



# **European Federation of Clinical Chemistry and Laboratory Medicine 2012 Annual Report**

EFLM is the regional federation of IFCC created in 2007 following the merger of FESCC and EC4 ([www.efcclm.eu](http://www.efcclm.eu)). Current membership of EFLM comprises the national societies of the following 39 member countries: Albania, Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, Macedonia, Montenegro, The Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom and Ukraine; there is also an Affiliate member from Ukraine and a Provisional member: Kosovo.

## **GENERAL ASSEMBLY**

EFLM is governed by its General Assembly formed by representatives of full member national societies. EFLM held a General Assembly (GA) at the 2<sup>nd</sup> UEMS-EFLM joint Congress in Dubrovnik in October 2012, the principle topic of which was the need for the establishment of a Common Syllabus to enable freedom of movement across EU borders for non-medical Specialists in Laboratory Medicine; this was supported by an address by Madam Bernadette Vergnaud MEP, Rapporteur for the Directive.

Following consultation with member societies and taking advantage of the now permitted electronic voting we repositioned the Federation's identity by agreeing that those engaged in our profession who meet the necessary attainments i.e. Eur.Clin.Chem. should use the description: Specialist in Laboratory Medicine wherever possible as this best reflects our role, but does not usurp national law. Following this change and further consultation the abbreviation of the federation was changed from EFCC to EFLM; these were highlighted at the GA.

The next GA will be held in conjunction with the Euromedlab 2013 meeting in Milan where the new Executive Board members and the venue of Euromedlab 2017 will be voted upon. In Milan, EFLM EB will also meet with IFCC Executive Board to discuss some issues of mutual interest.

The GA has approved the membership of Montenegro, as the new EFLM member. The consultation was done by electronic voting.

## Executive Board

EFLM operations are run by the Executive Board (EB) with the administrative support by Silvia Cattaneo, employed at the EFLM office hosted in IFCC's Office in Milan. Current officers of the EB for the two year term of 1 July 2011 – 31 December 2013 are as follows:

President	Ian Watson (United Kingdom)
Past President	Andrea Rita Horvath (Australia)
President-Elect	Mauro Panteghini (Italy)
Secretary	Ana-Maria Simundic (Croatia)
Treasurer	Peter Schuff-Werner (Germany)
Member-at-Large	Huib Storm (The Netherlands)
Member-at-Large	Tomas Zima (Czech Republic)

For more efficient operation, the EFLM EB has established monthly phone conference meetings. Those meetings were held 6 times during 2012. EFLM EB members have met face-to-face three times during 2012:

1. in Prague, 19-20 March 2012 in conjunction with the EFLM Symposium on Education, held in Prague, during 17-19 March 2012
2. in Milan 7-8 August, 2012
3. in Dubrovnik, 13-14 October 2012, in conjunction with the 2nd EFLM-UEMS European Joint Conference in Laboratory Medicine, held during 10-13 October in Dubrovnik, Croatia

The establishment of EFLM as a legal entity, endorsed by the National Societies, is nearing completion, we hope to finalise this in early 2013.

We have continued to maintain our relationship with UEMS Section of Laboratory Medicine; a fruitful meeting Prague in March on the need for a common syllabus for medical and non-medical Specialists in Laboratory Medicine which will inform levels of attainment and enable freedom of movement across EU member countries' borders.

Joint meeting of EFLM and UEMS Executives was held again in October 2012, in Dubrovnik during 2nd EFLM-UEMS Congress. As a result of this meeting, a joint EFLM-UEMS working group was formed with the aim to deliver a mutually accepted document defining the level of requirements in postgraduate training, based on the EC4 Syllabus and UEMS Blue book.

We launched a programme of EFLM officers attending Regional and National Meetings of National Societies. Through this program we hope to increase our visibility and relevance as well as to improve communication and interaction with our members. EFLM covers the travel costs of the EFLM speaker, and NS is expected to cover the cost of accommodation. During 2012 EFLM Executive Board members, representing EFLM, participated in the following meetings:

1. Peter Schuff Werner (October 2-4, Moscow, Russia)

2. Tomas Zima (May 12, Vilnius, Lithuania)
3. Ian Watson (June 12-15, Reykjavik, Iceland)
4. Simone Zerah (20 - 23 June 2012, Sinaia, Romania)
5. Ian Watson (September 18-22 , Belgrade, Serbia)
6. Ian Watson (September 27-29, Borovetz Resort, Bulgaria)

The President is now invited to one IFCC Executive Board meeting per year, he took the opportunity to raise concerns that there is a disconnect between the Regional organisations and IFCC and tabled a number of proposals, amongst which was the need to consider the lack of representation of Regions on the IFCC Executive Board and proposals to simplify subscriptions; these are to be considered by the IFCC Executive Board in 2013.

