with this frame of mind that I lived in Ethiopia for more than one year. And if I could I would still be there! I do consider that it is important for the more experienced members of our profession to assist younger people. I would like to share my professional experience and knowledge where it can be really useful. With this regard, I haveve recently joined the new Task Force on Global Lab Quality of the IFCC to support developing countries, and start a supervision of a project in Mexico. I would also like to make really available in daily clinical practice Biological Variation data that my WG has produced with a huge effort... In conclusion, I still do not have clear ideas about what I will do when I grow up!

Are you good in time management?

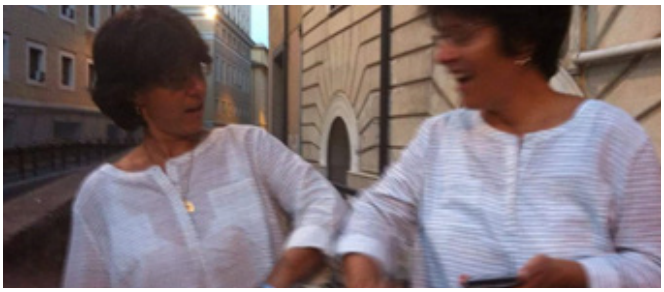
It is beyond doubt! In these years I have learned to manage time carefully. Actually, I am not completely sure that this is a merit. Indeed, I realize that very often I pretend from others the same time management, resulting to be impatient and petulant. Luckily, I am also aware that my EFLM friends, who know me very well, always forgive me.

What do you value most about your country and its culture?

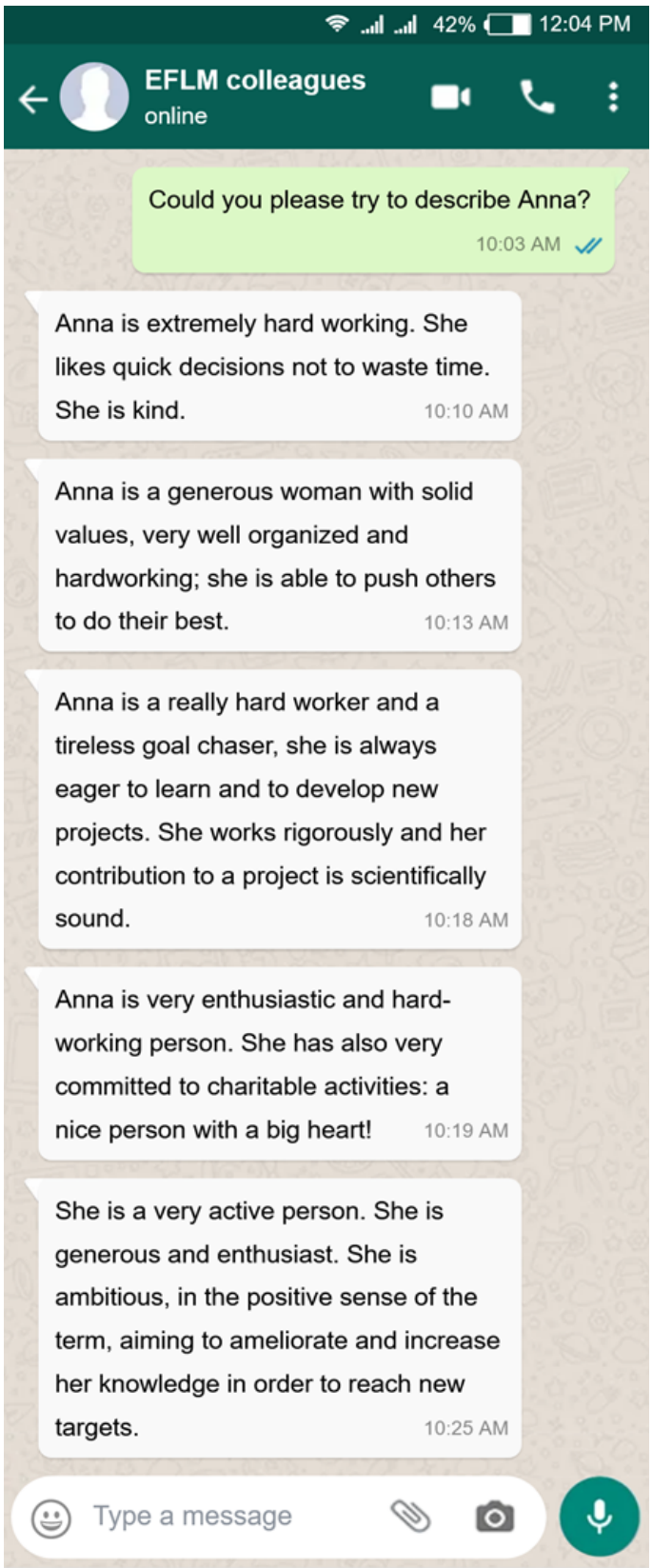
"Beauty will save the world" the famous quote from the mouth of an Idiot Prince Lev Nikolyaevich Myshkin, the protagonist of Fyodor Dostoevsky's great novel, represents my mind about my country. Italy is an incredible country with amazing cultural and natural masterpieces everywhere. I was born in Tuscany, my favourite region with breathless cities like Florence, Siena and Lucca. The beauty of these cities is followed even more by the culinary art and an excellent wine like the Tuscany Brunello di Montalcino! But also cities like Rome, Naples, Venice, Milan, and what about Palermo with the Cathedral of Monreale? Each city offer amazing places to visit and traditions.

Do you have a pet? *(feel free to share its photo with us, if you like)*

Yes I have it! I have a sweet and cuddly cat, his name is Tokyo. I have a small house in the hills, where I like to spend part of my holiday. The real owner of the house isTokyo, that becomes like a tiger on those occasions!



