

EuroLabNews

THE EFLM BI-MONTHLY NEWSLETTER

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



EFLM ANNUAL REPORT

EFLM Annual Report 2018

by Giuseppe Lippi, EFLM Executive Board Secretary

GENERAL MEETING

Michael Neumaier, EFLM President, greeted the audience and welcomed delegates to the General Meeting (GM) in Mannheim and presented the agenda. No matters emerged from the minutes of the last GM in Athens, June 2017 and minutes were otherwise approved. In the following part of the meeting the majority of the national societies voted in favour of LABAC to join the EFLM as Affiliate Member. The majority of the national societies also voted in favour of Kazakhstan Public Association «Federation of Laboratory Medicine» to join the EFLM as Affiliate Member.

The EFLM President then provided an overview on the current EFLM organization (Executive Board [EB], functional units), recent EFLM activities since the last GM in Athens (including recent official publications, meetings, bursary programs, EFLMLabX, participation of EFLM EB members to national societies' meetings, agreement with Clinical Chemistry and Laboratory Medicine, EFLM EB meeting with IVD representatives, EuroLabNews), and also gave a brief overview on the ongoing and future projects within the EFLM. Past President Sverre Sandberg provided an overview on the new IFCC statute which encompasses the presence of one EFLM representative in the IFCC board and briefly explained how the representative is elected by the EFLM and gave an

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Editorial information:

Newsletter Editor: Dr. Harjit Bhattoa, Faculty of Medicine, Dept of Laboratory Medicine, University of Debrecen, Hungary

EFLM Executive Board:

M. Neumaier, S. Sandberg, AM. Simundic, G. Lippi, H. Storm, T. Guimaraes, T. Zima

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Foreword

by Harjit Pal Bhattoa, Editor EFLM EuroLabNews



The current issue of the EuroLabNews is inaugurated by the EFLM Annual Report 2018 by Prof. Giuseppe Lippi, the EFLM Executive Board Secretary where all activities of the EFLM in the past year have been summarized. The role of Procalcitonin in the management of patients with Sepsis is presented by Philipp Schuetz and co-workers under the Hot Topic column. The key points of the upcoming webinar

Unmet clinical needs assessment for biomarker evaluation – a practical toolbox for Laboratory Medicine by Philip Monaghan are presented to encourage participation. Evgenija Homsak, Chair WG-CPE introduces an exciting novel EFLM initiative for National Society members in the form of EFLM Postgraduate Courses. The forthcoming events highlight the programs of events scheduled in Barcelona and later this year in Prague. Maria Stella Graziani, Chair of the Communication Committee gives an update of the EFLM publications. The Israel Society for Clinical Laboratory Sciences and the Macedonian Society of Medical Biochemistry and Laboratory Medicine report changing of the guard. The Spanish Society of Laboratory Medicine presents a consensus document on the use of Cardiac Troponin in the Emergency Department. The IFCC corner summarizes happenings in Laboratory Medicine with a global perspective. Last but not least, the Calendar of Events lists all events in our field.





overview of the current composition of IFCC Regional Federation Representatives. EFLM Treasurer Huib Storm gave a report on 2017 financial audit and balance sheet, and 2018 internal budget. The GM approved all accounts unanimously.

The EFLM President, then emphasized that achieving better health and healthcare through Laboratory Medicine would only be possible with involvement of EFLM National Society Members. This is the reason why during September 2017 they were asked to participate in the survey concerning the level of satisfaction towards EFLM. The main aim of the survey was to assess collaboration, specifically by understanding the needs of our National Societies, checking how National Societies see the relationships with EFLM and receiving suggestions on how to improve the relationship with EFLM. Starting from these results and from the ongoing items of the previous plan, the EB based the preliminary study to prepare the draft for the EFLM Strategic Plan 2018-2019. Compared to previous editions, it was considered important to have a Strategic Plan made for a 5-10 year horizon while maintaining shorter term 2-year action plans. A SWOT analysis was used by the EB to identify the main goals (7) where to concentrate the strategic plan and the 2-year related actions (18). Erik Kilpatrick, Science Committee Chair, reported about the past and ongoing activities within the EFLM functional units. Gilbert Wieringa, Profession Committee Chair, reported about the past and ongoing activities within the EFLM functional units. Wim Huisman, Quality & Regulations Committee Chair, reported about the past and ongoing activities within the EFLM functional units. Daria Pasalic, Education & Training Committee Chair, reported about the past and ongoing activities within the EFLM functional units. Finally, Maria Stella Graziani, Communication Committee Chair, reported about the past and ongoing activities within the EFLM functional units. All Power point presentations with the reports can be viewed and downloaded from EFLM website.

At the end of the meeting the EFLM President warmly thanked the audience and reminded that the next GM will take place in Barcelona, in concomitance with EuroMedLab 2019.

EXECUTIVE BOARD

Some of the leading activities planned and developed during 2018 are listed below:

- Initiative "invite an EB representative at your National Congress"
- Initiative "EFLM Postgraduate Courses on scientific writing and biostatistics"
- Involvement of EFLM in EC Medical Device Coordination Group
- Possible organization of an EFLM-APFCB Preanalytical Conference in Asia
- EFLM participation to the APFCB Congress in Jaipur
- APFCB participation to the CELME Symposium in Prague
- Establishment of an EFLM Task Force on Disruptive Technologies
- Approval of the new release of the EFLM Procedure Manual

COMMITTEES

Committee – Communication (C-C)

The C-C activity in 2018 focused mainly in consolidating the objectives of the Committee: to develop EFLM visibility, increase the collaboration with its member Societies (NSs) and to promote the profession increasing awareness of the importance of clinical laboratories in health care. We have been engaged in issuing the Federation Newsletter on a regular basis and have obtained an encouraging feedback from the member Societies: most of them read regularly the bulletin with a main interest in the Hot Topic section, where news and information about topics of recent interest and development in Laboratory medicine are exposed. Furthermore, the National Societies have been encouraged to send news about their own activities to be published in the Newsletter. In 2018 a regular section has been added to the bulletin, where to host news from IFCC.

The website update receives also great attention; the website statistics tell us that it is visited by around 2000 visitor per month. The most visited pages are the ones of the most active EFLM Working groups: the Biological Variation and the Pre-analytical phase WGs.

