

Editorial



Dear Colleagues,

I am pleased to introduce the next Newsletter of EFCC, before we have the opportunity to meet with you face-to-face at our forthcoming 4th General Assembly in Berlin. The General Assembly is the governing body of EFCC and will have the duty to elect the new Executive Board of EFCC, appoint a new member of the EC4 Foundation Board and select the venue and host National Society of the next EuroMedLab Conference in 2015.

EFCC and the EC4 Foundation Board kindly invite you to our joint General Assembly, which will give you a detailed account on recent and upcoming European activities in the profession. The 2010 Annual Report of EFCC and the detailed agenda of the meeting and the minutes of the 3rd General Assembly in Corfu can be downloaded from EFCC's website (www.efccim.eu). The General Assembly will be held on 15 May 2011 at 13:30-17:00, in Room 8 of the Internationales Congress Centrum.

It is also a great pleasure to invite you to participate in the joint IFCC WORLDLAB and EUROMEDLAB Congress 2011. Berlin is the second most populous and one of the most vibrant cities of Europe. Berlin is among the top three convention cities in the world, where research and development have established economic significance, and the Berlin Brandenburg region ranks among the top three innovative regions in the European Union.

Thus there is no doubt that Berlin, with its history and resources, provides an infrastructure which will enable all potential attendees to meet their needs and to

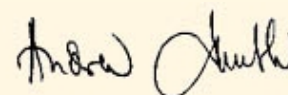
enjoy the scientific, cultural and social opportunities that this Congress offers.

As one would expect, a wide-ranging high quality scientific programme covering the cutting edge developments in laboratory medicine will be presented at this prestigious event. These include the role of prevention, theragnostics, new technologies and biomarkers in the era of "omics", the relevance of automation and IT and the education and training of our future professionals to cope with these challenges, particularly in a demanding and difficult economic environment.

This conference will be an opportunity to meet old friends and make new ones to interact with like-minded colleagues in the pursuit of common goals and interests in the ongoing development of clinical chemistry and laboratory medicine. Whether on the congress floor, or at the EFCC-IFCC booth, or sampling the attractions of Berlin, I am sure you will enjoy your attendance at a memorable meeting.

After the fall of the Berlin Wall in November 1989 the Brandenburg Gate, enhancing the approach into the Boulevard Unter den Linden, became not only a historical landmark but also the symbol of unity. So, let us unite the profession in Europe and all over the world in the exciting city of Berlin!

See you for an enriching professional conference and friendly exchanges over a famous German "Bier" or a refreshing drink Unter den Linden!



EFCC President

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Executive Board

Venue for the IFCC-EFCC EuroMedLab Congress in 2015

by Andrea Rita Horváth, Graham Beastall, Tomris Ozben, Elizabeta Topic

The venue for the IFCC-EFCC EuroMedLab Congress in 2015 will be chosen by a ballot of European National Societies at the EFCC General Assembly in Berlin to be held on Sunday May 15, from 13:30 to 17:00 in Room n. 8 at the Internationales Congress Centrum. Six National Societies have submitted their applications to host the EuroMedLab 2015:

Czech Rep. - Prague
France - Paris
Greece - Athens
Ireland - Dublin
Spain - Seville
Sweden - Stockholm

The IFCC Congresses and Conferences Committee (C-CC) and the EFCC Education and Training Committee (C-ET) have evaluated the submitted applications according to the EuroMedLab Guidelines (http://www.ifcc.org/pdf/congresses/guidelines/EuroMedLab_guidelines.pdf). We confirm that the members of both evaluation committees, who scored the bids, have no "conflict of interest" with any of the bidding societies. Results of this evaluation yielded the following rankings which serve as a guide only:

Rank Venue IFCC+EFCC scores:

1	Paris	66.75
2	Stockholm	64.62
3	Dublin	60.62
4	Seville	59.5
5	Prague	55.5
6	Athens	52

All EFCC member societies, who paid the 2010

annual membership fee before the date of the General Assembly, will have one vote to be cast by the EFCC National Representative of the society or an accredited representative notified to the EFCC office before the meeting.

Previous locations of the EuroMedLab Congresses are listed below:

Munich DE	1974
Prague CZ	1976
The Hague NL	1987
Milan IT	1989
Krakow PL	1991
Nice FR	1993
Tampere FI	1995
Basel CH	1997
Florence IT	1999
Prague CZ	2001
Barcelona ES	2003
Glasgow UK	2005
Amsterdam NL	2007
Innsbruck AT	2009
Berlin DE	2011
Milan IT	2013

We are looking forward to meeting you at the EFCC General Assembly in Berlin.

Committee and Working Group Activities

Quality Management Committee

EFCC Has Been Granted Recognised Stakeholder Status in EA

by Wim Huisman and Andrea Rita Horváth

As a result of ongoing strong collaboration between the European cooperation for Accreditation (EA)* and the European Federation of Clinical Chemistry and Laboratory Medicine (EFCC), EFCC has been admitted to Recognised Stakeholder Status in the EA on 13 December 2010.

Recognised Stakeholders of EA are organizations with significant membership from the EU and EFTA Member States, which have a distinct international role and predominantly a proactive contribution to European social and economic matters, and bear a clear interest in and commitment towards accreditation activities.

In the Recognised Stakeholder Agreement, signed by EA Chairman Graham Talbot and EFCC President Andrea Rita Horvath, both parties agreed to cooperate with the intention to further high standards in medical laboratory practice by stimulating accreditation in Europe.

Due to the Agreement representatives of EFCC will be entitled to formally participate in the work of technical committees, working groups and task forces of EA and will be informed and consulted about relevant policy and technical documents to provide inputs and comments representing the views of the medical laboratory profession.

EA and EFCC may arrange joint cultural/educational initiatives, such as conferences, seminars, workshops, training courses for the dissemination of activities related to accreditation.

EFCC delegated Wim Huisman, chairman of EFCC's Working Group on Accreditation and ISO/CEN Standards, and Simone Zerah, chair of EFCC's Profession Committee as official representatives in EA.

Both EFCC officers have been having long professional relationships with EA and their valuable contribution over the years has resulted in this international recognition.



The "European cooperation for Accreditation" is the association of nationally recognised Accreditation Bodies of the Member States of the European Union (EU) and of the European Free Trade Association (EFTA) and of countries that have been formally identified as candidates for membership of EU and EFTA. EA's mission is to provide, through its members, effective and reliable accreditation services fulfilling at best the needs of the European economy and society. Further information about EA can be found at <http://www.european-accreditation.org>.

Committee and Working Group Activities

EFCC Professional Committee

Our profession now has a European name: Specialist in Laboratory Medicine

by Simone Zérah, Janet McMurray and Andrea Rita Horváth

Why is the name so important?

In the era of 'omics' and with the advancement of technology everyday medical decisions are more and more influenced by medical laboratory data. Our profession is relatively young compared to other medical subspecialties. We come from different backgrounds (MDs, pharmacists, scientists), but whatever our background and whatever our specialties, we all work in medical laboratories.



Janet McMurray

When medical laboratories began to develop, each country used a different name for the profession. This is further complicated by the large variation of sub-specialties practised by medical laboratories in the different countries of Europe. Many of us are polyvalent, others are sub-specialised, but in principle we all practise the same profession.