Taking advantage from this nice opportunity to present myself better, I feel free to add a particular of my self. I have a twin sister identical to myself! Simona lives in Romania, a different European country, so that we do not spend a lot of time together like we used to do years ago. But for sure, she represents an important part of my life!



Coffee with Daria Pašalić

When did you join EFLM? What is your current role in EFLM? What are the activities of the functional unit in which you work?

I have joined EFLM as Croatian national representative in 2013. From that, moment I have did my best to inform Croatian membership about all opportunities, activities and novelties in the EFLM, and to recruit our members to join EFLM functional units as active members of different WG. My activities in EFLM, increased significantly in 2017, when I've joined WG-CPE under the Committee Education and training. Immediately I have start with study of newly established MedTech Code and try to find the best way for implementation of those very important rules in practice and to inform national societies about it. In 2018 Executive board, kindly asked me to accept nomination for C-ET Chair, and this is my position in EFLM.

What do you like most about EFLM?

I think EFLM connects the people in the profession from different regions and I think that EFLM do the best to improve and harmonies laboratory medicine. Exchange of experiences and various educational events contribute to this in many ways. In addition, we make new acquaintances and new friends from different parts of Europe and the world. We bring our national culture closer to each other and not only in a professional sense.
However, I also must give an accent on Silvia Cattaneo. She is a diligent person you can always count on, holding all the strings of the EFLM in her hands. There are no that questions she cannot answer. She is a professional and fast and above all kind and warm person, always ready to help.

How do you see EFLM in 10 years from today?

I can see it as a group of new, young people who will continue to improve the profession with their ideas, change what is needed, and improve our profession.

What do you like about your current job?

The nature of my current job is very dynamic and includes teaching with medical and dental students in graduate and postgraduate studies. In addition, 50% of my work involves scientific research, which brings new challenges with each new research. I love working with students, especially those who show an interest in the courses I teach. I also like working with postgraduates because here you see how young people develop their ideas through the profession for which they were educated, and we as experienced colleagues can learn a lot from them.

What are the qualities you appreciate most about people?

I especially appreciate tolerant people who respect the agreement and stick to deadlines, are willing to listen to advice, and especially those who know how to point out to others in an accessible way the possibility of recovery without emphasizing complacency. With such people, it is easy to function, build a profession or a private family life. I also really like it when people are simple, self-effacing, but fun and communicative nonetheless. I do not mean perfect people, but tolerant and empathetic people.

Do you have some hobbies?

Oh, yes I like singing and I'm the member of the church choir. But also, additionally, I like to practice recreational sports, such as aerobics, dancing, Nordic walking and running, and in summer my absolute favorite is swimming in our beautiful Adriatic Sea.

What are the things outside of your work that you are passionate about?

My family, husband and three children are absolute favorites of my life. I see the highest values in life in them. I look forward to their every success; I comfort them when they are having a hard time. How do you like to spend you free time? I love to hang out with my family and with friends, especially on trips in nature and in various public and private parties.

How would your spouse (wife, husband) describe you?

"How do I see my wife?
Extremely responsible, diligent and consistent to the end.
Responsible in my work and performing tasks, I saw it best when we stayed locked up at home for days due to the pandemic and lock down.
She loves and wants to be loved.
She does not like injustice, and appreciates honesty.
She is a responsible mother; she seeks and expects responsibility and respect.

She keeps to herself and her appearance. Above all is her family.

Gives maximum in business.

Conscientious and responsible in considerable commitments outside of work. She has a sense of being comfortable in communication, and sharp when such communication is needed. Sometimes she is timid and reacts too quickly."

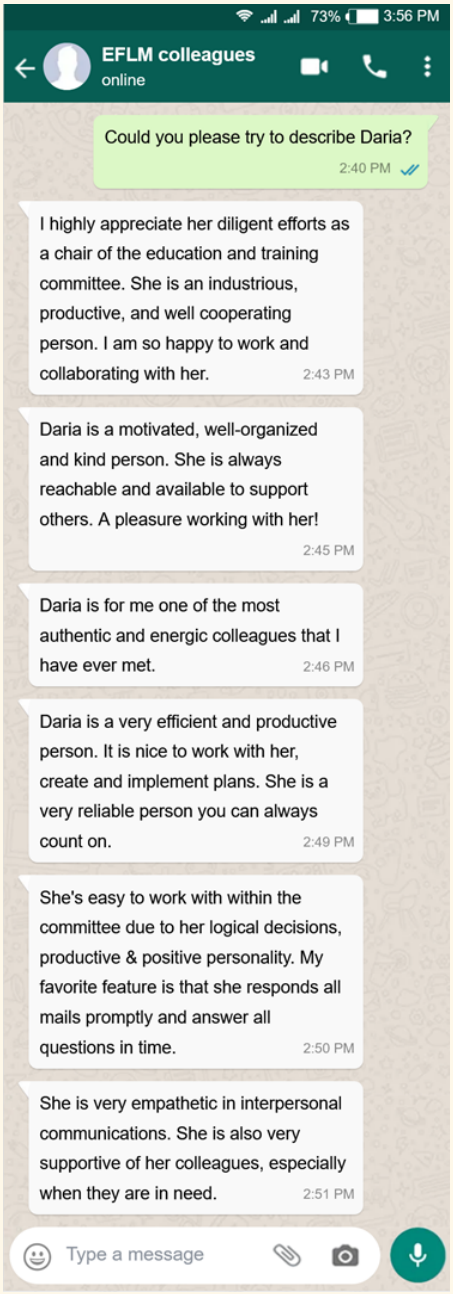
What are your greatest challenges? Are you good in time management?