The promotion of the field of Clinical Chemistry and Laboratory Medicine to the lay public has received new impulse from the collaboration with the Patient Focused Lab Med WG that resulted in publishing a report from the President of the UK National Association for Patient Participation in the December issue of the Newsletter.

The visibility of EFLM has also been promoted through the use of the social media: we are present in Twitter, LinkedIn, Facebook and YouTube (the last one to post the educational material produced by the C-ET). EFLM presence is slowly but continuously increasing in popularity and generates an important traffic back to our website. We consider the presence of the Federation in the social media rather relevant for its visibility.

Committee – Education and Training (C-ET)

EFLMLabX Project was launched by WG-CPE in January 2018 by an invitation sent to all EFLM NS representatives to join and to IVD for support. At the web page of the project more than hundred users and 15 laboratories are registered. WG-CPE also prepared a proposal for cooperation with IVD for supporting the bursaries for exchange program. For promoting the program, the WG published a paper on e-JIFCC and prepares the manuscript for CCLM. WG-CPE also made the proposal of announcement for the new type of low-budget postgraduate courses PGC. In 2019, under the supervision of EFLM and WG-CPE, two types of courses will be organized: "Biostatistics in Laboratory Medicine" and "How to write a good scientific and professional article". EFLM WG-CPE organized a two-member teams and according NS requirements and availability of the teams, in 2019 these courses will be organized in 6 different NS. Travel costs for lecturers for 2 NS will be economically supported by EFLM. WG-CPE also prepared the results of MedTech European Code survey initiated by WG-CPE, are which are being arranged for publishing. In 2018, WG-DE launched and upgraded the e-learning platform Moodle 3.5 and release, processed and published 8 webinars and issued 219 certificates of attendance. This WG also recorded lectures from the 2nd Strategic Conference, hold in Mannheim in

June 2018. WG-DE also updated and followed the materials on the social media Facebook and YouTube and noted an increase of followers. In the middle of 2018, the WG on Laboratory Medicine Credit Points was (WG-LMCP) established. This group will be responsible to establish and run the EFLM system to allocate credit points for educational events. TG on EFLM Syllabus Course prepared a plan for courses in cooperation with WG-DE. Courses should be recorded in 2019 and 2020, to deliver and maintain the EFLM Syllabus Courses recorded by e-learning platform. Chair of the TG-Syl Ralf Lichtinghagen is a member of the Congress Organizing Committee for the 23rd EuroMedLab in Barcelona.

Committee – Profession (C-P)

The start of 2018 saw auto-registration to the EFLM Register of Specialists in Laboratory Medicine further extended and now includes the Netherlands, United Kingdom and Croatia. Registrant numbers have grown from 1036 in 2017 to 1199 at end 2018. As we go into 2019 a further increase is expected with Slovenia being welcomed to the auto-registration ranks. Following approval from the EFLM General Assembly in June eligibility to join the register was extended from the 28 European Union countries with a national society affiliated to EFLM to all 40 European countries with a national society affiliated to EFLM. Further auto- and individual registration is anticipated. A survey of EU affiliated national societies highlighted that 14 countries can meet EFLM's Equivalence of Standards and would therefore be eligible to be amongst the minimum 10 countries required to present Laboratory Medicine's Common Training Framework under EU Directive 2013/55/EC (The recognition of professional qualifications). In this regard representatives from France, Spain, Ireland and Croatia were congratulated on their engagement at government level to present the case for recognition of specialist practice. With the cultivation of new links at EFLM Executive Board level to the EU Commission's office leading on implementation of the Directive the decision was taken to cease our reliance on an external agency to present Laboratory Medicine's case for recognition of specialists. The direct links that have been established are anticipated to prove valuable in aligning future strategy with EU Commission guidance.

Committee – Quality and Regulations (C-QR)

The WG published an article on traceability requirements according to ISO15189 and is working on different papers concerning retention time of documents, POCT and validation/verification of analytical methods. All members of the different countries contribute actively to make these widely acceptable. The Committee chair is active in ISOTC212 WG1, especially in relation with the new standard on risk management and the guideline for users of POCT equipment. Within ISO the work on the new edition of ISO15189 has started and the EFLM WG is focused on contributing to this most important standard for quality management in medical laboratories, as it did with the former editions. The paper by Thelen and Huisman on Harmonization of accreditation to ISO15189 can be considered as a specific view on this process. The chair of the WG QR is active in the EA Health Care Working Group to contribute to harmonization of accreditation according to ISO15189 in the European countries. The WG is focused on influencing the development and interpretation of ISO and CEN standards and in particular the implementation of the new EU IVD Regulation. This is reflected in the updated Terms of Reference for both Committee and Working Group.

Committee – Science (C-S)

The eight Working Groups (WGs) under this Committee (Biological Variation, Guidelines, Harmonisation of the Total Testing Process, Patient Focused Laboratory Medicine, Personalised Laboratory Medicine, Postanalytical Phase, Preanalytical Phase and Test Evaluation), two Task Groups (TGs) (Biological variation Database and Performance Specifications Based on Outcome Studies) and one Task and Finish Group (TFG) (Standardisation of the Colour Coding for Blood Collection Closures) have in the last year been joined by the introduction of three TG/TFGs, namely the TG-Cardiac Markers, TFG Urinalysis and TFG Autoimmunity Testing. All groups remain highly active in focusing on topics which are of direct relevance in improving the

effectiveness of laboratory medicine to patients. Particular highlights from 2018 include publications such as the EFLM recommendations on venous blood sampling (in collaboration with our Latin American colleagues), practical recommendations for handling hemolysed samples and serum indices as well as papers bringing more certainty to the assessment of uncertainty. There has also been the continued development of the biological variation database to help support its use in deriving analytical performance specifications and a biomarker workshop in Sydney, Australia. Special note should be made of the contributions members of the Science Committee WGs have made to meeting activities, including at the 5th Joint EFLM-UEMS Conference in Antalya, Turkey, and the 2nd EFLM Strategic Conference in Mannheim, Germany. The Science Committee cannot function in isolation, and depends on the continued support of the constituent National Societies as well as the collaboration with companion organisations such as the IFCC Scientific and Emerging Technologies Divisions.