Thus it is not surprising that even in our own countries people outside the profession do not understand, who specialists working in medical laboratories are, and what exactly they do. EFCC is now an established European organisation for the profession, but except for ourselves, few know whom exactly we represent.

Let us be clear: If we confuse ourselves, consider how confusing it is for people we are in contact with, such as EU politicians, administrators, civil servants! We have to convince these people of our skills and expertise and why we exist and are needed. Two of EFCC's missions are to represent laboratory medicine at European level to political, professional, scientific and other bodies, and to promote the profession in Europe [1]. Therefore, we need a common name to have a clear identity, which best describes the scope of the work we carry out for the patients.

Established medical specialties have a name that everybody understands and knows. It describes who they are and what they do: e. g. gynaecologist, cardiologist, radiologist, endocrinologist, etc. A clear and easily understood name, which reflects the level of education and training of a specialist in the medical laboratory, and

hence eligibility to be on the EC4 Register [2], is therefore needed.

History

For a profession made up of professionals from different backgrounds, we need a name that all groups and all countries will accept. In many countries names have been argued about for years and are jealously guarded. The importance of finding a name for our profession has been discussed for years at all national and European meetings:

- in Prague at the FESCC-UEMS meeting in 2004,
- in Warsaw at a European conference on education in laboratory medicine in March 2010,
- in Lisbon at the 1st EFCC-UEMS joint conference in October 2010 where it was decided that a common European name must be chosen.

How to choose the right name for the profession?

As with any name, it must be:

- a) acceptable to all, including those who specialise in different sub-specialties within the profession,
- b) short, clear and easy to remember.

Proposal for the name of our profession in Europe

EFCC officers suggested many possible names that were vigorously discussed. The three preferred names were then sent to all EFCC National Societies for consideration, with an invitation to vote for their choice.

The result of the vote and the new European name

Of the 39 European member National Societies 28 (72%) have voted. Eighteen (64%) of the votes cast were in favour of the name "Specialist in Laboratory Medicine".

We are most grateful to all who contributed to the discussion and to the National Societies for their interest and endorsement.

References

- [1] European Federation of Clinical Chemistry and Laboratory Medicine. <http://www.efcclm.eu>
- [2] Zérah S., McMurray J., Hallworth M. et al. Guide to the European Register of Specialists in Clinical Chemistry and Laboratory Medicine. Version 3-2010. Clin Chem Lab Med 2010;48(7):999-1008

Committee and Working Group Activities

EFCC Scientific Committee

From Dream to Reality – Pre-analytical Quality Improvement

by Karoline Laarmann, reprint from the *European Hospital Journal*

1-2 April 2011 – time for lab and clinical staff to be in Parma, Italy, at the 1st European Conference on Pre-analytical Phase. Organised by the European Federation of Clinical Chemistry and Laboratory Medicine (EFCC), the meeting presented a range of events to launch a platform for continuous knowledge and idea exchanges regarding pre-analytical aspects of lab medicine.



Pr. Sverre Sandberg

The spotlight is on two increasingly important topics: patient safety and the uptake of total quality management practices in clinical laboratories.

The time for a European Conference on Pre-analytical Phase is now,' says Scientific Committee Member Dr Sverre Sandberg, Head of the Laboratory of Clinical Biochemistry, Haukeland University Hospital, in Bergen, Norway and Chair of the Scientific Division in the European Federation of Clinical Chemistry and Laboratory Medicine.

'While in the past a lot of efforts were expanded to improve the quality of the analytical phase of laboratory practices, for example by the technical optimisation of test instruments, today it's increasingly realised that about 70% of errors in laboratory diagnostics happen before the samples hit the analysers at all.'

Standardisation processes played a big role at the Parma conference. Sources for errors lurk all around the lab department, from receipt up to final sample analysis. They range from wrong preparation to even a swapped specimen. Patient identification shows a big failure rate, but the actual figures can only be estimated. 'Before the era of computerisation about 2-3 % of samples were mixed up. Manual work is simply fault-prone. But still, even with barcode systems and automated technologies, specimen interchange can happen if samples are not correctly tagged. Hence the only way to prevent confusion of patient samples is to have strict workflow routines.'

Another question occupying lab experts is how to acquire proper samples. Obtaining the basic state of samples before analysis is the basic requisite for correct testing results, so the correct transport of substances plays a key role. For example, in wintry cold spells substances can inadvertently freeze during transport and thus falsify test results. Furthermore, many errors in the pre-analytical phase originate at the bedside, Prof. Sandberg emphasised: 'One of the most important things is to request the correct analytes to a certain question. If physicians are not educated right and take the wrong kind of test, they will not obtain the answers they were looking for.'

Thus, education and interdisciplinary communication are most important in order to avoid test errors. Consequently Dr Sandberg and colleagues hold regular meetings with clinical colleagues to discuss what tests to perform for which indications and how to interpret the results correctly. The latter cannot be taken for granted, he points out. Although clinicians have broad knowledge in their subject, it is not clear if they are familiar with suitable testing procedures.

In Parma, Prof. Sandberg lectured on the impact of biological variability on laboratory testing, to approach this problem. Biological variability occurs in 'between subject variation' as well as 'within subject variation'. The first means, for example, that haemoglobin has different concentrations in different patient groups, depending on factors such as gender or age. This is well known and held in reference intervals. The 'within subject variation' is a more complicated and crucial factor. It describes the variation of haemoglobin concentration in the blood of an individual patient. Some variation in constituents depends on the season, or time of day, others are more individual and due to unknown causes. This means that haemoglobin can vary between + / 5-10 % independent of the analytical imprecision. 'It means that we first have to draw the physician's attention to when would be the best point in time to perform the test, the best sample to take – for example capillary vs. venous samples – and then, after delivering test results to them, we must clarify what the variations in haemoglobin values in a patient really mean and what variations in test results can be expected from within-subject and analytical variation.'

Committee and Working Group Activities

EFCC Education and Training Committee

10th anniversary of the EFCC Postgraduate Course for Continuing Education in Clinical Chemistry and Laboratory Medicine in Dubrovnik

by Prof. Elizabeta Topic, Chair, EFCC Committee of Education and Training

In 2001, on the initiative of the Croatian Society of Medical Biochemists, an agreement was achieved with the Slovenian Association for Clinical Chemistry and Forum of European Societies of Clinical Chemistry and Laboratory Medicine (FESCC) on launching the postgraduate scientific courses of continuing education in clinical chemistry and laboratory medicine at the Interuniversity Centre Dubrovnik. The main purpose of the courses was presentation the state of the art in clinical chemistry and laboratory medicine and thus harmonization of the knowledge among laboratory and other health care professionals interested in laboratory medicine in Europe.

The selected common name of the courses was FESCC (now EFCC) Continuous Postgraduate Course in Clinical Chemistry: New Trends in Classification, Diagnosis and Treatment, each of them dedicated to a particular medical entity: Diabetes Mellitus (2001), Cardiovascular Diseases (2002), Neurological Diseases (2003), Tumor Diseases (2004), Autoimmune Diseases (2005), Metabolic Syndrome (2006), Molecular Diagnosis (2007), Kidney Diseases (2008), Thyroid diseases (2009), and Thrombophilia (2010). The EFCC courses have been granted IFCC Auspices. The organization of the courses was supported by IFCC, FESCC/EFCC, and with some help of the sponsors (Olympus, Abbott, Roche etc). A number of scholarships for each course were ensured thanks to IFCC and today to EFCC, enabling to a number of young professionals to attend the course.