Until about ten years ago, it was much easier for me to organize my time, even though I had small children and a lot that needed to be done in professional advancement. However, the time in which we are available to everyone at all times, almost day by day, forces me to change my well-thought-out plans and deadlines.

What do you value most about your country and its culture?

I can just easily say:
small country with many famous people-scientist, innovators, sportsmen, musicians, saints,... a list is much longer.
-A small country with a big heart people, entertaining and hospitable;
A country with beautiful and varied nature: with more than a thousand islands, crystal blue sea, mountains, hills, golden plains, known old neighborhoods full of cultural monuments,

And much more...



When did you join EFLM? What is your current role in EFLM? What are the activities of the functional unit in which you work?

I joined EFLM in 2013 as a National Representative at the Registration Commission of the EFLM, which was later transformed into the Working group Register of the Profession Committee, where I serve as Corresponding Member since 2017. In 2016 I became a Corresponding Member of the EFLM Working Group (WG) on Congresses and Postgraduate Education under the Education and Training Committee. In 2019 I was elected to the Executive Board (EB) of EFLM as a member-at-large. My term of office started in 2020, the beginning year of COVID-19 pandemic. That year was extremely challenging for me as a new officer, but together with the whole EB we managed to continue most of EFLM activities. In 2021 I became the member of the Task Group "EFLM Syllabus Course" of the EFLM Profession Committee

What do you like most about EFLM?

There are many good things within EFLM: EFLM Academy, high quality EFLM events, Guidelines, Consensus Documents and Position Papers, prepared by highly professional WG's members and their free availability to the members of National Societies (NS), equal possibility for each NS to be involved in the activities of EFLM.

How do you see EFLM in 10 years from today?

I see EFLM as a leader organization of laboratory medicine in Europe with a strong voice around the Globe.

What do you like about your current job?

I like the clinical laboratory work which is very dynamic to meet growing clinical needs in terms of quality, timelines and availability when needed. As a laboratory manager I like the opportunity to shape laboratory to serve customers better and to make working environment friendlier for the staff. For both purposes I like to use LEAN as the best tool that is easily available. Another interesting part of my job is teaching - to help students and young colleagues built their own competencies, professionalism, and responsibility.

Do you have a role model? If you do, what makes this person so special?

Well, perhaps I do not have one single role model. When I was a student, I had a professor of analytical chemistry Mrs. Jasinskiene. She was in her seventies already, but she presented all course of the subject without any glance to her notes, she was the first whose professionalism made me wish to achieve something similar in my own carrier. Later on, I've met many highly skilled and charismatic people, including some colleagues from EFLM as well.

Do you have some hobbies? What are the things outside of your work that you are passionate about? How do you like to spend you free time?

I don't have a hobby, but there definitely are things outside of my work I like - nature, travelling and music, mostly classical, and, of course, my dog. Quite recently I have found one more attraction – electric scooter. After an intensive day at work, it is so good to take a short ride just to unwind or to go for a little longer ride on the weekend.

How would your spouse (wife, husband) describe you?

When I asked her, she said I'm a highly skilled professional, who is almost impossible to live with as I want to implement LEAN in every possible situation.

What are your greatest challenges?

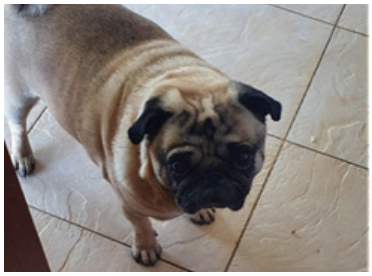
Perhaps, to say "No", especially when "No" can make somebody very unfortunate. Another one is to start working day early in the morning (lecture in morning – worst beginning of the day for me), as I'm totally an evening type of man.

Are you good in time management?

No, I'm not. I try to do most on time, but deadlines always make a lot of headaches for me. Even if I'm a big fan of LEAN, nowadays there is never enough time to do everything you wish. Still, I've never been late to any plane when travelling due to improper time management.

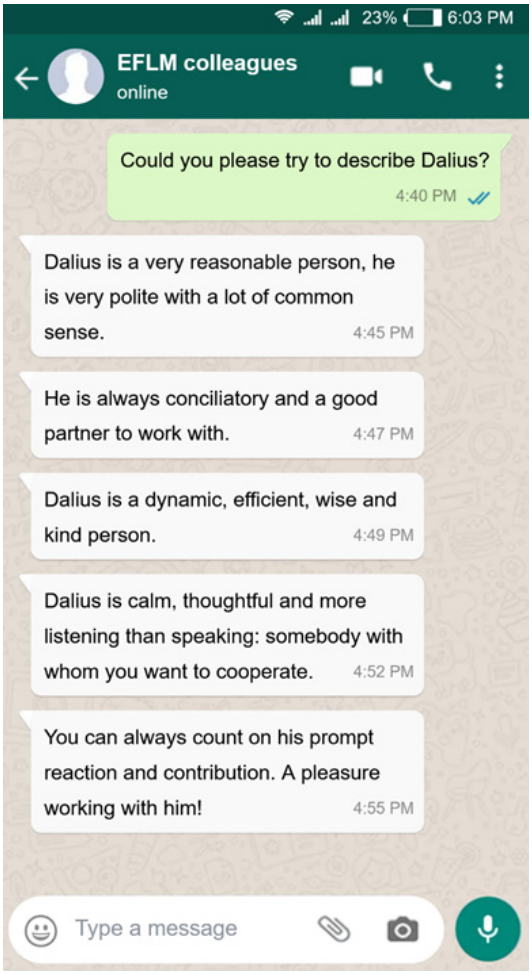
What do you value most about your country and its culture?