MEETINGS

EFLM has organized two official meetings in 2018:

1. The end of laboratory medicine as we know it? 2nd EFLM Strategic Conference. Mannheim, 18-19 June 2018.
2. 5th Joint EFLM-UEMS Congress. Antalya, 10-13 October 2018.

WEBINARS

EFLM has organized six Webinars in 2018:

- Pre-analytical mysteries
- Catheter Blood Collection Practices: Can A High Quality Sample for Laboratory Diagnostics Be Obtained?
- The order of draw
- The role of EQA in the verification of in vitro medical diagnostics
- How to perform tube validation?
- M-protein diagnostics of Multiple Myeloma patients treated with biologics

PUBLICATIONS

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Procalcitonin: Laboratory Support for more effective management of patient with sepsis?

by Magdalena Mueller, Monika Huembelin, Philipp Schuetz,
Department of Internal Medicine, Kantonsspital Aarau and University
of Basel, Switzerland



Antibiotic-overuse has been recognized as a main driver for the increase in multi-drug resistant pathogens posing dramatic a threat to global health. Therefore, reducing antibiotic overuse by improving antibiotic stewardship efforts is of high global interest. As clinical signs and symptoms of infection and sepsis may be ambiguous, the identification of objective, prognostic parameters

are needed to improve the decision whether start of antibiotic treatment is needed and to define the optimal duration of antibiotic therapy. This is particularly true because current treatment duration is mostly based on fixed antibiotic regimens recommended by practice guidelines. Individualizing antibiotic therapy has therefore great potential to improve antibiotic stewardship and thereby reduce the overall treatment exposure. In this regard, procalcitonin (PCT), a laboratory parameter of bacterial infection, was found to be most helpful. PCT is a polypeptide of 116 amino acids. Its expression is upregulated in epithelial cells upon contact with bacterial pathogens within six to twelve hours. Viral infection on the other hand leads to downregulation of its expression, which give PCT a diagnostic advantage over other inflammatory markers. Once the infection is controlled by the hosts immune system or by antibiotic therapy, PCT levels halve daily (1). Thus, PCT helps to discriminate between bacterial and viral infections, thereby helping to define whether antibiotic should be started in patients with unclear clinical pictures, and also provides prognostic information as a marker mirroring infection and treatment response over time. By tracking the resolution of infection, PCT also allows antibiotic treatment to end earlier (2). It is important to understand the kinetics and also limitation of PCT for its safe and effective use in clinical practice (3). In the context of a low-risk situation and a low pretest probability for bacterial infections (e.g., bronchitis patient), a low PCT level <0.25 ug/L aids in ruling-out bacterial infection and empiric antibiotic therapy should be avoided. If PCT is increased or the initial clinical assessment shows a high suspicion for bacterial infection, antibiotics should be considered and PCT testing every 24-48 hours can be used to stop antibiotics if PCT drops to levels ≤ 0.25 ug/L or if it decreases by 80% or more from its peak. In the context of a high-risk patient with sepsis (**Figure 1**), initial antibiotics should be used irrespective of PCT results, but a low PCT value may prompt additional diagnostic measures to rule out other non-bacterial causes of illness. In these situations, monitoring of PCT over time helps to track resolution of infection and decisions regarding early stop of antibiotic treatment. The concept of using PCT to guide treatment has been mainly studied in respiratory infection and sepsis. In respiratory tract infections, where clinical presentation often is inconclusive in regard of discriminating between bacterial and viral cause of infection, PCT can be of diagnostic use. Trials have shown that PCT <0.25 ug/L in combination with a low clinical probability for bacterial infection can help rule out a bacterial infection and thereby prevent unnecessary initiation of antibiotic therapy (2).

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Michael Neumaier, EFLM President



PCT use in the intensive care unit					
Initial clinical assessment (including microbiology)	PCT (µg/L)	Probability of bacterial infection based on PCT level	PCT Interpretation	Antibiotic Management	PCT Monitoring
Bacterial infection uncertain	< 0.5	Low Probability	Bacterial infection unlikely	Initiate empiric antibiotic regimen consider other diagnostic tests	repeat PCT within 24-48h and discontinue antibiotics if PCT still <0.5 µg/L
	≥ 0.5	High Probability	Bacterial infection likely	Initiate empiric antibiotic regimen consider other diagnostic tests	repeat PCT every 24-48h discontinue antibiotics when PCT <0.5 µg/L or decreases by 80%
Bacterial infection suspected	< 0.5	Low Probability	Bacterial infection possible	Initiate empiric antibiotic regimen consider other diagnostic tests	Repeat PCT test within 24-48h consider discontinuation of antibiotics if PCT still <0.5 µg/L
	≥ 0.5	High Probability	Bacterial infection highly likely	Initiate appropriate empiric or targeted antibiotic regimen	repeat PCT every 24-48h discontinue antibiotics when PCT <0.5 µg/L or decreases by 80%

Fig. 1: Procalcitonin protocol for patients with sepsis on the ICU as suggested by Neeser et al.

This concept has been studied in a recent individual patient data meta-analysis including 6708 patients with respiratory infections from 26 eligible trials in 12 countries (4). Results showed a 30% reduction in antibiotic days for patients managed by PCT guidance, which also translated into lower rates of treatment side effects and an overall mortality benefit of 15%. PCT has also been studied in the context of sepsis, where critical conditions do not allow to withhold empirical antibiotic treatment upon admission, but PCT has shown to be useful for early stop of treatment (5). Large, multicenter interventional trials like the PRORATA trial and the Stop Antibiotics on Procalcitonin Guidance Study (SAPS) have shown the potential of PCT to reduce antibiotic exposure and in case of SAPS, also to lower mortality (6,7). In both trials antibiotic treatment was discontinued once PCT decreased by $\geq 80\%$ from its peak value, or to a level ≤ 0.5 µg/L. A recent metanalysis investigated effects of PCT across sepsis trials and also found strong reductions in both, antibiotic exposure as well as mortality (5). The lower mortality rate was explained by several factors: first, a lower risk for antibiotic side effects with reduced antibiotic exposure has been found in several trials also including *Clostridium difficile* infection. Secondly, the prognostic information derived from PCT kinetics might influence therapeutic decisions and elicit further diagnostic assessment, which in turn may positively impact on outcome (8). Still, some studies failed to show an added benefit of PCT-guided antibiotic treatment (9). These studies highlight the importance of high protocol adherence and to use PCT algorithms relying on repeated measurements (every 24-48 hours) to have most gains from PCT measurement (3). There are several limitations to the use of PCT particularly for patients with chronic infections (e.g. endocarditis, osteomyelitis), where only few trials have investigated the usefulness of PCT – not including any interventional trials (10). Also trials have not included patients with pregnancy, immunosuppressed patients including HIV-infected patients or cystic fibrosis. Moreover, PCT levels are known to be elevated in patients with non-infectious conditions such as trauma, C-cell carcinoma or postoperative. A study conducted in a surgical department showed PCT-levels peaking on the second postoperative day and generally continuously decreasing afterwards. Whereas persistently elevated PCT-levels correlated with postsurgical infections (11). The clinical value of such observations needs further investigation allowing possible implementation into guidelines and algorithms. In conclusion, PCT has shown great promise for individualization of antibiotic treatment with an overall reduction in antibiotic exposure leading to reductions in side effects and improvements in clinical outcomes. PCT measurements should always be interpreted in consideration of the overall assessment of each patient. In addition, it should never delay the initiation of treatment in high-risk patients and critical states. However, it can then be used to monitor resolution of infection and therefore length of treatment.

