Clinical laboratory testing is now a global activity with laboratories no longer working in isolation but as regional and national networks, and often at international levels. Harmonisation refers to our ability to achieve the same result (within clinically acceptable limits) and the same interpretation irrespective of the measurement procedure used, the unit or reference interval applied, and when and/or where a measurement is made. It is often assumed by clinicians, patients and laboratories that tests performed at different laboratories are comparable in their quality and interpretation. However, this may not be so in which case there is the potential for misinterpretation of results, wrong treatments and adverse patient outcomes.

Therefore, how can we achieve harmonisation of our testing across all aspects of the total testing procedure (TTP) including the request, the sample, the analysis and the report (Figure)?

*to be continued on page 2*
A systematic approach to harmonisation is needed and requires:

1. Awareness by the Laboratory Medicine community that there is a need for harmonised processes not only for the analytical phase but across all steps of the TTP (1)
2. Awareness that harmonisation processes are complex; hence a systematic and evidence-based approach that reflects best laboratory practice is needed
3. An organisational plan or roadmap for the set-up and implementation of each harmonisation activity is a pre-requisite together with strong leadership and working groups that are prepared to do the work
4. Communication with main stakeholders, i.e. pathologists, scientists, clinical groups, diagnostic industry, regulatory bodies, IT developers, and consumer groups with a consensus outcome arrived at through cooperation and discussion.

The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) has established several working groups and task and finish groups to address a number of harmonisation projects relating to the test request and sample. These include test requesting, guidelines and position papers, patient preparation and sample collection, and sample handling and transport.

Harmonisation of the different aspects of analysis includes: promoting development of traceable assays, development of commutable secondary reference materials, harmonisation of measurement values for methods where no suitable reference material or reference measurement procedure is available, and harmonised mass spectrometry methodology. Key organisations involved in this analytical work are the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), the International Consortium for Harmonization of Clinical Laboratory Results (ICHCLR), national measurement institutes, expert specialist laboratory groups and external quality assurance (EQA) groups.

Post analysis there are a range of harmonisation activities that are being addressed including: standardisation of reporting units, terminology, calculated parameters and report formatting, harmonised approaches to validation of the quality of biological variation data, harmonised reference intervals, and harmonised processes for management and communication of critical laboratory results and of interpretative result commenting. Working groups and committees led by IFCC, EFLM and many national clinical chemistry societies including those in Australasia, Asia, Canada, Scandinavia, Turkey, and the UK have begun to address these issues (2).

Efforts are also being made to harmonise activities outside the domain of the laboratory and include the establishment of laboratory relationships with clinicians and patient-focused groups, and education of the public via the internet and accessing Lab Tests Online. Guidance about quality indicators to be used to assess the status of pre- and post-analytical tasks in the laboratory is being promoted across the global Laboratory Medicine community with EFLM, IFCC, and the Institute of Medicine jointly working to decrease laboratory errors. At the national level surveillance of the implementation of one or more harmonisation activities across a country is best undertaken through the national EQA provider. In Australia, for example, the Royal College of Pathologists of Australasia Quality Assurance Programs surveys the uptake of common reference intervals, calculations, test profiles, interpretative commenting and report formatting.

Harmonised test results will ensure that clinical guidelines that call for the use of laboratory tests and decision limits can be universally implemented. By doing this there is less confusion among clinicians and patients, thereby minimising misinterpretation of test results. Harmonised laboratory practices should be based on hard evidence that has been systematically compiled and agreed to. The implementation of harmonised practices requires support of laboratories by the national Laboratory Medicine profession and, importantly, there must be close interaction between the laboratory and the clinician at the local level. Although harmonisation is a pragmatic process that aims to reduce the unnecessary variation in laboratory test practices, it still allows for innovation through discussion and the input of new ideas. I encourage you as a Laboratory Medicine professional to be involved.

References
The terms of reference for each WG are available at www.eflm.eu.

Member position.

A vacancy arose and we are calling nominations for 1 Full

European laboratories in EA, ISO TC212 and CEN TC140 & EU

regulatory frameworks and to harmonize accreditation in Europe.

The aim of the EFLM Working Group on Accreditation and

nominations: 30 June 2017

ISO/CEN standards” – deadline to send

EFLM Working Group “Accreditation and

through the standards it sets and the code of conduct it expects

from its registrants the Register has identified a cohort of nearly

3000 individuals with unique knowledge, skills and competencies

for leading/delivering high quality laboratory medicine services.