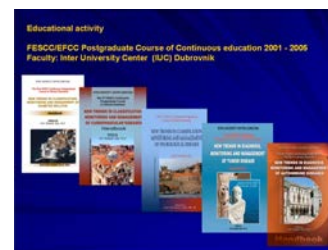
For ten years now, these weekend courses have covered particular fields in medicine, mostly conditions deserving special attention due to emerging new biomarkers resulting from epidemiological studies or diseases in which great advances have been achieved in diagnosis and/or treatment. Other criteria for selecting particular topics were new recommendations or standardization of laboratory analytes and new laboratory technologies.

Renowned experts from numerous European countries have participated in these specialized EFCC/FESCC courses covering the clinical and laboratory aspects of particular medical entities. The integrated knowledge of the lecturers and experts in different fields provided each course participant with the latest information.

The course program was usually divided into three sections. Basic concepts, risk assessment and management of the disease. The latter section was usually devoted to standardization and quality assessment of biochemical markers of medical conditions, as well as IFCC proposals for standardization, or international recommendations for diagnosis, treatment monitoring, or strategies of disease prevention. Often at the end of the last session, short introductory practical training was organized to allow the participants to master the new technology or methods.

At the end of the course each participant received a handbook containing all lectures presented. To make this worthy material available to a wider audience, the manuscripts from 2001-2008 courses have also been published in eJIFCC. From 2009 the course manuscripts can be found on the EFCC web site.

The 2010 EFCC course was organized in cooperation with European Thrombosis Research Organization (ETRO). Such cooperation with a



Committee and Working Group Activities

European clinical sister organization has greatly contributed to the quality of the Course. The Course organizers will continue such cooperations in the future.

Another progress from this Course is the publication of the manuscripts as an online supplement in the Journal CCLM.

We do hope that the EFCC Courses have met the intended goals of organizers by presenting the state-of-the-art in clinical chemistry and laboratory medicine, thus contributing to harmonization of the new trends in diagnosis, monitoring and management of different medical entities. This flagship project would not be possible without great enthusiasm of numerous world renowned lecturers and organizers and I take this opportunity to thank them all for their readiness and efforts invested.

Course lecturers

We also wish to thank all the companies which supported the delivery of these courses in the last 10 years. We look forward to meeting you at the forthcoming events in Dubrovnik!

Izet Aganovic (HR), Zrinka Alfirevic (HR), Vesna Barac-Latac (HR), Paolo Beck-Peccoz (IT), Zsuzsanna Bereczky (HU), Nikola Bešić (SI), Luigi M. Biasucci (IT), Victor Blaton (BE), Dubravka Bosnic (HR), Borut Božić (SI), Mojca Božić Mijovski (SI), Vesna Brinar (HR), Pierre Carayon (HR), Paola Carrera (IT), Darko Cerne (SI), Mirjana Cubrilo Turek (HR), Tanja Cufer (HR), Hans Deckmyn (BE), Joris R. Delanghe (BE), Vida Demarin (HR), Hassan Dihazi (DE), Tina Dušek (HR), Lea Duvnjak (HR), Maurizio Ferrari (IT), Simona Gaberšček (SI), Koraljka Gall-Trošelj (HR), Maksimilijan Gorenjak (HR), Bernard Gouget (FR), Philip G. de Groot (NL), João-Tiago Guimarães (PT), Manfred Herold (AT), Sergej Hojker (SI), Sanda Jelisavac Cosic (HR), Esther Jensen (DK), Dubravka Juretic (HR), Markus Ketteler (DE), Mladen Knotek (HR), Tamás Koszegi (HU), György Kosztolányi (HR), Gábor L. Kovács (HU), Zvonko Kusic (HR), Tanja Kveder (SI), Zdravko Lackovic (HR), Hermann Lage (DE), Mitja Lainščak (SI), Christopher Lam Wai Kei (CN), Michel Langlois (BE), Roberto Lorenzet (IT), Janja Lukac Bajalo (SI), Branko Malenica (HR), Christine Mannhalter (AT), Sandra Margetic (HR), Janja Marc (SI), Maurizio Margaglione (IT), •eljko Metelko (HR), Emese Mezosi (HU), Kor Miedema (NL), Paolo Mocarelli (IT), Mathias M. Müller (AT), László Muszbek (HU), Michael Neumaier (DE), Edith Oláh (HU), Tadej Pajic (SI), Vladimir Palicka (CZ), Krešimir Pavelic (HR), Mauro Panteghini (IT), Daria Pašalic (HR), Ivana Pavlic-Renar (HR), Draško Pavlovic (HR), •eljka Peteli (HR), Mladen Petrovec (HR), Marko Pokorn (SI), Kari Pulkki (FI), Hansotto Reiber (DE), •eljko Reiner (HR), Maja Relja (HR), Harald Renz (DE), Yolanda B. de Rijke (NL), Blaž Rozman (SI), Mirjana Sabljarić-Matovinovic (HR), Jadranka Sertic (HR), Ron H.N. van Schaik (NL), Wilhelm H. Schmitt (DE), Sándor Sipka (HU), Roy Sherwood (UK), Ana Stavljenic-Rukavina (HR), Mojca Stegnar (SI), Grazyna Sypniewska (PO), László K. Sztriha (HU), Ana-Maria Šimundić (HR), Andrea Tešija Kuna (HR), Elvar Theodorsson (SE), Dorota Tomalik-Scharte (DE), Elizabeta Topic (HR), Alenka Trampuš Bakija (SI), Milica Trbojevic (HR), Zdenka Turk (HR), Sabine Urbanits (AT), Ines Vukasovic (HR), Allan S. Wiik (DK), David L. Williams (UK), Alfred Winfried (DE), István Wittmann (HU), Renata Zadro (HR), Oren Zinder (IL), Tihana •anic-Grubišić (HR).

EFCC Events in Collaboration with Partner Organizations

2nd IFCC-EFCC-SFBC Ortho Clinical Diagnostics (OCD) Conference

by Jean-Claude Forest, Chair, Scientific Program

The 2nd IFCC Ortho Clinical Diagnostics Conference entitled "Disease and the Clinical Laboratory - Pregnancy Related Disorders: Present Perspective and Emerging Challenges" was held in Paris, 25-26 February 2011. Over 120 people from 28 countries participated in the conference. Thirteen speakers presented the most recent developments on subjects such as prenatal screening for chromosomal aneuploidies, neonatal screening for metabolic diseases, new tools to detect early in pregnancy women at risk of developing preeclampsia, prediction of preterm birth, recent advances in the investigation of the infertile obese women, screening for gestational diabetes, and measurement of foetal nucleic acids in maternal blood and proteomics as new means to predict adverse pregnancy outcomes.

The proceedings of the conference will be published in CCLM before the end of the year. Meanwhile the speakers' presentations are available on the IFCC website in the section "Congresses & Conferences". The President of the IFCC, Graham Beastall, has warmly congratulated the organizing committee: Jocelyn Hicks, Jean-Claude Forest, Ian Young, Philippe Gillery and Bernard Gouget and the speakers for this very successful meeting.