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New EFLM initiative for its national society members: EFLM Postgraduate Courses (PGC)

by Evgenija Homsak, Chair of the EFLM Working Group on Congresses and Postgraduate Education

We are delighted to announce the launch of a new EFLM initiative addressed to EFLM National Societies as a reply to the request for educational tools: **the EFLM Postgraduate Courses (PGC)** proposed and organised by the EFLM Working Group on Congresses and Postgraduate Education (WG-CPE), under the EFLM Education & Training Committee.

PGCs will be organized on specific topics as a "turnkey courses", i.e. with a defined structured programme and designated speakers' team ready to travel to your country to deliver the EFLM course.

The first two courses that we are proposing are:

- **Biostatistics in Laboratory Medicine**
- **How to write a good scientific and professional article**

Each course is structured on 2 days, with two speakers and addressed to a small group (up to 50 participants). It is a low budget course (not profitable) ideally to be organized as a satellite meeting on occasion of a National Societies Congress or another national educational event.

The EFLM Education & Training Committee and the EFLM Executive Board are working to find financial support from IVD companies for this project in order to be able to deliver a good number of these courses but, in the meantime, the Executive Board decided to offer one course in 2019 where the speakers' travels will be directly covered by the EFLM budget.

1. Biostatistics in Laboratory Medicine

Framework programme:

1. How to prepare and plan the research properly; define the subjects, hypothesis and the aim
2. How to represent the data of the investigation
 - 2.1. Measures of central tendency and dispersion. Distribution of the data
 - 2.2. Statistical hypothesis, tests and power analysis
3. Statistical methodology
 - 3.1. How to compare continuous data sets (dependent and independent)
 - 3.2. How to compare categorical data
 - 3.3. Confidence intervals
 - 3.4. Correlation and regression
 - 3.5. Multivariate analyses
 - 3.6. Tests for validation and verification of laboratory tests

Speaker's teams:

Team 1: *Ana-Maria Simundić (Zagreb, HR) and Vanja Radisic Biljak (Zagreb, HR)*

Team 2: *Matteo Vidali (Borgomanero, IT) and Andrea Padoan (Padova, IT)*

2. How to write a good scientific and professional article

Framework programme:

1. Journal selection. Instruction for authors
2. Title. Abstract and Key words.
3. Introduction, hypothesis and the aim of the study.
4. Material and methods
5. Presenting the results-text, graphs, tables and figures.
6. Discussing the results, added value, limitation of the study and conclusions.
7. Literature list, deferent styles in presenting the literature, DORA-statement.
8. Research ethics

Speakers' teams:

Team 1: *Sverre Sandberg (Bergen, NO) and Elvar Theodorsson (Linkoping, SW)*

Team 2: *Ferruccio Ceriotti (Milan, IT) and Martina Montagnana (Verona, IT)*

Team 3: *Paola Pezzati (Florence, IT) and Martina Zaninotto (Padova, IT)*

Team 4: *Ana-Maria Šimundić (Zagreb, CRO) and Daria Pašalić (Zagreb, CRO)*

In September each year, EFLM National Societies will be invited by the Working Group: Congresses and Postgraduate Education to apply to this initiative.

We do hope that you can find this new EFLM initiative a fruitful opportunity for your National Society! (More news on how to apply you can be found on the EFLM website/WG-CPE: <https://www.eflm.eu/site/page/a/1127>).

UPCOMING EFLM EVENTS

EFLM Webinar: Unmet clinical needs assessment for biomarker evaluation - a practical toolbox for Laboratory Medicine

Daniel Rajdl, Chair of the EFLM WG Distance Education and eLearning informs about next webinars. EFLM is happy to remind you that the attendance to the webinars is free of charge and that the recording of the lectures will be available afterwards on at the EFLM elearning platform for those unable to attend.

Speaker: Phillip Monaghan (UK), Moderator: Christa Cobbaert (NL)
Date: 23rd April at 18:00 CET



The translation of promising biomarkers to clinical application is a critical opportunity for laboratory medicine; to provide information that enables clinicians to make better decisions about the care of their patients. Inherent to this concept is consideration of the unmet clinical need that a laboratory test is aiming to address. However, as testing guides downstream clinical interventions to improve patient outcomes, the link between testing and outcomes is often indirect. There is a major opportunity here for laboratory professionals to play a key role in the development and implementation of clinical care pathways for new and existing laboratory tests. Stakeholder involvement; working together to overcome the conventional silos across disciplines is paramount to drive the adoption of innovative tests with robust implementation planning, so that test results are available and acted upon in an appropriate and timely manner, with a strong link to clinical intervention and outcomes.

The EFLM Working Group for Test Evaluation (WG-TE) has developed a 'practical toolbox' providing a Test Evaluation Framework and Interactive Unmet Clinical Needs Checklist (hosted on the EFLM eLearning platform) to assist laboratories and other key stakeholders in clinical translational research, to undertake clinical needs assessment and clinical care pathway development. Dr. Philip Monaghan is a consultant clinical scientist at The Christie Pathology Partnership, in Manchester (UK). He is also an honorary lecturer at the University of Manchester in the Faculty of Medical and Human Sciences, Institute of Inflammation and Repair. Dr. Monaghan is a member of the EFLM Working Group for Test Evaluation and Deputy Chair of the ACB Scientific Committee: Working Group on Traceability and Harmonisation of Calibration. He was awarded the Silver Research Medal from the Royal College of Pathologists for work on cortisol.