First established in 1997 by the European Communities

Confederation of Clinical Chemistry and Laboratory Medicine (EC4),

the merger of EC4 with FESCC culminated in 2016 with the transfer

of the Register to EFLM.

Why join?

• The Register supports the case for recognition of Specialists in

Laboratory Medicine under EU Commission Directive

2013/55/EU – the Recognition of Professional Qualifications.

Achieving recognition extends opportunities for specialists to

practice in other EU countries without having ‘compensation

measures’ imposed e.g. re-taking of local professional

examinations which can delay and detract the individual from

professional migration.

Why join?

• Minimum 9 years (ideally 10) years academic (4/5 years) and

specialist (5 years) training;

• Education and training to standards set in the EC4/EFLM

syllabus (ref to 2012 syllabus);

• A Master’s degree in Medicine, Pharmacy or Science;

• An EFLM Profession Committee recognised ‘Equivalence of

Standards’ exit qualification;

• Evidence of participation in continuous professional

development (CPD).

Through the standards it sets and the code of conduct it expects

from its registrants the Register has identified a cohort of nearly

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EuroMedLab Athens 2017: Free shuttle service airport / Megaron Convention Center / airport
From Saturday June 10 to Thursday June 15
A free shared shuttle service, kindly offered by Mindray, is offered to you from and between Athens airport (arrival hall B – Door 5) and the Megaron Convention Centre (main entrance) and back:

SATURDAY 10 JUNE – 8am-8pm – every 1 hour from the airport to the Megaron directly
SUNDAY 11 JUNE – 8am-8pm – every 1/2 hour between 8am-12am and every 1/2 hour between 12am – 8pm, from airport to the Megaron directly
MONDAY 12 JUNE – 10am-6pm – every 1 hour from Megaron to the airport and from the Megaron back to the airport
TUESDAY 13 JUNE – 10am-6pm – every 1 hour from Megaron to the airport and from the Megaron back to the airport
WEDNESDAY 14 JUNE – 10am-6pm – every 1 hour from Megaron to the airport and from the Megaron back to the airport
THURSDAY 15 JUNE – 8am-15pm – every 1/2 hour from Megaron to the airport directly

EuroMedLab Athens 2017: Opening Ceremony
Sunday June 11 at the Herodes Atticus Theatre
20.15 - 20.30 Arrival of Delegates
20.30 - 21.00 Welcome addresses - Announcement of Awards
21.00 - 21.30 Opening Lecture David Epstein:
“The Original Olympic spirit: the evolution of athletes and the tiny margins between good and great”
21.30 - 21.40 Intermission
21.40 - 22.00 Cultural Event “Facades” by Andonis Foniadakis
A ballet specially created for EuroMedLab Athens 2017
22.00 Welcome Party

In order to assist to the opening ceremony people must be registered to the Congress and show at the entrance a valid EuroMedLab badge or the printout of the invitation received by e-mail from the Congress Secretariat.

VENUE OF THE EVENT: GAZARTE, 32-34 VOUTADON STR.- GAZI, KERAMEIKOS STATION.

... and mark in your agenda also the other events addressed to Young Scientists:

“MEET THE EXPERTS” SESSIONS: six interactive sessions (on Monday, Tuesday and Wednesday) have been organized by the Scientific Congress Committee in collaboration with the Young Scientists Division of IFCC covering subjects of general interest. An interesting opportunity to join a small group of interested colleagues for an intense and interactive discussions. Sessions are open to all delegates but require a free pre-registration as the seats’ availability is limited for practical reasons. For more details visit www.athens2017.org and download the scientific programme.