As I have already mentioned before, I am a big nature lover. Therefore, one can only assume, I have deep appreciation for the natural pearl, The Curonian Spit, that decorates Lithuania's west coast. The nature there is more than alluring, and every year I find myself in awe as to how this very rare natural phenomenon just so happens to be here, in my country. Other than appreciating every inch and corner of our little sand pearl, I have loads of sympathetic feelings for the capital city Vilnius, especially the old town, which, together with the Curonian Spit, is listed in the UNESCO World's Heritage List. As for the cultural part of this question, I must say, that the thing that makes me the proudest of my country and its culture, is surely the one and only, Lithuanian language. It is one of the most complex things, I have been gifted the chance to come across, but on the other hand, there's nothing to be surprised about, as it is one of the oldest Indo-European languages, settings it's roots in the early forms of Sanskrit.



Do you have a pet? *(feel free to share its photo with us, if you like)*

Yes, I do. Six years ago, I've got a baby pug for my birthday. He was 2 months old then. It didn't take a long time for him to become a true friend of mine. Now we spent a lot of my free time together around home, going for a walk or even napping on the couch.



Coffee with Jorge Díaz-Garzón

When did you join EFLM? What is your current role in EFLM? What are the activities of the functional unit in which you work?

I started to collaborate with the EFLM in 2014 after the Milan conference to define analytical performance specifications. Currently, I am a young scientist member from the Biological Variation Working Group

What do you like most about EFLM?

I can meet and share knowledge and experiences with other laboratory medicine professionals. I also like the new EFLM academy that help us supporting education, training and continuous professional development

How do you see EFLM in 10 years from today?

I hope the EFLM had developed strategies to improve the laboratory quality through regulatory mechanisms, reached homogeneity among laboratory professionals in Europe and had closely linked our society with other European clinical societies (multidisciplinary working groups).

What do you like about your current job?

As a central service, from the lab medicine department we are in touch with most of the clinical units, from primary care to intensive care unit. I like to provide advice for result interpretation, test profile design and to validate emergent measurands for new clinical needs. I believe these are essential tasks for the healthcare network.

Do you have a role model? If you do, what makes this person so special?

Yes, I have more than one role model. However, the qualities that inspire me the most are perseverance and dedication.

What are the qualities you appreciate most about people?

Honesty, modesty and resourcefulness.

Do you have some hobbies? What are the things outside of your work that you are passionate about? How do you like to spend you free time?

I like to practice sports such as snowboarding, trekking and climbing but currently my passion is the triathlon where I can combine swim, run and bike. My next challenge will be the Ibiza half-triathlon, by 24th of October.

How would your spouse (wife, husband) describe you?

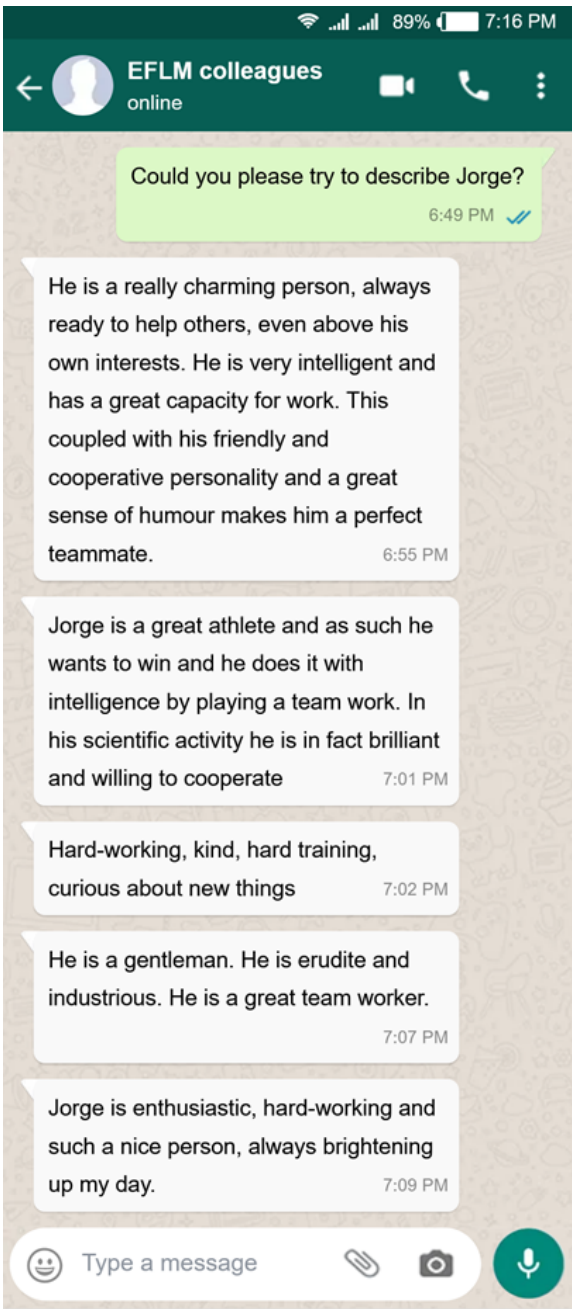
Sonia: "Jorge is a tenacious, enthusiastic person with enormous curiosity. Everything he undertakes, he does with courage and great determination."

What are your greatest challenges? Are you good in time management?

I think one of my challenges is the time management and task organization to improve my performance at work.

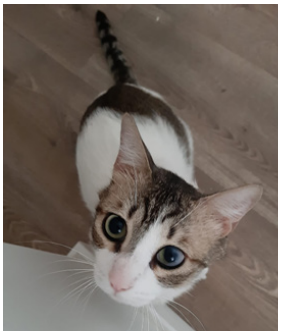
What do you value most about your country and its culture?