Registration at <https://elearning.eflm.eu/enrol/index.php?id=42>

Did you miss any EFLM webinar?

Do not worry: the recorded version of all EFLM webinars is available at <https://elearning.eflm.eu/>

New posted recorded webinar: New parameters of hematology analyzers and their clinical significance (Speaker: Johannes (Hans) Hoffmann, DE)

EUROMEDLAB 2019: 23rd IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine



The EUROMEDLAB 2019, the 23rd IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine will be held in Barcelona, Spain from the 19th to 23rd of May.

The Congress Organizing and the Scientific Programme Committees members has been working hard for the last two years to prepare an outstanding event. The scientific program has been prepared in collaboration with the European Societies through the International Scientific Advisory Board and we all are really excited about its content. A carefully selected combination of lectures, symposiums, viewpoint sessions and educational workshops has been included

in the program. The scientific level of the speakers is remarkable, and they will cover a large variety of areas in laboratory medicine. Many scientific and technological areas will be combined with some others related to professional and organizational development. Advances in mechanisms of aging, epigenetics, microbiome, big data or CRISPR are examples of trending topics in laboratory medicine that will be presented during the congress. Updated information about quality in laboratory medicine, diabetes, kidney, liver or thyroid diseases, invitro fertilization, stroke, personalised immunosuppression, noninvasive prenatal testing or dyslipemia will be presented with the aim of improving clinical laboratory practice for all the attendees.

The scientific programme of this 5-day event includes:

- 1 Opening lecture - on recent progress on the mechanisms of aging and its medical applications
- 4 Plenary lectures - scheduled on each morning at 9:00 and no other sessions will be held simultaneously
- 20 parallel Symposia - scheduled each day from Monday to Thursday from 10:30 to 12:30.
- 6 Viewpoint Sessions - to promote debate on thought-provoking subjects
- 37 Educational Workshops - scheduled on Monday, Tuesday and Wednesday in the afternoon

Three Satellite meetings will also take place in before the congress organized by the Spanish Society of Laboratory Medicine regarding laboratory medicine and quality, standardization and recommendations in the laboratory of haematology and breast cancer and environment.

Every day at lunch time, there will be a two hours break, to visit and discuss the posters.

The congress venue is CCIB - Centre Convencions Internacional de Barcelona, located at Plaça de Willy Brandt, is an integral part of Diagonal Mar, the newest section of Barcelona's seafont.

Early registration deadline was 31 March 2019.

Check out the congress website for more information:
<http://www.euromedlab2019barcelona.org/2019/home>

UPDATES ON EFLM PUBLICATIONS

Updates of the EFLM Publications list

by MariaStella Graziani, Chair of the EFLM Communication Committee

Some interesting EFLM papers have been published recently.

A consensus statement has been produced by the EFLM Working Group Accreditation and ISO/CEN standards (WG-A/ISO)

Documenting metrological traceability as intended by ISO 15189:2012: A consensus statement about the practice of the implementation and auditing of this norm element.

Thelen M, Vanstapel F, Meško Brguljan P, Gouget B, Boursier G, Barrett E, Kroupis C, Lohmander M, Šprongl L, Vodnik T, Bernabeu-Andreu F, Vukasović I, Sönmez C, Linko S, Brugnoli D, Vaubourdolle M, Huisman W, Panteghini M on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group Accreditation and ISO/CEN standards (WG-A/ISO Clin Chem Lab Med 2018. doi.org/10.1515/cclm-2018-1212

This paper deals with ISO15189:2012 requirement for medical laboratories to document metrological traceability of their results and discusses how this requirement should be met by the medical laboratory and how this should be assessed by accreditation bodies.

The main scope of the document is to encourage the International Laboratory Accreditation Cooperation (ILAC) to revise its recommended policy for the assessment of metrological traceability in medical laboratories seeking ISO 15189 accreditation. The statement stresses in particular that the accreditation policy should allow for risk mitigation by other means that are already obligatory in the accreditation process such as internal quality control, external quality assessment and risk management.

The second one is a paper published by the EFLM Working Group on Preanalytical phase (WG-PRE)



Preanalytical challenges – time for solutions

Lippi G, Betsou F, Cadamuro J, Cornes M, Fleischhacker M, Fruekilde P, Neumaier M, Nybo M, Padoan A, Plebani M, Sciacovelli L, Vermeersch P, von Meyer A, Simundic AM on behalf of the Working Group for Preanalytical Phase (WG-PRE) Clin Chem Lab Med 2019. doi.org/10.1515/cclm-2018-1334

Education is (and has always been) a core activity of the WG-PRE; as a consequence, a series of European conferences have been organized every second year across Europe.

This collective article summarizes the leading concepts expressed during the lectures of the fifth EFLM Preanalytical Conference "Preanalytical Challenges – Time for solutions", held in Zagreb, 22–23 March, 2019. The topics covered include:

1. sample stability,
2. preanalytical challenges in hematology testing,
3. feces analysis,
4. bio-banking,
5. liquid profiling,
6. mass spectrometry,
7. next generation sequencing,
8. laboratory automation,
9. the importance of knowing and measuring the exact sampling time,
10. technology aids in managing inappropriate utilization of laboratory resources,
11. management of hemolyzed samples,
12. preanalytical quality indicators.

A special issue of Clin Chem Lab Med has been dedicated to the 2nd EFLM Strategic Conference that was held from 18th to 19th June 2018 in Mannheim, Germany. The congress was entitled "**The End of Laboratory Medicine as we know it? Handling disruption of Laboratory Medicine in digital health**".

Neumaier M and Watson ID

Clin Chem Lab Med 2018. doi.org/10.1515/cclm-2018-1264

This is the Editorial illustrating the Conference content and summarizing the key points of the five sessions:

1. Disruptive technologies in laboratory analytics
2. Disruption through biomedical informatics technologies
3. Integrating laboratory and clinical data - a game for the lab?
4. Interpretation and communication of test results: the stakeholder's perspectives
5. Patient empowerment and the laboratory

CHANGING OF THE GUARD IN EFLM NATIONAL SOCIETIES

Israel Society for Clinical Laboratory Sciences

Dr. Avi Peretz (Dept of Microbiology, the Baruch Padeh Medical Center, Poriya) is the new President of the Israel Society for Clinical Laboratory Sciences replacing Dr. Nurit Algor. A warm welcome to Dr. Peretz and a thank you to the outgoing President, Dr. Algor, for the support to EFLM activities.