OPEN MEETING & QUIZ OF THE IFCC TASK FORCE FOR YOUNG SCIENTISTS:
Tuesday June 13 from h. 9.00 to 12.30 at the Hilton Hotel (Meeting room: Santorini 4-5-6) - Young Scientists like surprises - Prizes for Quiz winners;
ALL DELEGATES ARE INVITED! To confirm the presence please contact: guilaineboursier@yahoo.fr

IN ORDER TO ASSIST TO THE OPENING CEREMONY PEOPLE MUST BE REGISTERED TO THE CONGRESS AND SHOW AT THE ENTRANCE A VALID EUROMEDLAB BADGE OR THE PRINTOUT OF THE INVITATION RECEIVED BY E-MAIL FROM THE CONGRESS SECRETARIAT.
Welcome to the 13th EFLM Symposium for Balkan Region
by Nada Majkić-Singh, President of the Symposium

The Society of Medical Biochemists of Serbia has the pleasure to organize the 13th EFLM Symposium for Balkan Region under the title “Laboratory Medicine Management: Leadership Skills for Effective Laboratory”. European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) appointed Belgrade (Serbia) and the Society of Medical Biochemists of Serbia as the organizer of educational symposia for chemists in the Balkan region and as a result of these decisions, twelve symposia have been organized thus far very successfully. The 13th EFLM Symposium for Balkan Region is organized under the auspices of the International Federation of Clinical Chemistry (IFCC), Ministry of Education, Science and Technological Development of Serbia and Ministry of Health of Serbia.

The Society of Medical Biochemists of Serbia as a member of the IFCC and EFLM greatly appreciates the role it has in the continuous development of our discipline according to the IFCC and EFLM mission and the Strategic Plan. The 13th EFLM Symposium for Balkan Region is organized on September 21st and 22nd, with participation of the European and domestic specialists in field of: Type of Medical Laboratory and Strategy, Laboratory Medicine Planning and Organization, Medical Laboratory Accreditation and Competence and Laboratory Medicine Environmental Health and Safety. These topics will be presented by European lecturers (Paul Collinson, Ivan Branslund, Mario Plebani, Per E. Jørgensen, Sverre Sandberg, Bernard Gouget, Matthias Nauck, Herbert Stekel, Tomas Zima and Ciprian-Valentin Mihali) and from Serbia (Nada Majkić-Singh, Vera Lukić, Snežana Jovičić, Nataša Bogavac-Stanojević, Svetlana Ignjatović, Zorica Sumarac, Jelena Kotur-Stevuljić and Verica Milatović).

Update of the EFLM publication list
by MariaStella Graziani, Chair of the EFLM Communications Committee

Improving quality in the preanalytical phase through innovation, on behalf of the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for Preanalytical Phase (WG-PRE)


Despite the many advances made for achieving a high degree of quality and safety in the analytical part of diagnostic testing, many hurdles in the total testing process remain, especially in the preanalytical phase ranging from test ordering to obtaining and managing the biological specimens. In keeping with these issues, the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) has established a specific Working Group for the Preanalytical Phase (WG-PRE), the aims of which are mainly aimed at mitigating the vulnerability of many preanalytical activities, releasing official documents, guidelines and recommendations, as well as providing continuous education for laboratory professionals and other healthcare operators. This collective article follows the previous three opinion papers that were published by the EFLM WGPRE on the same topic, and therefore provides continuous education for laboratory professionals and other healthcare operators.

The full list of the EFLM publications is available on www.eflm.eu under EFLM Publications, where you can download the full papers.

Change of the Guard in EFLM National Societies

Netherlands Society for Clinical Chemistry and Laboratory Medicine
Dr. M.G.L.M. (Marc) Elisen (MC Groep MC Zuiderzee, KLC, Lelystad) is the new President of the Netherlands Society for Clinical Chemistry and Laboratory Medicine replacing Dr. Claudia Pronk-Admiraal. A warm welcome to Dr. Elisen and a thanks to Dr. Pronk-Admiraal for her collaboration and support to EFLM activities during these past years.

Swedish Society for Clinical Chemistry
Prof. Lars Breimer (Laboratory Medicine, USÖ, Örebro) is the new President of the Swedish Society for Clinical Chemistry replacing Dr. Maria Berggren Söderlund. A warm welcome to Prof. Breimer and a thanks to Dr. Berggren Söderlund for her collaboration and support during her presidency.

The Association for Clinical Biochemistry & Laboratory Medicine
Prof. Ian Young (School of Medicine, Dentistry and Biomedical Sciences, Centre for Public Health, Institute for Global Food Security, Queen’s University, Belfast) is the new President of the Association for Clinical Biochemistry & Laboratory Medicine replacing Dr. Gwyn McCreanor. Prof. Young will also act as EFLM National Representative. A warm welcome to Prof. Young and a big thanks to Dr. Gwyn McCreanor for her collaboration and always prompt support to EFLM activities as National Representative and ACB President during these past years.
News about EFLM National Societies

MERGE OF LABORATORY MEDICINE’S NATIONAL SOCIETIES IN UKRAINE

The EFLM Full Member “Ukrainian Society of Clinical Laboratory Diagnostics (USCLD)” merged with the EFLM Affiliate Member “Association of Clinical Chemistry & Laboratory Medicine of Ukraine (ACCLMU)” which now will represent the Full Member for Ukraine. Congratulations to the National Societies Presidents of USCLD and ACCLMU on this important step.