I like very much the food, the weather (I love the sun) and overall the closeness of the people.



Do you have a pet?
(feel free to share its photo with us, if you like)

Yes, I have a cat, his name is Juce and he has conquered our hearts since we adopted him from an animal protection center the last November.



EFLM OFFICE INFORMS

Two issues of CCLM are available on-line!

New issues of CCLM, the scientific Journal of EFLM, are available on-line. Click here to access CCLM **Vol 59, Issue 9-10-11**.

Do you wish to freely access all articles in CCLM? Become an EFLM Academy Member! Click here to know more. We remind EFLM Academy Members that to free access papers in CCLM is only possible through the personal area in the EFLM Academy where some other interesting opportunities await for you such as for example the access to some other international journals, the EFLM webinars and the access to CLSI documents* (*this latter opportunity is reserved only to EFLM Academy members en-bloc registered by National So-cieties).

To know more, contact: eflm@eflm.eu

EFLM BURSARY PROGRAMME

EFLMLabX: the experience of an applicant

Reported by Berrak Guven, Zonguldak Bülent Ecevit University, Faculty of Medicine, Department of Biochemistry, Kozlu/Zonguldak, Turkey

From the left: Evegnija Homsak (the host), Berrak Guven (the guest)

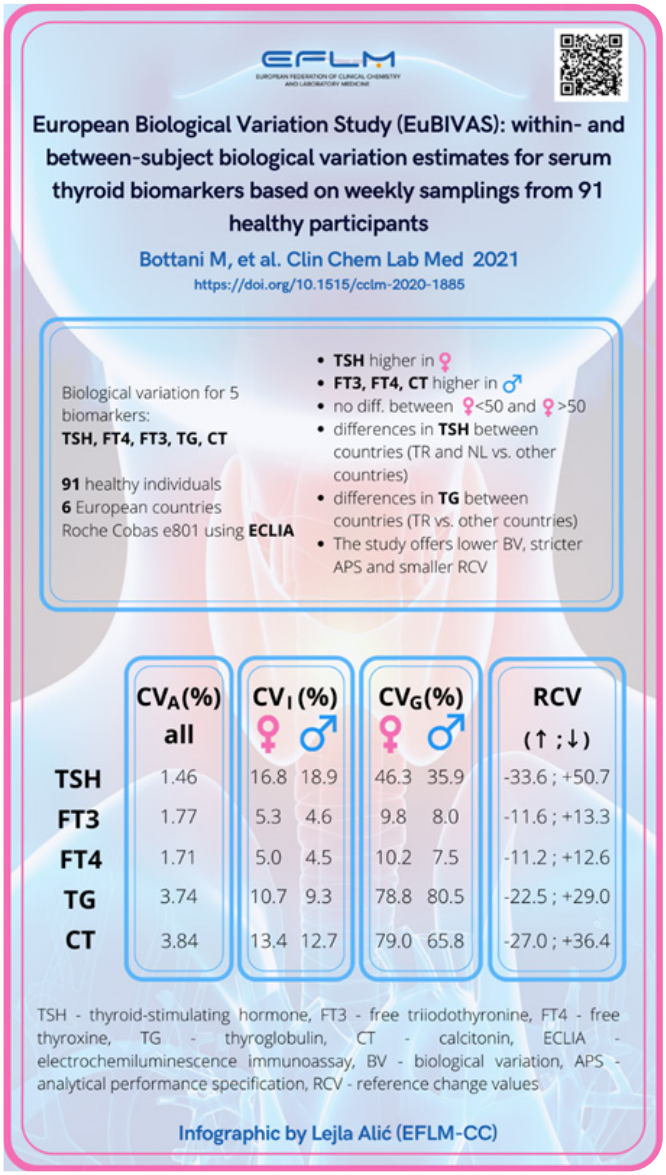
There have been many things I wanted to do throughout my career. But what I would most was an opportunity for international cooperation. Unfortunately, although I am a scientist who writes international articles, I have never had the opportunity to communicate internationally in my professional life. Moreover, I was over the age of 40, when all scholarship opportunities were over. When I thought that was not possible anymore, I discovered the EFLM-Labx service and applied. And, I was accepted University Clinical Center Maribor in Slovenia for Laboratory diagnostics of autoimmune diseases with EFLMLabx scholarship.

I am no stranger to autoimmune diseases because I have medical education. But, laboratory diagnosis of autoimmune diseases was not in my field during my clinical chemistry training, despite there is a significant overlap between Clinical Chemistry and Immunology.

Therefore, training in the diagnosis of autoimmune diseases with an EFLMLabX Scholarship has been a great opportunity for me. This experience taught me, above all, how to manage tests used in the diagnosis of autoimmune diseases in the organizational structure of clinical laboratories. Dr. Evgenija Homsak, who accepted me for the training, was with me at every stage of this training and enlightened me. I am grateful that she shared with me knowledge, experience, and best practice in autoimmune disease diagnostic tests. In addition to detailed observations and applications related to autoimmune tests, I had the opportunity to observe the work in all laboratory departments. For this, I am very thankful to the valuable laboratory staff of the UKC-Maribor Laboratory Diagnostics Department. They were very kind and helpful. Hopefully, this good communication will lead to potential collaborations for research in the future.
As a result, I had a great time. Many thanks to the EFLMLabX program, which allowed me to have this unique experience.