Macedonian Society of Medical Biochemistry and Laboratory Medicine

Dr. Katerina Tosheska-Trajkovska (Dept of Medical and Experimental Biochemistry, Medical Faculty, University Ss."Kiril and Metodij", Skopje) is the new President of the Macedonian Society of Medical Biochemistry and Laboratory Medicine replacing Prof. Danica Labudovic. A warm welcome to Dr. Tosheska-Trajkovska and a thank you to the outgoing President, Prof. Delpech, for her always prompt support to EFLM activities.

NEWS FROM EFLM NATIONAL SOCIETIES

News from the Spanish Society of Laboratory Medicine (SEQCML)



Prepared by the Spanish Society of Laboratory Medicine (SEQCML), the Spanish Society of Urgent and Emergency Medicine (SEMES), and the Spanish Society of Cardiology (SEC)

Consensus document on the use of cardiac troponin in the Emergency Department

- The concentration of cardiac troponin increases early in blood when there is myocardial damage from any cause
- Increases in cardiac troponin, together with clinical signs and symptoms, make it possible to diagnose acute myocardial infarction with certainty and precocity
- The absence of an increase in cardiac troponin rules out the existence of significant myocardial damage; this allows shorter observation times to rule out acute myocardial infarction in patients who do not have it

Madrid, November 6, 2018. The possibility of measuring cardiac troponin (TNC) has been for many years a major step forward

in the diagnosis of acute myocardial infarction (AMI) and other cardiac and extra-cardiac pathologies affecting the heart. Currently, in clinical practice, there are coexisting methods that allow for the measurement of normal, low, or very low TNC concentrations with the recommended analytical quality. Measuring very low concentrations of TNC (high sensitivity TNC, TNC-hs) allows for the identification of myocardial damage that is not detectable with methods that do not measure such low concentrations (TNC -contemporaneous) with the recommended quality. Given this varying ability of analytical methods to recognize myocardial damage, the use of TNC in cardiac diagnosis can generate confusion in certain circumstances. For this reason, the Spanish Societies of Laboratory Medicine (SEQCML), Urgent and Emergency Medicine (SEMES), and Cardiology (SEC) have developed a consensus document on the use of TNC in the differential diagnosis of AMI, whatever the measurement method used. This document has been published in the journal *Emergencias*, an organ of the SEMES, and can be accessed through the SEMES website and in the member-restricted area of the SEQCML website.

"TNC is very commonly used in emergency services because it is very simple to determine and the information it provides is very valuable. It allows for rapid differentiation between a potentially serious patient with high TNC and a potentially less severe patient with a non-elevated TNC; this differentiation is an excellent help for Emergency Department doctors", explains Dr. Juan Sanchís, head of the Interventional Cardiology Unit of the Hospital Clínic Universitari de Valencia. Dr. Sanchís points out that a high concentration of TNC may be indicative of diseases other than AMI, so it is necessary to interpret this biomarker well. "One of the drawbacks of the measurement of TNC, especially if it is measured with high sensitivity methods, is to cause over-diagnosis of AMI, because it tends to prioritize this diagnosis over other alternatives that a patient with elevated TNC may present", adds the specialist.

"Despite all the valuable contributions of TNC, some doubts have been generated in the interpretation of its results, which this consensus document aims to clarify," says Dr. Sanchís. These questions are summarized in three questions to which the document gives an answer: "How are the various immunoassay methods for measuring TNC different?"; "Does a normal troponin result rule out an AMI and can it guarantee a rapid and safe discharge of the patient from the emergency department? "; and finally, "When does an elevated TNC indicate an AMI and when does it signal other causes of myocardial damage?".

Dr. Aitor Alquézar, medical staff of the Emergency Department in the Santa Creu i Sant Pau Hospital in Barcelona and co-author of the consensus, agrees on the reasons that made this document necessary. "In the first place, there is a great diversity of immunoassay methods to measure TNC, with different decision values and different diagnostic performance. This situation can generate errors in the interpretation of TNC values if the doctor evaluating the patient does not know the characteristics of the method available in his center," he explains, before adding that it is necessary to reach an agreement on what TNC concentrations are significant from the clinical point of view. "For the Emergency Physician, the main objective is to avoid inappropriate discharges (avoid false negatives), while for the cardiologist it is important to admit patients with a high probability of AMI (avoid false positives)", concludes Dr. Alquézar.

High sensitivity methods

Given that the absence of elevated TNC allows one to rule out the existence of myocardial damage, the current challenge for the clinical use of the biomarker is to shorten the observation

times to rule out AMI in those patients who do not present it. This shortening of observation times is achieved by measuring the TNC with so-called high sensitivity methods (TNC-hs). "The measurement of cardiac troponin (TNC) is available in practically all healthcare centers involved in the diagnosis or exclusion of myocardial infarction. Another thing is what happens with the measurement of high sensitivity troponin (TNC-hs), which is widely implemented in tertiary hospitals, but not so much in other levels of care," explains Dr. Jordi Ordóñez, member of the Spanish Society of Laboratory Medicine and senior consultant in Clinical Biochemistry at the Hospital de la Santa Creu i Sant Pau.

"In this sense," he explains, "given the greater sensitivity of the TNC-hs to detect myocardial damage, this measure should be used systematically in these evaluations. However, not all centers have the necessary equipment to measure TNC-hs. For this reason, this consensus deals with the advantages and disadvantages of using both the TNC measurement with high sensitivity methods and with the preexisting methods, which are still in use".

"Currently, methods are being developed with even greater sensitivity than those of high sensitivity, which could identify with almost 100% security if a patient does not have an AMI at the time or two hours after the onset of symptoms," concludes the specialist.

What does the measurement of cardiac troponin contribute to the clinic?

TNC is a biomarker that increases in blood when the heart muscle (myocardium) suffers damage. The precision and analytical sensitivity of the methods to measure TNC have improved from the first generation of reagents (developed 25 years ago) to the most recent ones, called high sensitivity, which allow for the detection of even minimal myocardial damage.