EFLM has been invited to participate in the AACC initiated Harmonization Project at a cost of \$50.000 per annum. Unfortunately, this is unaffordable. However, EFLM is prepared to participate on a project by project basis.

We initiated Young Scientist membership in all EFLM Working Groups, we were impressed and encouraged by the number and quality of applicants; following assessment by the relevant Committee Chairs appointments were offered and made.

The Executive Board reviewed the functioning of three Committees: Finance, Publicity & Public Relations and Quality Management. The EB felt there was no need for a Finance Committee and therefore financial issues henceforth will be through the Treasurer and he will be responsible to the EFLM EB. Other two Committees were renamed into Communications Committee and the Quality and Regulations Committee and new Chairs were appointed to those Committees.

We have provided support to National Societies who have required it when dealing with their national authorities and legislature.

We endeavour to collaborate with other professional European and international organisations as well as industry and regulators, through our committees and working groups.

## **Committee Reports**

### **Committee – Communications**

This committee has issued 3 issues of EFLM newsletter (January, June, September) during 2012. They are distributed electronically via Mailchimp to nearly 2000 email addresses.

The annual full committee face-to-face meeting was held on the occasion of the 2nd EFLM-UEMS Congress. In addition to the development of Newsletter, Website and promotional activities, the distribution of the Newsletter via Email list was worked upon. Issues such as enabling unsubscription, the maintenance of the list and facilitating updates from the EC4 database were addressed. Another face-to-face meeting was held in Birmingham (4<sup>th</sup>

December) where new website Content Management System was discussed as well as the Newsletter management function and expansion of the mailing list.

As a part of the mutual agreement with Clinical Chemistry journal, free annual journal subscriptions to the journal for 2012 were distributed to recipients from Cyprus, Poland, Romania, Serbia, Croatia, Bulgaria, Estonia and Greece.

Due to the current chair relocating to Australia, the appointment of a replacement is required. This will be completed in the first quarter of 2013.

### **Committee – Education and Training**

Key activities of this committee were support in organization of scientific events. Committee members have served as members of Scientific Board of 2nd EFLM-UEMS Congress in Dubrovnik. Auspices were granted to 18 events during 2012. Committee has worked together with UEMS on drafting Guidelines for organization of EFLM-UEMS joint meetings and evaluation of applications for the venue of the 3<sup>rd</sup> EFLM-UEMS congress.

Committee had two face-to-face meetings, one in Prague, organized by in March, 2012 and the other in Dubrovnik, on Oct 14, 2012. In between, Committee members have had several conference call meetings.

The WG-DL/e-learning has developed the Position paper: developing an e-learning platform for the education of stakeholders in laboratory medicine, which is now being under review by EB members. The WG will work on the survey to monitor the educational needs of the National Societies (Pierre Carayon, Damien Gruson, Henrique Reguengo).

### **Committee – Professional**

Key committee activities were the publication of the 4<sup>th</sup> edition of the European syllabus for education and training in clinical chemistry and laboratory medicine, establishment of a working group with UEMS to develop a single syllabus for education and training across Europe – the “Blue Syllabus”, and submission of proposed amendments to the 2005/26/EC Directive on recognition of professional qualifications across the EU community. Professional committee has continued lobbying with CEPLIS for passage of the Directive through the EU parliament

9 EU EFLM member states were identified as candidates for developing a ‘common training framework’ for laboratory medicine, an EU requirement upon passage of the Recognitions Directive. Furthermore, post-nominal acronym EuSpLM (European Specialist in Laboratory Medicine) was adopted as a replacement for EurClinChem

EC4 and EFLM have been fully integrated and respective reporting routes were identified. Heavy promotion of EC4 register was done in order to increase ‘Specialist in laboratory medicine’ registrants from 2679 to 3104. Auditable mechanisms were established for auto-registration of specialists in NL and UK.