NEWS FROM EFLM NATIONAL SOCIETIES

From SFBC - French Society of Clinical Biology

What’s going on about accreditation of the French Medical Labs?

by Bernard Gouget, Counselor for Public Health FHF, President-Human Healthcare Committee-COFRAC, Chair-IFCC-Nominations Committee, General Secretary of the International Francophone Federation of Clinical Biology and Laboratory Medicine (FIFBCMIL), Member-SFBC-International Relations Committee

In France, the medical biology tests are carried out in a medical laboratory located on one or more sites situated either in the same Health territory or in three connecting health territories. The “Health territory” is defined as the relevant area for management of care aiming to propose a more incremental managerial strategies. The Hospitals participating in the territorial grouping organize jointly the activities of diagnostic and medical biology. The medical biologists have to contribute to the shared medical project to define their territorial strategy. The hospital participating in the group may constitute an inter-establishment medical biology pole with several accreditations, or to establish a unique medical laboratory with one accreditation.

As regard to the competition between the private public sectors and the commercial labs, what we are witnessing is a powerful trend towards concentration of medical labs in the private and public sectors and the establishment of a market “cartels” rather than of a genuinely competitive market. In this context, accreditation is a differentiating factor. The accreditation of the French medical labs is mandatory since 2010 by order and by law since May 30 2013. The accreditation process is under the responsibility of the Healthcare section of the Comité français d’accréditation (COFRAC). This section is totally dedicated to human healthcare issues with two instances composed by representatives from the Ministry of Health, its permanent offices in regions, the High Authority of Health, medical biologists and pathologists, patients, prescribers, accredited medical laboratories. The section committee participates in the elaboration of the strategy for accreditation of medical laboratories as well as in preparing the documents useful to evaluate and accredit. The commission for accreditation studies evaluation reports and looks at the candidatures of technical assessors and experts

The current agenda for accreditation is formed by: 1) 50% of medical biology tests by volume with at least one test in each of the three lines (biochemistry-genetic; immunology-hematology-reproductive biology; microbiology) which have to be accredited by December 31, 2017, and 2) by 100% of tests have to be accredited by November 1, 2020. Facing these challenges and having in mind the medicalization of the profession, the COFRAC team optimized their working methods to improve its efficiency, particularly regarding assessment scheduling and reviewing rules for assessment reports.

In 2016, there were 1034 assessments performed: 29% were initial assessments and 32% were assessments with a scope extension. In April, there are 945 multisites medical labs (314 public, 631 private ) with approximately 3400 sites in total. COFRAC assessed a total of 100% of the medical labs at least once, and 81% (769) of the medical labs are complying with 50% of the tests accredited. In addition, 11 hospital medical labs are accredited for POCT according to the standard NF EN ISO 22870. as well as 15 Pathology labs with NF EN ISO 15189. The accreditation remains reliant on the availability of the technical assessors whose numbers (384) are still low to ensure under optimum conditions compliance with the agenda. The Healthcare section is continuing with its activity encouraging medical biologists to become technical assessors agreeing to carry out more assessments.

Quality and promotion of accreditation are the core concerns of the Medical Biologist community. They have shown strong commitment to the accreditation project and have generously contributed with their professional timetable and resources to do this work. This was reflected in the important overall growth of the COFRAC’s Healthcare section’ activity. To achieve the challenge of 100%, there is a strong need to have a coordinated strategy and to adopt a more proactive approach to respond to the changing of the international laboratory medicine landscape.