Click here to know more about the EFLM Laboratory Exchange Programme: EFLMLabX

European Biological Variation Study (EuBIVAS): within- and between-subject biological variation estimates for serum thyroid biomarkers based on weekly samplings from 91 healthy participants



Bottani M, Aarsand AK, Banfi G, Locatelli M, Coşkun, Díaz-Garzón J, Fernandez-Calle P, Sandberg S, Ceriotti F, Carobene on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine Working Group on Biological Variation
Clin Chem Lab Med 2021; Available from: https://doi.org/10.1515/cclm-2020-1885

Reported by Lejla Alić, member of the EFLM WG-Promotion & Publications

A recent publication by the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working Group on Biological Variation (BV) reports biological variation estimates of thyroid biomarkers from the European Biological Variation Study (EUBIVAS). Namely, five biomarkers have been evaluated: thyroid-stimulating hormone (TSH), free thyroxine (FT4), free triiodothyronine (FT3), thyroglobulin (TG) and calcitonin (CT). The study has been performed in 91 healthy individuals from six European countries (EUBIVAS) and biomarkers have been measured on Roche Cobas e801 using electrochemiluminescence immunoassay (ECLIA). As being completely compliant with the Biological Variation Data Critical Appraisal Checklist (BIVAC), this study offers lower BV estimates, stricter analytical performance specifications and smaller reference change values, in comparison to the previous data available in the EFLM BV database.

OTHER RECENT EFLM PUBLICATIONS:

The European Biological Variation Study (EuBIVAS): Biological Variation Data for Coagulation Markers Estimated by a Bayesian Model
Aasne K. Aarsand, Ann Helen Kristoffersen, Sverre Sandberg, Bård Støve, Abdurrahman Coşçkun, Pilar Fernandez-Calle, Jorge Díaz-Garzón, Elena Guerra, Ferruccio Ceriotti, Niels Jonker, Thomas Røraas, and Anna Carobene, on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine Working Group on Biological Variation

Clin Chem *2021* https://doi.org/10.1093/clinchem/hvab100

Improving the laboratory result release process in the light of ISO 15189:2012 standard
Hikmet Can Çubukçu, Florent Vanstapel, Marc Thelen, Francisco A Bernabeu-Andreu, Marith van Schrojenstein Lantman, Duilio Brugnoni, Pika Mesko Brguljan, Neda Milinkovic, Solveig Linko, Michel Vaubourdolle, Ruth O'Kelly, Christos Kroupis, Maria Lohmander, Luděk Šprongl, Mauro Panteghini, Guilaine Boursier, European Federation of Clinical Chemistry, Laboratory Medicine EFLM Working Group Accreditation, ISO/CEN standards WG-A/ISO

Clin Chim Acta *2021* https://doi.org/10.1016/j.cca.2021.08.013

Implementation of the new EU IVD regulation – urgent initiatives are needed to avert impending crisis
Christa Cobbaert, Ettore D. Capoluongo, Florent J. L. A. Vanstapel, Patrick M. M. Bossuyt, Harjit Pal Bhattoa, Peter Henrik Nissen, Matthias Orth, Thomas Streichert, Ian S. Young, Elizabeth Macintyre, Alan G. Fraser and Michael Neumaier

Clin Chem Lab Med *2021* https://doi.org/10.1515/cclm-2021-0975

EFLM Academy webinar: The general principles of laboratory biosafety

On **November 23rd, 2021**, at **18:00 CET Dr. Gijsbert van Willigen** (NL) will hold a webinar with the title: The general principles of laboratory biosafety. The moderator of the webinar will be Dr. Dionysis Vourtsis (GR) and the webinar manager will be Dr. Oguzhan Zengi (TR).

The webinar is accessible for EFLM Academy members only.

More information can be found in EFLM eLearning platform.

EFLM Academy webinar: Stem cells therapy and applications

On **September 15th, 2021,** at **18:00 dr. Yael Porat (IL)** held a webinar in which she presented an unique patented technology employing activated immune dendritic cells that specifically direct stem/progenitor cell therapeutic activity *in-vitro*. As a result of this technology, enriched endothelial progenitor cells (EnEPCs; BGC101) product can be generated from a standard blood draw within a day. Dr. Yael reported long-term outcomes of a pilot study of BGC101 for treating patients with severe Critical Limb Ischemia (CLI) with no available surgical option. She presented exciting results of the study and concluded that the therapy shows promising therapeutic effects, as shown by the outcomes including limb salvage, increased leg blood flow and wound healing, as well as in walking ability, reduction of pain, decreased usage of narcotic medications and improved quality of life. The presentation was followed by a discussion, with a specials emphasis on the possibilities of automatization of the process. Moderator of the webinar was Dr. Dganit Itzhaky (IL) and the Webinar manager was Dr. Svetlana Evgina (RU)

More information can be found in EFLM eLearning platform (accessible for EFLM Academy members only).

2nd EFLM on-line Postgraduate Course: Leadership Skills

From **September 13th to 23rd, 2021,** the second postgraduate course in leadership skills was held. The course was organized on-line, by the EFLM's long-term partner MZ Congressi. During the nine days of the course, imminent and world-renowned experts in biomedicine, business and education held engaging, inspiring and very helpful presentations, including topics such as communication skills, leadership styles, change and conflict management, emotional intelligence, etc.
The course was attended by more then 90 participants and was evaluated as very successful. EFLM would like to thank all the speakers for their brilliant contributions and for sharing their knowledge and experiences.

News from the Spanish Society of Laboratory Medicine (SEQC^{ML})

II Interhospital Conference 'Approach to pregnant women in a multidisciplinary team: the importance of the Clinical Laboratory'

Approximately 12% of pregnant women in Spain have gestational diabetes mellitus, a prevalence that has increased in recent years due to various factors, including a higher rate of obesity in the population and the older age of pregnant women.