From left to right: Graham BEASTALL, IFCC pdt, Bernard Gouget, SFBC-EFCC representative, IFCC EB member, Jocelyn Hicks, Past Pdt IFCC, Ann Gronowski, AACC Pdt, René Frydman, CHU Antoine Beclère AP-HP, Jean Claude Forest, Chair of the Scientific Committee



The Speakers' presentations of the 2nd IFCC/OCD Conference on "Pregnancy Related Disorders" are now available in the IFCC website under the section "Congresses & Conferences"

EFCC Events in Collaboration with Partner Organizations

From Systems Biology and Functional Genomics to Personalized Health

by Gérard Siest

The 5th Biologie Prospective Santorini Conference, Island of Santorini, Greece, 30th September - 2nd October 2010, organized by Biologie Prospective (Prof. Gérard Siest) and the University Cardiovascular Genetics Team, EA 4373 (Dr. Sophie Visvikis-Siest), brought together 170 participants from the academic and industrial world of 30 different countries.

For the first time, it was organised jointly with the AACC (American Association of Clinical Chemistry) and the CSLM (Chinese Society of Laboratory Medicine).

Three major topics were developed over three days: systems biology, nutrigenomics and pharmacogenomics, illuminated particularly by genome-wide association studies.

The conference started with a satellite meeting specifically on genome-wide association studies (GWAS). The successive speakers — John P.A. Ioannidis (Stanford University, USA), Philippe Froguel (UMR 8199, CNRS and Institut Pasteur, Lille, France; Genomic Medicine, Imperial College London, United Kingdom), Sophie Visvikis-Siest (EA 4373 Cardiovascular Genetics, Henri Poincaré University, Nancy, France) and Eleftheria Zeggini (Wellcome Trust Sanger Institute, Cambridge, United Kingdom) — showed how this approach is developing with the aim of identifying novel variants of chronic diseases. Applications in type 2 diabetes, cardiovascular diseases and pancreatic or neuropsychiatric conditions have all revealed potential new markers with openings towards gene-gene and gene-environment interactions. Limitations were also openly discussed, in particular differences between populations, as well as the importance of demonstrating the effects of structural variants.

Allen Roses (Deane Drug Discovery Institute, Durham, USA) also presented a new aspect for predicting Alzheimer's disease by sequencing a specific region involving the Apo E and TOMM 40 (a mitochondrial transporter) genes. The risk can be estimated better from studying their linkage.

In addition to all these papers there were presentations by manufacturers (Genomatix, Illumina, Bruker and Affymetrix) who, through the quality of their devices, have greatly contributed to the development of this discipline.



Santorini Group

The conference then went further into the subject with a very stimulating presentation by Andreas Papassotiropoulos (University of Basel, Switzerland) on the links between genetics and memory in Man. Using genetic markers, such relationships can be demonstrated for emotional memory and certain medicinal compounds can be tested. Often, however, cellular models simpler than the human must be used to be able to progress more rapidly.

Knowledge of epigenetics can also be integrated into a systems biology strategy and while these data allow the evolution of Man to be understood, they can also be useful for defining the metabolic pathways better that are involved in multifactorial diseases. The proteins found in these pathways are no longer simple markers but are directly involved through being multi-protein complexes, the allosteric and cooperative properties of which must be integrated.

In this systems biology approach, the effect of the environment, in particular of biological rhythms, is useful information for adapting treatments and doses, for example, of anticancer drugs. Here again, cellular modelling provides a great deal of information.

EFCC Events in Collaboration with Partner Organizations

Inflammation is often at the heart of any chronic condition. After a short session on infectious diseases such as AIDS and tuberculosis, with propositions for new markers, the papers following highlighted the major similarities between rheumatoid and atherosclerotic conditions, often through the involvement of NF-kappaB transcription factors. Lipid activators or mediators are also implicated in the regulation and control of these inflammatory processes. Micro-RNAs and heat shock proteins have been suggested as potential biomarkers, but discoveries in this area could be derived from new screening strategies using novel methods based on antibodies produced against the atherosclerotic plaque proteins subsequently identified in the plasma by mass spectrometry.

The second day was dominated by nutrigenomics which aims at better understanding of the individual responses that we each have on ingesting proteins, carbohydrates and lipids. Owing to very sophisticated mass spectrometry methods and other physicochemical techniques, trials on healthy volunteers subjected to different diets have shown variations in the metabolites in the plasma, particularly the amino acids. Due to these results the capacity for adaptation over time can be tested, and its variation in each individual.

More specific papers showed the effects of variations in unsaturated fatty acids or zinc on the response to glucose or cytokines measured in the plasma of obese children or diabetic or insulin-resistant patients. Circulating blood cells can sometimes form interesting substitutes for following variations in tissue which are difficult to access.

Finally, the last day was entirely dedicated to pharmacogenetics and pharmacogenomics. After an introduction recalling the history and development of this discipline by Urs A. Meyer (Biozentrum, Basel University, Switzerland), examples were discussed of the usefulness and difficulties of using genetics to predict reactions to treatment with anti-virals, statins, anticoagulants or aggregation inhibiting agents. Variable effects in populations such as the Chinese and Thais have been found for certain antidepressant drugs.

In a morning devoted to fundamental progress, the influence of transcription factors and regulator regions on small RNAs established a new basis for our understanding of drug interactions. As well as oxidative enzymes and P450 cytochromes, the function of transporters is now seen as being more and more important: they are also involved in interactions between drugs and natural substances. Finally, the variation in all of these enzymes should not be forgotten in the diseases of organs containing them, particularly the liver.

Pharmacogenetics is not limited to drug metabolism but also concerns the pharmacological targets, particularly G proteins which are an integral part of many surface receptors and neurotransmitters. They influence the response to antidepressant treatment, vasoconstrictor and lipolytic effects via many specific mechanisms.

Finally, in a more practical session and round table led by Bryan Dechairo (Medco Health Solutions Inc, Bethesda, USA) and Alain Huriez (Europe Personalized Medicine Diagnostics – EPEMED – and TcLand Expression, Nantes, France), the very slow introduction of genetic and genomic markers in personalized therapy was discussed following specific presentations on the pharmacogenomics of cardiovascular, immunosuppressant, antidepressant and anticancer drugs.

A more detailed account of the conference and the round table will also be published in Personalized Medicine and Pharmacogenomics.

EFCC Events in Collaboration with Partner Organizations

EFCC/Bio-Rad Symposium in Portugal Opens the Gates to Challenges of Quality Management and Accreditation

by Claude Giroud, Biorad and Bernard Gouget, EFCC-Professional and Public Committee

After the success of its first edition, in 2009, in Paris, Bio-Rad



Laboratories organized the Second Symposium on Quality Management in Laboratory Medicine in Lisbon, Portugal, along with the Laboratory Medicine in Healthcare – First European Joint Congress of EFCC and UEMS, on Saturday, October 16th, 2010.



Biorad Symposium Speakers

This Symposium, organized in duplex with Prague (Czech Republic) is under the auspices of EFCC and IFCC. The aim of this Symposium was to focus on various aspects of quality management, willing to increase awareness, development and implementation of them in laboratory medicine in Europe. The program included an update on the accreditation according to ISO 15189, by Wim Huisman, and of the auditing practices by Jean-Claude Libeer, as well as a presentation of the multilateral recognition by Leopold Cortez. Overviews of local quality recognitions were done by Jorge Nunes Oliveira for Portugal, and Tomas Zima - in duplex from Prague –for Czech Republic.