When TNC is measured with a high sensitivity method, a normal result of it in serial samples (e.g. at admission and at 1-2 hours), allows us to rule out an AMI with very high probability in a patient with chest pain (thoracic pain). The security of being able to discharge a patient who has suffered an episode of chest pain and shows a normal TNC result is the main contribution of TNC to the clinic. Given that the majority of patients who consult in the Emergency Room for chest pain do not have an AMI, their early, safe discharge improves the functioning of saturated emergency services.

The elevation of TNC in successive blood samples indicates an AMI if the patient's symptoms and/or electrocardiogram are compatible with this diagnosis. However, TNC also rises in numerous heart diseases, other than AMI, and extra-cardiac issues, which cause damage to the heart by mechanisms other than infarction. This may cause some diagnostic uncertainty for AMI with unclear clinical signs, but the value of TNC is always of clinical importance because its increases, whatever their cause, are associated with a high risk of complications and require careful evaluation of patients.

To know more about the 3 organisations:

Spanish Society of Laboratory Medicine (SEQCML)-
<http://www.seqc.es/>

Spanish Society of Cardiology (SEC) - <https://secardiologia.es/>

Spanish Society of Urgent and Emergency Medicine (SEMES)-
<https://www.semes.org/>



Symposium Cutting Edge Laboratory Management in Europe CELME 2019 Prague, October 3 – 4, 2019

Organized by



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- Join us to share the latest innovative thinking in the delivery of the best laboratory medicine activities.
- Learn from expert innovators presenting new ways of solving the financial, quality and organizational problems we all have to face.
- If you want to lead your laboratory service to “first class” performance then join us and experience the shared opinion of like-minded professionals.
- Number of attendees is limited, first come, first served, so don't hesitate to register today!

Sverre Sandberg, Ian Watson, Tomáš Zima
symposium chairs

PRELIMINARY PROGRAM

Thursday, October 3rd, 2019

11.00 Registration opens

PART A

13.00 – 14.30 Opening Ceremony, Welcome

Funding Models that Reward Laboratory Innovation with Savings for Frontline Services
Hugo Ribeiro (Abbott)

The Business of Introducing New Biomarkers
Phillip Monaghan (The Christie NHS Foundation Trust)
Discussion

14.30 – 15.00 Coffee break

PART B

15.00 – 16.45 The “Omics” revolution

Is there Synergism in Laboratory and Radiology Services Interaction?
Prof. Schonberg, prof. Neumaier

NAVIFY A New Generation of Diagnostic Solution for Decision Making Processes in Oncology Treatments
JP Bogardi (Roche)

How to Utilise Best Practices of Risk Management in Laboratory Medicine
Endang Hoyaranda (APFCB)
Discussion

16.45 – 17.15 Coffee break

17.15 – 18.30 We are Talking about Big Data – Are we using it?

EU infrastructure – ELIXIR
Jiri Vondrasek (Czech Republic)

Laboratory Medicine and Biobanking for Future Patient Benefit EU infrastructure BBMRI-ERIC
Dalibor Valik (Czech Republic)
Discussion

Friday, October 4th, 2019

PART C

9:00 – 11:00 Normalising Data to Aid Continuity

Mathias Orth

Innovation in QC Practice
Tony Badrick (APFCB)

Should we have Different Performance Specifications when we Know the Clinical Reasons for Requesting a Test?
Sverre Sandberg

Reflective Testing – Who Decides what we are Allowed to do?
Julian Barth
Discussion

11.00 – 11.30 Coffee break

PART C

11.30 – 13.00 Panel Discussion – Pro vs Con

Can a Centralised Laboratory Service Support Disseminated Healthcare?

Tomas Zima + Ian Watson

Drone Transported Samples – Vision or Reality?
Timothy K. Amukele (USA)

Zero Touch Sample Handling and Laboratory Resulting
Sunil Sethi (APFCB)

Discussion

13.00 – 13.30 Discussion / Future Perspectives

Closing remarks

13.45

Lunch

Symposium Secretariat: **Congress Business Travel spol. s r.o.**
Lidická 43/66, CZ-150 00 Prague 5 – Anděl,
Czech Republic
Phone: +420 224 942 575, 224 942 579
Fax: +420 224 942 550



celme2019@cbttravel.cz

"Predatory Conferences": Beware the Traps

by Howard Morris President, IFCC, Maurizio Ferrari Past-President, IFCC

We often open our email inbox to find something like this from someone unknown:

"Dear Dr....., I'm writing to follow-up my last invitation as below, would you please give me a tentative reply? Thank you very much. I apologize for the inconvenience if the letter disturbed you

more than once.... It is our great pleasure and privilege to welcome you to join the 7th Annual World Congress on....., which will be held during November 13-15, 2018 in Singapore. On behalf of the Organizing Committee, we would be honoured to invite you to be a chair/speaker while presenting about **Comment on Bristow et al.: Dietary calcium: adverse or beneficial effects of supplements? at the upcoming conference...."**

This practice is known as "predatory conferences". It is like "predatory publishing" and is based on the business model of scientific conferences organized by revenue-seeking companies exhibiting the following traits: [click here to read more](#)

The IFCC-Abbott Visiting Lecturer Programme - a tool to facilitate international exchange of knowledge

With the generous support of Abbott Diagnostics, the IFCC Visiting Lecturer Programme (VLP) has been a flagship project and a highly successful effort to promote knowledge exchange in laboratory medicine throughout the world. IFCC Member societies can apply for the VLP to obtain funding so prominent experts can visit and lecture in their countries or regions. Visiting lecturers are required to make at least two presentations usually one as a plenary lecture and the other as an interactive workshop on a topic of interest to the hosting country. During the past three years (2016- 18), 36 applications were awarded, submitted from a variety of regions.