Gestational diabetes mellitus is associated with various complications such as increased risk of pre-eclampsia, polyhydramnios (excessive accumulation of amniotic fluid), macrosomia, increased perinatal mortality, foetal hypertrophic cardiomyopathy, neonatal respiratory problems, or metabolic complications in the neonate such as the presence of hypoglycaemia, hyperbilirubinemia, hypocalcaemia, or polycythaemia. In addition, if the pregnant woman has sustained hyperglycaemia during organogenesis, the risks of having a miscarriage and congenital anomalies increase. Treatment of patients with gestational diabetes mellitus can reduce the risk of developing these complications.

Gestational diabetes is just one of the pathologies or conditions that can affect pregnant women. In fact, Dr. Blanca Montero San Martín, member of the Residents and Young Scientists Group of the Spanish Society of Laboratory Medicine and of the Clinical Laboratory of the *Hospital Universitari Arnau de Vilanova*, Lleida, notes that as well as an increase in gestational diabetes mellitus due to the increase in maternal age, a higher prevalence of Down syndrome has also been observed, with 1 case every 450 live births. Likewise, other aneuploidies with a high prevalence are trisomy of chromosome 13 (Patau syndrome) and trisomy of chromosome 18 (Edwards syndrome) with a prevalence of around 2.25 cases per 10,000 and 6.86 per 10,000, respectively.

For this reason, with the aim of raising awareness of the importance of pregnancy as a clinical condition of major importance given the numerous metabolic changes that take place and possible associated pathologies, the II Interhospital Conference 'Approach to pregnant women in a multidisciplinary team: the importance of the Clinical Laboratory' was held, organized by the Residents and Young Scientists Group of the Spanish Society of Laboratory Medicine (SEQC^{ML}), with the collaboration of the Spanish Society of Gynaecology and Obstetrics (SEGO), the Spanish Society of Infectious Diseases and Clinical Microbiology (SEIMC), and the Commission for Prenatal Diagnosis and Commission for Biological Magnitudes related to Medical Emergencies of the SEQC^{ML}.

Dr. Montero explained that these virtual sessions, which were held thanks to the collaboration of all the participants, maintained the initial program from April 2020 before SARS-CoV-2 invaded our laboratories and our lives. They emphasized the need for and benefits of multidisciplinary teams in the healthcare field, and for this reason they included speakers specialized in Clinical Analysis, Microbiology, and Gynaecology, all members of the main corresponding national scientific societies.

Similarly, Dr. Alex Larruzea, from the Clinical Analysis Service of the Mollet Health Foundation, stated that the objective of the conference was to acquire knowledge about the approach to pregnancy from a multidisciplinary approach. For this reason, topics such as gestational diabetes, thyroid disease, gestation from a microbiological point of view, aneuploidy screening, pre-eclampsia, and the importance of the laboratory at the precise moment of delivery were discussed. For example, the taking and handling of samples of the foetal shell and cord is of vital importance when it comes to giving reliable and real results of the condition of the foetus. For this, the laboratory must play an active role and collaborate with the clinical team by providing training and advice on the appropriate way to process this type of sample. Likewise, since approximately 3% of newborns have some type of congenital anomaly and a quarter of these are chromosomopathies, these were also analysed within the framework of the Conference. The sessions also featured a presentation of clinical cases, which generated debate to reinforce the knowledge covered in each session, emphasizes Dr. Larruzea, who also highlighted the opportunity that this gathering offered to residents and young adjuncts to participate by presenting a session in public , in this case online, and the importance of being able to discuss this in a multidisciplinary forum, with health professionals from both different medical specialties and different geographical areas.

Role of the clinical laboratory professional in the multidisciplinary team

A multidisciplinary approach and coordination between various professionals in the care of pregnant women is especially important. According to Dr. Montero, the benefits of the multidisciplinary approach in any pathology have been widely demonstrated. Contact between different clinical professionals favours an exchange of points of view, giving rise to the creation of new work algorithms that translate into an improvement in patient diagnosis, which implies a decrease in time, and an improvement in the management of demand and in the treatment received.

In this context, according to this expert, a laboratory professional should be a member of the multidisciplinary team for the care of pregnant women, as they can provide knowledge about the tests carried out, which contributes to the diagnosis and monitoring of possible pathologies.

Similarly, Dr. Larruzea considers that in order to reach a correct diagnosis of each of the pathologies or special situations of pregnant women, the laboratory professional must advise the clinical team in every one of these situations, advising both when taking biological samples and in the different action protocols and with regards to the various possible test results.

It is clear that the laboratory professional is involved in a wide variety of aspects throughout the progression of a woman's pregnancy: they help in monitoring of the thyroid and gestational diabetes, collaborate in genetic tests to detect the most frequent aneuploidies, monitor all the microbiological aspects, and participate in the correct processing and reporting of the tests that can be performed at the time of delivery. In addition, the consulting and advisory function of the laboratory professional in a hospital's clinical team is very important when requesting the corresponding tests, interpreting the results, and establishing the protocols for action.

This applies in the case of gestational diabetes mellitus in which laboratory professionals must actively participate, from the control of preanalytical conditions in which the various samples are extracted, to management of the demand for tests and validation of the test results. Laboratory professionals must take part in the design of the different algorithms and in the investigation of new analytical methodologies. Recently, mass spectrometry-based methods have been developed in which differences in metabolic profiles can be observed in patients with gestational diabetes mellitus compared to healthy people; they can also distinguish pregnant women who will be normoglycemic after pregnancy from those who will suffer Type II postpartum diabetes mellitus, in the opinion of Dr. Montero.