Technical subjects were developed by Guisepppe Lippi (pre-analytics), Graham White (Measurement Uncertainty) and Michel Vaubourdolle (accreditation technical requirements). A broad audience of more than 200 medical laboratory and healthcare professionals attended the symposium.

Accreditation according ISO 15189

According Dr. W. Huisman, chair WG on Accreditation EFCC ISO 15189 "Medical laboratories – Particular requirements for quality and competence", recognized by the European cooperation for Accreditation, is the standard, most fit for medical laboratories. It is replacing gradually ISO 17025 in most countries. Accreditation is wide spread in the Nordic countries, UK and The Netherlands. It is increasing in the other countries but still in a minority of the laboratories.



*Wim Huisman and
Fernando Pessoa
(Portuguese poet)*

In France accreditation has become mandatory. The way accreditation is performed is different between the countries. The difference in time spent in preparation and actual visits is one of the items discussed in the EA Health Care Committee. Other items are competence and composition of the assessment teams, and the way non-consistencies should be categorized and handled. More fundamental aspects



are the discussion about flexible scope: consultation as an integral part of the service, inclusion of majority of the tests. It is important that the medical laboratory professionals play an important role in the discussion about these aspects. The WG on Accreditation of the EFCC is representing these professionals aspects, but unfortunately it is the only one in this EA Committee.

EFCC Events in Collaboration with Partner Organizations

The various schemes for quality recognition in PT

Jorge Nunes Oliveira – President of the APAC reminded that in March 1987 the first national legislation for private laboratories established that labs were committed to follow the quality control programs that are defined by the Ministry of Health in collaboration with the Pharmacists' or Medical Orders, which was given the responsibility to recognize technical scientific capacity and compliance with the deontological code. In 1999 and in 2004 the current legislation was published and it defined the rules of quality and safety to which all public and social sector laboratories must obey. It approved the Best Practices Manual that must integrate the processes of laboratorial quality control.

In February 2009 the "Department for Quality in Health" of the Ministry of Health is given the competences to create and implement an independent and voluntary National Program, to accredit all the entities that rendered health care services. In December 2003 the Health Regulation Entity (HRS) was created with the goal of implementing a rating system for labs similar to the one used by hotels, possibly based on "stars, points or letters". The continuity of this process is still unknown. Since 1992 a voluntary participation, the National Program of External Evaluation of Laboratory Quality, is organized by INSA.

The PNAEQ currently on its minimal services, so there's a lot to be done in order to achieve its goals and the expectations and needs of laboratories. Since the year 2000, an impressive number of laboratories initiated certification, through the ISO 9001 standards. Six laboratories have been accredited, by IPAC, following some parameters of the ISO 17025 and eight labs, through the ISO 15189 in the same way.

74 laboratories have a Double Certification through the - ISO 9001 Standard + Clinical Laboratory Standard - (this Standard by the Pharmacist's Order, based on the Best Practices Manual and excerpts from the 15189 Standard), obtained after an audit by an external entity of the laboratories' choice, where it is mandatory that at least one of the auditors is a



Leopoldo CORTEZ,
IPAC Director

specialist in clinical analysis. The Portugal shares with our colleagues from other countries the same doubts and anxieties concerning accreditation standards. The principal issues that concern us are the cost of the 15189 Standard for the whole of the services provided by the laboratory; the question if it is legitimate for a laboratory to advertise itself as "Certified by the 15189 Standard Laboratory" when it isn't certified in turn for all the parameters and services that it provides; the question of whether we need a system that guarantees a metrological quality or a clinical interest quality; the importance of having more specialists that work effectively in the laboratories and that are responsible for the provided health services in order to have a more active and decisive role in the discussion of quality norms applicable to the laboratory, bearing in mind the economical reality of society and the economical capacity of the institutions that pay for the clinical analysis.



Jean-Claude Libeer,
EFCC Quality
Management Committee
Chairman

Experience of auditing

In his lecture on Experience of auditing according to ISO 15189, Jean-Claude Libeer - EFCC Quality Management Committee Chairman shared his experience on assessing medical laboratories according to the standard ISO 15189. From his experience he could set up a list of the most observed non conformities:

1. unclear organogram
2. insufficient management of the pre-analytical phase and poor description of the sample collection manual as required in item 5.4.3 of the standard
3. inconsistency in reported data
4. the set-up of an efficient system of internal QC still remains a problem
5. poor or no traceability of reference range data
6. inconsistency in accredited tests
7. poor standardisation procedures in microbiology
8. incorrect raw data verification
9. poor internal audits and management review
10. lack of knowledge of medical staff so that information reported to clinicians is not correct

EFCC Events in Collaboration with Partner Organizations

In conclusion, the same type of errors was observed in different countries. The standard ISO 15189 is a great tool for the management of the quality of medical information provided. Much attention is given to the contribution to patient care (these words are quoted 14 times into the standard). It is worth sharing this type of information between national accreditation bodies.

Quality management in CZ

According to Tomáš Zima at the beginning of the 21st century there are defined priorities in laboratory medicine such as accreditation of laboratories aiming to improve the quality of patient care. Laboratory attempts to improve quality aim to reduce diagnostic errors and decrease turnaround time with traceability of all laboratory procedures. The gold and widely accepted in lab community standard is ISO 15189 for clinical laboratories accreditation in Europe. The first meeting focusing only for system of clinical labs accreditation was in Czech Republic in 2000. There was discussion which way of implementation QMS will be effective - ISO or national standards. Accreditation based on ISO 17025 was started in pioneer labs in 2003. Now, the accreditation of clinical labs is provided by Czech Institute of Accreditation (CIA), national accreditation body, according to ISO 17025 and ISO 15189 preferably. The assessor team consists of laboratory professionals and expert of QMS. There is close cooperation between CIA and professional scientific societies. The total number of accredited labs are 79 and most of them are in biochemistry, microbiology and hematology fields. The Czech Medical Association established National Authorization Centre of Clinical Laboratories (NACCL) with the aim to educate the lab about QMS and prepare the labs for accreditation according ISO 15189. The professional societies set up national standards incorporating requirements from ISO 15189, ISO 9001 and ISQ. The NACCL provides registration of labs, consultations and issue the certificates – Audit I (key and basic requirements) and Audit II (70%-80% requirements from ISO 15189).

Audit I has 71 labs and audit II 3 labs. The CZ colleagues have a voluntary system but accreditation becomes more and more conditional for reimbursement of laboratory tests for health care insurance companies. The companies ask for accreditation or audit I or II from NACCL before signing the contract. Accreditation is not about who is the best, but who has a system of standard procedures.

Accreditation is instrumentality not the aim, which is increasing the quality with high standard of services for clients – patients, physicians.

Estimation and implementation of measurement uncertainty in Australasian Labs

Graham H. White, SA Pathology, Australia gave a detailed presentation on "Estimation and implementation of measurement uncertainty (MU) in Australasian laboratories". Repeated measurements of an analyte in the same sample generally produce different results, even when conditions are unchanged, so there is always uncertainty about the true value of a measured quantity. MU estimates the combined magnitude of all effects arising within a measuring system which deviate results from their true values.