## **Committee – Quality and Regulations**

C-Quality and Regulations was focused on influencing activities in the field of quality management, accreditation of medical laboratories, composing standards and guidelines related to these aspect, and contact with IVD industry (EDMA) concerning mutual interests in these matters. Committee feels that IVD regulation is an important item. The work was done by working groups. At this moment that are: WG IVD and WG Accreditation and ISO/CEN standards.

A draft IVD Directive (Regulation of the European Parliament and Commission : In vitro diagnostic medical devices) was published this year and WG IVD was focused on influencing the EU regulatory framework concerning In Vitro Diagnostics. In an earlier stage the EFLM has send in proposals concerning which items should be revised. Some of those proposals are already included in the revised draft IVD regulation, WG IVD members feel that IVD directive needs additional revision. For medical laboratories it is important to lobby in all EU countries to get improvement. To help the different societies the WG IVD has send around comments on the proposal and have indicated which person is important to contact. EFLM will send document with the same content.

Contacts were established with EDMA in order to propose a combined guidance document concerning information, and interpretation of ISO15189 in relation with validation and calibration.

As part of the key activities of the WG Accreditation and ISO/CEN standards Wim Huisman and Jean Pierre Brochet have represented the medical laboratory professionals in the meetings of the EA Health Care committee in Utrecht, Netherlands in June 2012 and in Zagreb, Croatia in December 2012. Important items were new edition of ISO 15189, POCT, pre-analytical aspects, multi located laboratories, and liaison with EFI.

WG has performed two survey during 2012, one about retention time and the other concerning the heterogeneity of assessors, their roles, their training and calibration.

The first questionnaire was sent around to EFLM NSs. 8 countries have replied, of which 2 indicated they had no specific data in their country. It was therefore decided that guidelines are needed to provide some guidance on this subject. The response to the second questionnaire was satisfactory with a response from 16 national accreditation bodies

Wim Huisman joined the EA General Assembly in May 2012 in Madrid, Spain.

Members of the WG were present during the August meeting of the ISO TC212 in Berlin. The FDIS of ISO15189 is accepted by the standard bodies and was the third edition published in November 2012. Important items now are: POCT 22870 revision and a guidance document on Measurement Uncertainty. Furthermore work is in progress concerning technical specification on prospective risk analysis and on pre-analytical requirements.

## **Committee – Science**

The science committee tries to stimulate and facilitate the work in the working groups as well as to inform them about EFLM activities as well as guidelines for their work and publication. The committee also initiates new projects after initiatives from members and from the Board. Committee has in 2012 had the following WGs:

WG- biological variation

WG- guidelines

WG- post-analytical external quality assurance

WG- cardiac markers

WG- pre-analytical phase

WG- test evaluation

TFG on Critical Results

Three new WGs have been accepted by the Board and will probably start working early in 2013. First one is WG- personalised laboratory medicine. This WG will function in cooperation with the European Society of Pharmacogenomics and Theranostics. Mario Pazzagli has been appointed to chair this WG. Another group is WG- patient focused laboratory medicine. Ian Watson has been appointed to chair this WG.

The Committee has in itself not had any physical meetings during 2012. The chair has during the year been in close contact with the chairs of the different working groups and other committees

WG-biological variation

During 2012 this WG was working on the development of biological variation Checklist (<http://www.biologicalvariation.com/Tools.html>). WG met once, in October, in Dubrovnik, where future WG activities were discussed.

WG-guidelines

The key activities of this WG were various studies and related activities in the field of guideline development and implementation. The WG has had one face-to-face meeting in Dubrovnik (12-13 October).

WG-post-analytical external quality assurance

During 2012 WG has organized two surveys in European countries: 1) A questionnaire to hospital laboratories. Tentative title of the publication "How do laboratories interpret unexpected APTT prolongation? Post-analytical external quality assurance survey in laboratories of 35 countries". 2) A questionnaire sent to medical doctors at intensive care units. Tentative title of publication: "Are standardized algorithms with clinical decision rules and D-dimer testing used in clinical practice to aid in the diagnostic work-up for suspected venous thromboembolism? A study in 7 European countries". Prof. Sandberg ended his term of office as WG chair on December 31 and a new chair will be appointed for 2013.