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Lab Tests Online Italy (labtestsonline.it)

by Giuseppe Lippi, Section of Clinical Biochemistry, University of Verona, Verona, Italy

In 2001, the American Association of Clinical Chemistry (AACC) launched a website named “Labtestsonline” (LTO), designed to help patients and the general public understand the significance of most laboratory tests. The site included also a lippidiagnostic tests. The content of the website, even if very detailed, was and is easy to read and understand. Despite people can now easily find information about their health and clinical tests on Web platforms, the content of LTO is certified by experts in laboratory medicine. Moreover, year after year, laboratory testing has become more and more complex, so that LTO may also serve as an easy and quick reference tool for medical professionals. In 2016 LTO USA recorded nearly 3 million visits and over 5 million pages visited.

In 2004, the European Association of Diagnostic Manufacturers (EDMA) started a project based on translation of the site content into the languages of many European and non-European countries. Beside Italy, since 2004 many countries have decided to join the project: Australia, Brazil, Chine, Czech Republic, France, Germany, Greece, Hungary, Korea, Poland, Portugal, Romania, Spain, United Kingdom, Turkey along with many others. The project was carried out through the National Societies of Clinical Biochemistry and, in Italy, the Italian Society of Clinical Biochemistry and Laboratory Medicine (SIBioC) was charged with this task. At the beginning, many SIBioC members contributed, on a voluntary basis, to translating and reviewing of tests. Later on, due to the growing number of tests to be translated, SIBioC and Assodagnostici (the Italian branch of EDMA) financed a grant for a young post-graduate student in charge of the translations. The articles, before publication in the website, are reviewed always and carefully reviewed by senior Clinical Biochemists. The website undergoes regular updates and now includes more than 300 tests and over 100 clinical conditions. Beside translation of tests and conditions from the AACC site, SIBioC stimulated the chairs of its active Working Groups to assemble brief reports aimed to describe current news related to the topic of the Working Group. The collection of most recent articles include the description of tumor markers, myocardial infarction, therapeutic use of Cannabis and vaccinations. SIBioC strongly believes that these reports are ideal tools to easily communicate with the general public and disseminate qualified opinions of Society along with top stories, breaking news and interesting information about Laboratory Medicine. The number of visits to the Italian LTO website during the last three years are shown in the Figure, which reflects the growing interest of the public in this project. It is the firm strategy of SIBioC to place additional efforts for continuous improvement of the contents of the website, thus offering to the public a highly reliable and certified means for obtaining qualified laboratory medicine information.

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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/](https://www.eflm.eu/site/page/a/1048/) or email eflm@eflm.eu

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**Calendar of EFLM events and events under EFLM auspices**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Location</th>
<th>Website/Link</th>
</tr>
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<tbody>
<tr>
<td>26 September 2017</td>
<td>Reliable estimates of biological variation - the way forward</td>
<td>EFLM webinar, online</td>
<td><a href="https://www.eflm.eu/site/elearning/detail/1060">https://www.eflm.eu/site/elearning/detail/1060</a></td>
</tr>
<tr>
<td>4-7 October 2017</td>
<td>Annual meeting of the European Society for Pharmacogenomics &amp; Personalised Therapy (ESPT)</td>
<td>Catania, Italy</td>
<td><a href="http://www.2017ESPtcongress.eu">www.2017ESPtcongress.eu</a></td>
</tr>
<tr>
<td>19-23 May 2019</td>
<td>EuroMedLab 2019</td>
<td>23rd IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine</td>
<td>Barcelona, Spain</td>
</tr>
<tr>
<td>26 October 2017</td>
<td>International Conference on Laboratory Medicine “Uncertainty, Quality, Safety And Accreditation in Laboratory Medicine”</td>
<td>Padova, Italy</td>
<td><a href="http://www.iccongressi.it/home_eng.htm">http://www.iccongressi.it/home_eng.htm</a></td>
</tr>
<tr>
<td>14 November 2017</td>
<td>Harmonization of preanalytical phase in Europe</td>
<td>EFLM webinar, online</td>
<td><a href="https://www.eflm.eu/site/elearning/detail/1266">https://www.eflm.eu/site/elearning/detail/1266</a></td>
</tr>
<tr>
<td>10-13 October 2018</td>
<td>5th EFLM-UEMS Joint Congress - Laboratory Medicine at the clinical interface</td>
<td>Antalya, Turkey</td>
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**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 4,500 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:

<table>
<thead>
<tr>
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<th>6 issues per year</th>
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<td>500 €</td>
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Those companies interested in this opportunity can contact the EFLM Office at silvia.cattaneo@eflm.eu

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The EFLM Newsletter n. 3/2017