[Click here to read the interview to Prof Rifai, IFCC VLP Chair, who explains the VLP initiative](#)

LEADERSHIP BASICS FOR CLINICAL LABORATORY PROFESSIONALS: C-CLM brings in a new manual to prepare laboratory leaders

by Sedef Yenice, IFCC C-CLM chair

The IFCC is happy to present the Manual on **"LEADERSHIP BASICS FOR CLINICAL LABORATORY PROFESSIONALS"**. The success of organizational strategies is essentially dependent on an effective leadership strategy. Compiling the best players for a team is no guarantee for success without a great coach to lead. Good leadership strategy assures effective work teams. The manual is one instalment towards achieving these goals. It also complements the C-CLM *Clinical Laboratory Leadership Certificate Program*. We promote six leadership strengths towards business and personal success including demonstrating social intelligence; adopting a flexible leadership style; empowering others; developing trust; managing risks in an environment of uncertainty, and seeing the big picture. Those strengths provide a valuable model in the clinical laboratory workplace, whether one is already in a leadership position or aspiring to get there. [Click here to download your copy of the Manual.](#)

The new IFCC Committee on Bone metabolism (C-BM) is now on its wheels!

by Etienne Cavalier, IFCC C-BM Chair

The new IFCC Committee on Bone metabolism (C-BM) results from the merge of 3 different IFCC working groups, namely on PTH (Chairwoman: Dr C. Sturgeon), vitamin D (Chairman: Dr C. Sempos) and bone markers (Chairman: Dr E. Cavalier) standardization. The Chairmanship of this new Committee has been given by the IFCC Scientific Division to Etienne Cavalier (BE) for 2 years. The members of this committee's board have just been elected and are Drs A. Heijboer (NL), C. Ulmer (US), S. Vasikaran (AU) and HP Bhattoa (HU). They will be helped in their new tasks by Drs C. Sturgeon, C. Sempos and H. Vesper (consultants), Dr K. Makris (IFCC SD liaison), National and IVD representatives. The terms of reference for the new committee include the standardization/harmonization of PTH, vitamin D metabolites and bone markers assays. Indeed, the lack of standardization amongst these assays results in important issues potentially leading to different clinical decisions. The details of the projects of the C-BM can be found on the IFCC website <http://www.ifcc.org/ifcc-scientific-division/sd-committees/c-bm/>. In short, we aim to promote the use of commutable international standards, reference measurement procedures, accuracy-based external quality assessment schemes and performance guidelines for standardized methods. The C-BM will also try to find partnerships with clinical societies to involve clinicians in the process. We are already proud to announce that this committee will be a joined committee with the IOF (International Osteoporosis Foundation). The C-BM will have its first official meeting during the EuroMedlab 2019 Congress in Barcelona. From a personal perspective, I am really proud to lead such a talented team and I would like to thank Professor Morris, Professor Gillery and the IFCC office for their confidence, as well as our corporate partners for their support.

Calendar of EFLM events and events under EFLM auspices

4-5 April 2019

10th European Symposium on Clinical Laboratory and In Vitro Diagnostic Industry 'The clinical laboratory in the pregnancy monitoring'
Barcelona (SP) <http://www.iec.cat/jornades/laboratoriclinic2019.asp>

18 June 2019

Monitoring of Internal Quality Control System Using Patients' Data, EFLM webinar
On-line <https://elearning.eflm.eu/enrol/index.php?id=40>



5 April 2019

Cardiac Marker Dialogues - "High Sensitivity" Cardiac Troponin – Still got it after all these years: Is there anything new around the corner?
Glasgow (UK) <https://www.cmdmeeting.org.uk>

22-26 September 2019

MSACL 2019 EU
Salzburg (AT) <https://www.msacl.org>

11-12 April 2019

15th Belgrade Symposium for Balkan Region "Neighbouring Countries: The Same Professional Aim"
Belgrade (SRB) www.dmbj.org.rs

3-4 October 2019

CELME 2019: Emerging Challenges in Laboratory Medicine
Prague (CZ) www.celme2019.cz



18-21 April 2019

12th International & 17th National Congress on Quality Improvement in Clinical Laboratories
Tehran (IR) www.iqctehran.ir

16-18 October 2019

5th ESPT Congress Precision Medicine and Personalised Health
Seville (SP) <http://www.2019esptcongress.eu/>

23 April 2019

Unmet clinical needs EFLM webinar
On-line <https://elearning.eflm.eu/enrol/index.php?id=43>



23 October 2019

International Conference on Laboratory Medicine "From Bench to Diagnostic-Therapeutic Pathways"
Padova (IT) <http://www.lccongressi.it/laboratorymedicine2019/>

1-3 May 2019

Focus 2019 – Annual Meeting of the ACB
Glasgow (UK) www.acb.org.uk/focus

6-8 November 2019

3^{èmes} Journées Francophones de Biologie Médicale
Munich (DE) www.jfbm.fr

16 May 2019

40th LABAC Conference
Paris (FR) www.labac.eu

7-9 November 2019

The Value of Laboratory Medicine into Clinical Medicine
Erice (IT) For information: chiara.bellia@unipa.it

18 May 2019

VII International Symposium Laboratory Medicine and Quality. Satellite Meeting EuroMedLab 2019
Barcelona (SP) www.seqc.es

28 November 2019

13th International Scientific Meeting of the Centre of Metrological Traceability in Laboratory Medicine (CIRME) "The Internal Quality Control in the Traceability Era"
Milan (IT) <https://sites.unimi.it/cirme/category/events/>

19-23 May 2019

EuroMedLab 2019
23rd IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine
Barcelona (SP) <http://www.euromedlab2019barcelona.org>



7-8 December 2019

Journées de biologie praticienne
Paris (FR) <https://www.revuebiodiemedicale.fr/les-journees-de-biologie-praticienne.html>

19 May 2019

International Symposium: Breast Cancer and Environment. Satellite Meeting EuroMedLab 2019
Barcelona (SP) www.seqc.es

9-12 June 2020

XXXVII Nordic Congress in Medical Biochemistry
Trondheim (NO) www.nfkk2020.no

19 May 2019

International Symposium: Standardization and Recommendations in the Laboratory of Haematology. Satellite Meeting EuroMedLab 2019
Barcelona (SP) www.seqc.es

16-20 May 2021

EuroMedLab 2021, 24th IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine
Munich (DE)



5-7 June 2019

3rd Conference of Romanian Association of Laboratory Medicine (RALM)
Iasi (RO) <http://www.congres-amlr.ro/>

Do not miss the opportunity to have your event listed here.
Apply for EFLM auspices! For more information visit:
<https://www.eflm.eu/site/page/a/1048/>
or email eflm@eflm.eu