A single measurement result is the best available estimate of the true value, and the MU provides an interval of values around the result, within which the true value is believed to lie with a stated level of confidence e.g. plasma glucose concentration = $x \pm y$ mmol/L, ~95% confidence. Therefore MU provides a quantitative statement about the quality of measurement results. The MU concept assumes significant known bias is eliminated e.g. by re-calibration, and therefore remaining error is due to imprecision. MU estimates adequate for routine laboratory purposes can be made using long term QC data because it captures the combined effects of all sources of MU (top down approach). The MU parameter (u) is 1 SD, calculated in the usual way from QC data. In practice, 2 SD (expanded MU (U)), is more useful by providing a 95% confidence interval for enclosing the true value. MU estimates apply to all types of measurement, including where a final qualitative result is based on a measurement e.g. serology.

An MU record for a measurement procedure should identify the measurand, the measurement procedure, the MU goal based on biological variation or other criteria and the MU estimate(s) using QC data. Action taken when MU fails to meet MU goals should be recorded. MU is essential for method verification, assessing if methods meet required quality for clinical applications, comparing results and decision values and defining grey zones for clinical decision limits. MU should not be reported with patients' results.

News from National Societies

6th EFCC Symposium for Balkan Region

by Professor Dr. Nada Majkic-Singh, President of the Society of Medical Biochemists of Serbia and the Scientific Committees of the Congress and Symposium

During the 17th Congress of Medical Biochemistry and Laboratory Medicine the 6th EFCC Symposium for the Balkan Region took place, organized separately under the title Implementing Laboratory Automation, Quality and Efficiency. Symposium coordinators were Professor Nada Majkic-Singh on behalf of the Society of Medical Biochemists of Serbia and Professor Victor Blaton, Former EFCC President, on behalf of the European Federation for Clinical Chemistry and Laboratory Medicine.

The Congress and Symposium were held under the auspices of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), European Federation of Clinical Chemistry and Laboratory Medicine (EFCC) and the Balkan Clinical Laboratory Federation (BCLF), as well as the Ministry of Science of the Republic of Serbia.

During the opening ceremony, Professor Victor Blaton received an honorary diploma from the Society of Medical Biochemists of Serbia, the highest recognition awarded by the society, for his contribution to the development of clinical chemistry and laboratory medicine in Serbia and the Balkan region and for promoting these disciplines in Serbia and the global professional community.

Professor David Goldberg from Canada gave the opening lecture on "Wine and Health: A Paradigm for Alcohol and Antioxidants" explaining the relative contributions of ethanol and the polyphenolic antioxidants of red wine by considering their potential to inhibit atherogenesis and the mechanisms involved. In the course of the 6th EFCC Symposium for Balkan Region prominent foreign and local experts introduced to the participants the means for achieving full automation and laboratory consolidation with the goal of adhering to the philosophy of Lean and Six Sigma laboratory efficiency.

Experts from Italy, Germany, Switzerland, Austria and Belgium revealed their experiences along with distinguished local scientists. The following lectures were presented: "Implementing Laboratory Automation, Quality and Efficiency" (Svetlana Ignjatovic and Nada Majkic-Singh), "Medical Errors: Preanalytical Issue in Patient Safety" (Mario Plebani), "Preanalytical Workstation as a Tool for Reducing Laboratory Errors" (Giorgio Da Rin), "Progressive Automation – the Solution of Choice for Improving Lab Efficiency" (Jan-Michel Valid), "Centralization, Consolidation and Automation in a Local Hospital Network" (Gerd Hafner), "Concepts for Lean Laboratory Organization" (Gabriele Halwachs-Baumann) and "Automation, Lean, Six Sigma – Synergy in Tactics to Improve Lab Efficiency" (Davide Villa), "Concepts for an In vitro Diagnostic Organization: Consulting Services to Develop Customized Economical and High Quality In Vitro Diagnostic Solutions" (Gerhard Wirl) and "Lean and Six Sigma Sample Analysis Process in a Microbiology Laboratory" (Vojislav Stoiljkovic).

The topics selected covered in a multidisciplinary fashion the field of laboratory medicine and other medical sciences. A number of experts in various areas actively took part by contributing their work, which further accentuated the multidisciplinary character of the Congress.

Like in previous years, this Congress has, therefore, made it possible for the latest scientific and expert results to be presented to clinical chemists from Serbia and the Balkan region and has served as a place for exchanging experiences in order to promote contemporary laboratory practice.

During the closing ceremony, Professor David Goldberg gave a very interesting and important lecture entitled "Science at the Crossroads: Fact or Fiction?"

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in which he examined the direction contemporary science took a while ago and offered some valuable advice.

Round table discussions on the topics presented served as the basis for reaching conclusions and guidelines in this area of laboratory medicine, with the aim of achieving the best possible treatment results for the benefit of patients. A permanent exhibition of equipment and reagents was on display during the Congress and Symposium, and many practical workshops were organized by various companies.

We also sincerely hope that Belgrade, our ancient city upon two rivers, was recognized as a kind and interesting host that the Congress participants will carry in their hearts for a long time.

All lectures are published in the national journal of the Society of Medical Biochemists of Serbia – Journal of Medical Biochemistry 2010; 29: 131-230, and 29: 231-492 (www.versita.com).



Professor Victor Blaton receiving the Honorary Diploma from Professor Nada Majkic-Singh, president of the Society of Medical Biochemists of Serbia

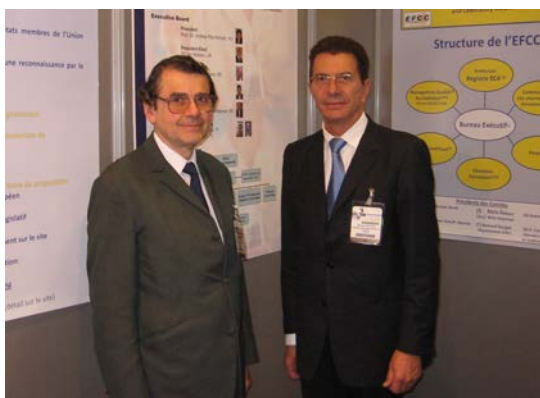


The Participants on 6th EFCC Symposium for Balkan Region, from left to right: S. Ignjatovic, V. Blaton, E. Piva, G. Da Rin, J-M Valid, N. Majkic-Singh

News from National Societies

BCLF: Impressions from Attending "Journées Internationales de Biologie", 2-5 November 2010, Paris, France

by Pr. G. Benga, President BCLF



G. Bengha and B. Gouget

The 2010 edition of the Journées Internationales de Biologie (JIB) took place in the famous CNIT (Centre National d'Innovation et Technologie), located in the beautiful "new" part of Paris, La Defense, near the Grand Arche, a modern replica of the well known Arc de Triomphe.

It was a magnificent scientific event, organized mainly by Syndicat des Biologistes et Société Française de Biologie Clinique (SFBC), in collaboration with Institut National de la Santé et de la Recherche Médicale (INSERM), Journées Biologiques de Lariboisière (JBL), Société Francophone Vitamines & Biofacteurs (SFVB), Société Française d'Etude et de Recherche sur les Éléments Toxiques et Essentiels (SFERETE), Biologie Moléculaire Initiatives (BioMi), under the auspices of IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) and EFCC (European Federation of Clinical Chemistry and Laboratory Medicine), under the High Patronage of the French Ministry of Health and Sports and the French Ministry of Ecology, Energy, Sustainable Development and Sea.