For more information: www.seqc.es

Was it really such an unbearable summer with Delta, fires, heat wave–as Dr. Gouget explains in his very interesting article in the IFCC eNews issue? It is true that for the first time all these consequences of the climate crisis, in addition to the Delta variant, were present at the same time in many places around the world. We all witnessed this unprecedented summer. But at the same time, thanks to the vaccines, we had the chance to enjoy some moments of real holidays, the countryside, the sun, the sea, meeting with friends (not big gatherings, of course)–to enjoy peaceful moments. Within the IFCC there is a lot to anticipate during the coming months. The Townhalls, the new meetings, where our voices can be heard, are explained and presented by our President in this issue. We are all looking forward to Euromedlab in Munich at the end of November and we hope to attend in person after a period of "untouchable" meetings. Let's hope that we will have a peaceful fall and winter waiting for us". Click here to read the full issue.

Prof. Adeli, IFCC President's Message

My sincere greetings to you all. I hope everyone has had an enjoyable summer and a great time with family and friends. Here at IFCC, we are very excited for the Fall, with many important events planned. First, I am delighted to announce a new strategy to enhance internal communications within the IFCC community, the annual IFCC Regional Town Halls, starting this fall in regions around the world. The first two IFCC Regional Town Halls took place virtually on: September 15th in the European, African, and Middle Eastern time zones and all regional federations and national societies affiliated with EFLM, AFCC, and AFCB were invited to participate; on 21st September for all Corporate Members who were invited to join in. Click here to read the full message.

IFCC Professional Scientific Exchange Programme (PSEP)

My internship at the Unit of Auto-inflammatory Diseases of the Arnaud de Villanueve Hospital, in Montpellier (France)
I was granted with the IFCC Professional Scientific Exchange Programme to do my international rotation at the Unit of Auto-inflammatory Diseases of the Arnaud de Villanueve Hospital, in Montpellier (France), during my residency at the Puerta de Hierro Majadahonda University Hospital (Spain). Click here to read the full report on this Exchange experience, supported by IFCC.

Celebrating National Liver Awareness Month with Best Practices from Around the Globe

October is Liver Awareness Month and with that is a reminder of the importance of liver health. Maximizing liver health through implementation of a novel intelligent liver function testing (iLFT) algorithm is exactly what a cross-disciplinary team from Dundee, Scotland did with top recognition from the 2019 UNIVANTS of Healthcare Excellence awards. Don't miss your chance to be recognized for novel and innovative care projects, apply today at univantshce.com.

Calendar of EFLM events and events under EFLM auspices

Do not miss the opportunity to have your event listed here.
Apply for EFLM auspices! For more information visit here or email eflm@eflm.eu
Due to COVID-19 alert throughout the world, some upcoming events could have been cancelled or postponed, please direct check with the organizers if the date is confirmed.

7-10 October 2021
46th ISOBM Congress
Bled (SL) Click here for information

11-13 October 2021
53rd National Congress of SIBioC-Laboratry Medicine "Laboratory Medicine in Proximity Medicine: telemedicine, roles and competences"
Virtual Click here for information

10-12 October 2021
XIV Congress of Slovak Society of Clinical Biochemistry
High Tatras (SK) Click here for information

27-30 October 2021
International Biochemistry Congress 2021 / 32nd National Biochemistry Congress of Turkish Biochemical Society (TBS)
Gaziantep (TR) Click here for information

10-12 October 2021
XV Congress of Czech Society of Clinical Biochemistry with International Participation
Zlin (CZ) Click here for information

4-6 November 2021
19th National Congress of Clinical Chemistry - Greek Society of Clinical Chemistry Clinical Biochemistry
Hybrid Click here for information

19 November 2021
Annual Meeting of the Royal Belgian Society of Laboratory Medicine (RBSLM) - Hybrid event
Bruxellles (BE) Click here for information

23 November 2021
EFLM Webinar: The general principles of laboratory biosafety
Online Click here for information

JPB 2021
Journees de Biologie Praticienne
Paris (FR) Click here for information

26-28 November 2021
XVth International Congress of Paediatric Laboratory Medicine
Munich (DE) Click here for information

28 November - 2 December 2021
EuroMedLab 2021 - 24th IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine
Munich (DE) Click here for information

1-2 December 2021
Journées de l'innovation en biologie (JIB 2021)
Paris (FR) Click here for information

Date to be announced
XXII Serbian Congress of Medical Biochemistry and Laboratory Medicine and 16th Belgrade Symposium for Balkan Region Click here for information

10-11 February 2022
Annual Meeting of the Royal Belgian Society of Laboratory Medicine (RBSLM) - Hybrid event
Helsinki (F) Click here for information

15-18 March 2022
6th EFLM Conference on Preanalytical Phase
Online Click here for information

23-26 May 2021
The 10th Santorini Conference "Systems medicine and personalised health & therapy" - The odyssey from hope to practice: Patient first - Keeps Ithaca always in your mind
Santorini (GR) Click here for information

4-9 October 2022
FEBS Advanced Course: 360-degree Lysosome; from structure to genomics, from function to disease-update
Izmir (TR) Click here for information

November 2022
14th CIRME International Scientific Meeting "Implementation of metrological traceability in laboratory medicine: where we are and what is missing"
Milan (IT) Click here for information

Boost your brand and increase your company's visibility through the EFLM Newsletter!
EuroLabNews is the digital bi-monthly newsletter of EFLM targeting more than 8,500 laboratory medicine professionals and is also published on the EFLM website. The Newsletter features information on EFLM initiatives and activities of its functional units, news from EFLM National Society members and includes a calendar of the major events in the Clinical Chemistry and Laboratory Medicine field.

The EFLM IVD partners are offered the possibility to advertise on EuroLabNews as follows:

	1 issue	6 issues
1 quarter of page	500 €	2000 €
Half a page	1000 €	4000 €
Full page	1500 €	6000 €

Those interested in this opportunity can contact the EFLM Office at **silvia.cattaneo@eflm.eu**