A TFG-Critical Results was established in 2012 with Dr. Eva Ajzner as chair. The aim of the TFG was to carry out a survey on Critical Results in Europe, and the TFG will be closed when

this is done. The WG had 13 phone meetings using Webex to discuss and plan the surveys. There has been one physical meeting in Budapest November 23-24<sup>th</sup> to plan the writing of the papers.

#### WG-cardiac markers

During 2012, this WG has focused its activities on the preparation of the next survey to be sent out Jan 2013. WG had one face-to-face meeting on Oct 14, 2012 in connection with the UEMS-EFLM Conference in Dubrovnik.

#### WG-preanalytical phase

WG-PA has performed its 1<sup>st</sup> survey on phlebotomy practices, during 2012. 30 EFLM NSs have sent their responses. Manuscript is ready and will be submitted in March 2013 for publication. WG has been involved in organization of the 2nd EFCC-BD meeting in Zagreb, March 1-2nd, 2013. WG members are Scientific committee members and have finalized the scientific program for Zagreb2013 conference. WG had one successful face-to-face meeting during 12-13 April 2012 in Zagreb, Croatia.

## **EC4 Foundation Board**

EC4 Foundation Board (FB) has had its 7<sup>th</sup> meeting during 2<sup>nd</sup> EFLM-UEMS Congress in Dubrovnik.

Role and position within EFLM was discussed by the FB delegates. On 4 Oct, 2012 there were 3104 registrants within the EC4 Register.

The need for succession planning and the relationship of EC4 to EFLM Professional Committee was agreed between the EC4 Foundation Board and the EFLM Executive Board. This is very necessary due to on-going activities to establish a common syllabus.

## **Meetings**

Joint EFLM-UEMS meeting on Postgraduate Education was held in Prague in March 2013. There were participants from 23 European countries. The focus of the conference was pre-graduate education and postgraduate training.

Joint AACC-CSKB-EFLM Point of Care Meeting in June in Prague, meeting is organised by AACC.

2<sup>nd</sup> EFLM-UEMS Congress was held during 10-13 October in Dubrovnik, Croatia. Congress was well attended. There were 392 participants, 63 Invited speakers and 26 chairs. There

were 263 poster presentations at the Congress, out of which 10 were selected to receive the awards. Award of 2250 Euros was granted from the EC4 Bursary fund to support 3 applicants' participation in the 2nd EFLM/UEMS conference in Dubrovnik. EFLM has also granted 5 travel grants to support this meeting.

The 8<sup>th</sup> EFLM Balkan symposium under the title Vitamin D Deficiency: A new challenge for laboratory medicine for the Balkan region was successfully held in Belgrade on September 18, 2012. The one day Balkan Symposium was organized in the frame of the 20<sup>th</sup> Balkan congress - 20<sup>th</sup> Meeting of the Balkan Clinical Laboratory Federation, and 18<sup>th</sup> Congress of Medical Biochemists of Serbia in September 18–22, 2012. Around 150 participants attended the Symposium.

12<sup>th</sup> EFLM Postgraduate continuous course in clinical Chemistry and Laboratory Medicine at IUC Dubrovnik, Nov 10 – 11, 2012, entitled 'New trends in classification, diagnosis and monitoring of gastrointestinal diseases'. 30 students mostly from different South East European countries attended the course. Travel and accommodation grants were available for young participants (under 35 years).

Course materials were published in a course handbook. Course handbook is available at EFLM website ([www.efcclm.eu/downloads](http://www.efcclm.eu/downloads)).

Forthcomming EFLM meetings:

The 2<sup>nd</sup> Pre-Analytical Errors conference will be held in Zagreb on March 1-3, 2013

The EuroMedLab 2013 in Milan will be held from May 19 to 23, 2013, hosted by SIBioC

The 3<sup>rd</sup> EFLM-UEMS Congress is to be held in Liverpool jointly with the ACB, October 8-10<sup>th</sup> 2014.

The EuroMedLab 2015 will be held in Paris from June 21 to 25, 2015.

For EuroMedLab 2017, three bids have been received: Athens, Barcelona & Prague.

Ian D Watson

President