In parallel with scientific sessions and workshops a large exhibition (salon) of equipment, supplies for medical laboratories, books and journals in the field of laboratory medicine or connected areas (biology, biochemistry, cell and molecular biology, genetics,

microbiology, virology, immunology, parasitology, was organized. With about 10,000 registered participants JIB is undoubtedly one of the largest events in laboratory medicine in the world, while the exhibition was comparable with what I have seen at well known international congresses: Worldlabs (IFCC), Euromedlabs (EFCC).

JIB 2010 had a special topic: "Health & Environment: a Challenge for Biology", aimed to better appreciate the impact of environment on human health. The scientific (thematic) sessions were dedicated to: general processes of biological response and adaptation to environmental change, allergy, auto-immunity and environment, environment and cardiovascular diseases, reprotoxics, nutrition, vitamins & trace-elements.

Round-table discussions on practical issues such as the ISO-EN15189 accreditation, training of laboratory professionals, on specific issues of laboratory technicians (organized by Syndicat des Biologistes) or of young scientists (organized by IFCC and the IFCC Task Force for Young Scientists) were organized. All sessions and round-table discussions included excellent presentations by scientists not only from France, but also from Belgium, Finland, Italy, Sweden and USA. In addition, JIB included practical study sessions on virology specials and endocrine chemical disruptors, as well as innovation workshops organized by companies (genomic techniques applied to diagnostics, automation, platforms of molecular diagnostics etc.).

In this way participants were informed in various ways: in thematic sessions, about physiological and pathological consequences of alterations in environment, about prevention programs and disease control projects implemented by public authorities associated with all medical physicians. In parallel, participants were informed with various topics related to medical biology daily practice and the latest breakthroughs, which are likely to change healthcare concepts.

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In poster sessions over 100 papers were presented by authors from France, Spain, Belgium, UK, Sweden, however the majority were from French speaking African countries: Algeria, Ivory Coast, Morocco, Senegal, Tunisia. In this way JIB was a very important scientific event of Francophony. In very well planned social events JIB provided unique opportunities for scientific and friendly discussions between scientists from various countries, for meeting people with responsibilities in IFCC, EFCC, various national societies, for planning future scientific events.

Congratulations to all people involved in organization, including the kind and expert professionals of Reed Expositions France, manager of JIB. For me it was essential to see such a good example of how to organize a successful international event in the field of laboratory medicine, considering my task of organizing next year the 19th Meeting of the Balkan Clinical Laboratory Federation (BCLF) in Bucharest, Romania (21-23 September 2011).

5th Cyprus Congress of Clinical Chemistry and Laboratory Medicine

by Spyroula Christou, EurClinChem, President of the Organising Committee



The Cyprus Association of Clinical Laboratory Directors, Biomedical and Clinical Laboratory Scientists is in a position to say that the 5th Congress of Clinical Chemistry and Laboratory Medicine held under the auspices of the Cyprus Minister of Health, honourable Mr. Christos Patsalides, and the EFCC between the 18-20 of March 2011 at the Amathus Beach Hotel Limassol, ended with the best of impressions

The Scientific and Organising Committee worked hard for the past 14 months, so that our speakers and delegates would feel that it was a congress of high quality and standard covering all laboratory disciplines, hematology, clinical chemistry, molecular genetics, cytogenetics, and microbiology.

Our keynote speaker professor in hematology Mr. Ioannis Meletis gave a very interesting opening lecture "The peripheral blood film in the diagnostic approach of common and rare diseases". Distinguished scientists from Cyprus (The Institute of Neurology and Genetics, The Bone Marrow Donor Foundation, Cyprus University) Greece and other European countries were invited to speak at our congress.

Dr. Thomas Zima addressed the congress on behalf of the EFCC President Dr. Rita Horváth and gave a very interesting lecture for the new trends in laboratory diagnosis. The EC4 Registration Commission Chair Mrs. Simone Zérah and the EC4 Registration Commission Secretary were also there. They introduced to the audience the role and the implementation of the EC4 Register for Specialists in Clinical Chemistry and Laboratory Medicine. The Minister of Health and the European MP Dr. Eleni Theocharous, both addressed the congress during the opening ceremony. The so many interesting lectures combined with an absolutely lovely weather made the three day congress a great success. The President of the Association and President of the 5th Congress Mr. Charis Charilaou was very moved during his farewell

News from National Societies

speech in the closing ceremony, because the comments he received during the congress overcame his expectations. Mr. Charilaou called to the podium his associates, the President of the Scientific Committee Mr. Elias Ziras, the President of the Organising Committee Ms. Spyroula Christou and all the members of both Committees and gave his many thanks. Poster Presentation Awards were given during the closing ceremony.



The introduction of the EC4 Registration Commission Chair Mrs. Zerah with Dr. Eleni Theocharous, who is member of the European Parliament as well as member of the European Health and Environment Committee.

EDMA News

ECCA and EDMA Advance the EU Health Literacy Debate

As part of the 2011 European Cervical Cancer Week, EDMA, the European Diagnostic Manufacturers Association and the ECCA, the European Cervical Cancer Association jointly organized the "Better Health Literacy for Better Health in Europe" dinner debate in presence of Vic Blaton, EFCC past president and some EFCC representatives.



Mariam Harkin, MEP; Dr. Silvia De San José Longueras, Dr. Isabel de la Mata, DG Sanco

ECCA and EDMA made a timely contribution to the debate on health literacy at a lively dinner debate held in the Members Salon of the European Parliament on the evening of 25th January. Hosted by Irish MEP Marian Harkin, the event gathered numerous stakeholders from patient organizations, medical associations, the corporate world and the NGO community to debate how health literacy can be improved in the EU.

Mrs. Harkin opened the debate by highlighting the fact that poor health literacy in Europe is a significant barrier to both EU and national goals for improving the health of Europeans.

She also noted that poor health literacy has serious economic consequences for Europe, because it is associated with increased medical interventions that run up unnecessary costs for the European healthcare systems.

Dr. Philip Davies of the European Cervical Cancer Association focused on the fact that health literacy is associated with increased participation in disease prevention programs such as cervical cancer screening. Unfortunately, low health literacy

accompanies social deprivation so it is therefore mainly lower socioeconomic groups across Europe that fail to take advantage of these programs, and consequently bear an inequitable burden of disease.

Dr. Isabel de la Mata, Principal Public Health Advisor at DG SANCO of the European Commission, presented an overview of the efforts and the future steps the EU executive will make to foster health literacy and therefore have healthier citizens.

Dr. Jürgen Schulze, President of EDMA, noted that the IVD industry is very concerned about health literacy in Europe and very interested to make a positive contribution to the debate. Moreover, he pledged a closer collaboration between all the involved stakeholders to by-pass common prejudices and ultimately to achieve the objectives of having sustainable public finances and better empowered patients.



Jürgen Schulze, EDMA President



Mariam Klouche, LTO EU coordinator

To this end, EDMA has delivered on a long standing commitment by launching Lab Tests Online (www.labtestsonline.info): a global, multilingual, peer-reviewed, patient-centred information portal on laboratory testing organised by the American Association for Clinical Chemistry and coordinated by EDMA in Europe.

European Project

Final Europlan Conference Takes Stock of the Progress of Member State National Strategies for Rare Disease

On 25th February in Rome, Italy, the final conference of the Europlan (<http://www.europlanproject.eu/Home.aspx>) project was held. Europlan, a three-year DG Sanco-funded project coordinated by the Italian National Centre for Rare Diseases (Istituto Superiore di Sanita) launched in April 2008, as an instrument to help the European Union Member States (MS) define a strategic plan for rare diseases following the adoption of a council recommendation on an action in the field of rare diseases that calls on the MS to elaborate and adopt a rare disease plan or strategy by the end of 2013. Europlan is an inclusive project with 57 associated and collaborating partners - including clinicians, scientists, health authorities, and patient groups from 34 countries.

The Europlan project created a "toolbox" designed to aid countries determine their priority areas and actions to include in a national plan. Some 15 individual EU countries hosted national conferences via the project. These conferences, designed to move forward the process of developing a national strategy for rare diseases, followed a format based on Europlan guidance documents. The final reports of these national conferences are available on the Eurordis website (<http://www.eurordis.org/content/europlan-guidance-national-plans-and-conferences#EUROPLAN20%20National%20Conference%20Final>).

The European Dimension

At the final Europlan meeting, it was observed that one of the strongest elements of the Europlan project was its role in adding the European dimension to individual national strategies. This point is critical to the field of rare diseases, which relies on coordination and collaboration at the European and international level. The recent Eurobarometer survey results demonstrate that there is support for European cooperation (<http://www.orpha.net/actor/EuropaNews/2011/110316.html#Edito>). Catherine Berens (DG Research) adduced the E-Rare project (<http://www.e-rare.eu/>) as an effective strategy for the funding of collaborative research. A round table meeting reviewed some of the overall results of the Europlan project, such as its role in harmonising concepts and

terminology between the MS and in helping to raise awareness at the MS level for key EU documents in the field

of rare diseases and orphan drugs. During this session, the need for integrating the elements of the national rare disease plans into the national health care systems was discussed. The importance of mapping existing resources – which Orphanet, the pan-European information portal for rare diseases and orphan drugs, is doing – was also evoked. Other elements identified include the need for inclusivity – i.e. involving all the various stakeholders in the development of a national plan; the need for the national protocols for diagnostics and care of a disease to include the provisions for patient coverage for testing and care; and the healthcare pathways – the multidisciplinary algorithms of care structured to support the implementation of clinical guidelines and protocols.

At the National Level

Discussion of the status of particular countries was also raised. While Bulgaria has a concrete plan, accessing funding remains problematic, especially in the area of diagnostics. Croatia hopes to put forward a plan in 2012. Denmark is in a period of regression, illustrated by the country's information centre exclusively for rare diseases that has been extended to encompass all diseases. Greece has a plan on paper, but it is not yet legally recognized and the country has no national committee to implement it. There are also significant problems with access to orphan drugs in Greece.

Starting a process to develop a plan in a country with 21 autonomous regions is a priority Italy – but the country's organization presents a daunting challenge. Italy also reports a long time for orphan drug approvals to be processed. The Netherlands is a country with a solid general health plan, which could explain why the Minister of Health is not in favour of developing a plan specifically for rare diseases. Furthermore, the country's Steering Committee for Orphan Drugs is to be shelved at the end of 2011. In Poland, the process of elaborating a plan has not yet begun, but



European Project

awareness is increasing. Poland needs to focus on all elements of rare disease strategising – not just the orphan drugs.

Spain does have a plan, but it has neither a budget nor a time-table. The UK seems to be moving forward, thanks in large part to the steam of the Rare Disease UK and similar patient-driven efforts.

A Challenging Dynamic

With several plans existing only on paper, other countries such as Denmark and the Netherlands reporting a regression, and other MS lacking resources, the dream that each MS will have a specific strategy to care for its rare disease patients, and which includes cooperation between the EU countries to share resources, is a fragile one. This is a critical time for each stakeholder to continue acting as a catalyst to push change forward.

The recent adoption of the Cross Border Health Care Directive increases the need for concerted effort, with

each EU country identifying its pockets of expertise and making them known, within the context of acknowledging and respecting the individual dynamic of each country, particularly its size and resources. Analysis of the results of this first Europlan project can help refine the second leg of the plan, which is being funded via the upcoming DG Sanco three-year joint action, support to the implementation of national plans/strategies on rare diseases and related measures to implement Council Recommendation and Commission Communication on rare diseases.

The second Europlan will continue to offer support and guidance to countries that have delineated a strategy and will aid countries that have not developed a plan to move forward, taking into account the specifics of each country in terms of size, prioritisation of measures and health care systems. There will also be an emphasis on the exchange of expertise between countries, as well as identifying outcome indicators that can be monitored. Twenty national conferences are being planned for the second Europlan.

EFCC Forthcoming Events

IFCC WorldLab-EuroMedLab 2011 Berlin

21st International Congress of Clinical Chemistry and Laboratory Medicine
Berlin, Germany



19th IFCC-EFCC
European Congress of
Clinical Chemistry and Laboratory Medicine

IFCC Berlin - Internationales Congress Centrum May
15th-19th, 2011

For more information please visit: <http://www.berlin2011.org>

VI European Symposium: Clinical Laboratory and in Vitro Diagnostic Industry

"Clinical laboratory accreditation according to the standard ISO 15189:2007 in the European Union" Barcelona, May 5-6, 2011



For more information please visit: <http://www.acclc.cat/continguts/prog2010f.pdf>

EFCC Forthcoming Events

7th EFCC Symposium for Balkan Region Biomarkers from Standardization to Performance - June 23-25 2011 - Belgrade - Serbia

For more information please visit:
www.dmbj.org.rs



4th BBBB International Conference on Pharmaceutical Sciences

29th September - 1st October 2011, Bled - Slovenia

For more information
please visit:
www.bbbb-eufeps.org



National Meeting of the Bulgarian Society of Clinical Laboratory

Prof. Dr. Kamen Tzatchev (Medical Faculty, 1G,
Sofiisky Str., 1431 Sofia; Tel/Fax: 0 (359) 2 9230922,
E-mail: tzatchev@medfac.acad.bg) and Prof. Dr.
Liljana Lambreva, Chair of Clinical Laboratory and
Clinical Immunology have the honor to invite you to
attend the national meeting of Clinical Laboratory/
Golden Sands Resort, September 08-10, 2011

11th EFCC Continuous Postgraduate Course in Clinical Chemistry

New trends in classification diagnosis and
management of inflammation -
October 22-23, 2011 - Dubrovnik - Croatia

For more information please visit:
www.dubrovnik-course.org

Xth Czech National Congress of Clinical Biochemistry - September 20-22, 2011 - Pilsen - Czech Republic

For more information please visit:
www.sjezdcskb2011.cz



BCLF 2011

The 19th Meeting of the Balkan Clinical Laboratory
Federation will take place in Bucharest, Romania
(21-23 September 2011), see www.bclf-2011.org.

Pr. Gheorge Benga,
BCLF president
(ggbenga@gmail.com)



and his board have the pleasure to invite you to
contribute to the success of the 19th Meeting of the
Balkan Clinical Laboratory Federation (BCLF 2011)
which will be held in Bucharest in September 2011.

For more information please visit: www.bclf-2011.org

About the EFCC Newsletter

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