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1. EFCC 3rd General Assembly
Chandris Hotel, Dassia, Corfu, Greece, 17 April 17 - 2010

EFCC held its General Assembly on 17 April linked to the IFCC General Conference in Corfu. Several colleagues were unable to attend the meeting due to airport closures in many European countries as a result of the Icelandic volcanic activity. The President, AR. Horvath welcomed delegates from 22 EFCC member countries to the General Assembly. The General Assembly of EFCC normally takes place biannually, but the IFCC General Conference seemed to be an ideal opportunity to come together as there were several important issues to discuss and to vote for. The President expected this to be an interactive meeting where national society representatives would voice their opinions and feedback. Key topics on the agenda were an agreement on the Strategic Plan of EFCC and a discussion about the current status and the future of European congresses.

AR. Horvath outlined the goals of EFCC and described the work carried out during the last year (Annual Report).

This included:

- finalization of the structure, statutes and terms of reference of the new organisation
- establishing new committees and working groups
- agreeing the relationships with IFCC and setting the budget
- designing and launching the website
- discussions with UEMS and EDMA about future co-operation
- developing congresses and educational initiatives
- revising Euromedlab guidelines
- promotion of science and education within CCLM
- representation of the profession at European Commission level
- representation of professional interests of specialists in CEPLIS and promotion of the profession at EU level and registering professionals on the EC4 Register
The structure of EFCC consists of an Executive Board and six Committees: Scientific, Education and Training, Quality Management, Professional, Public and Professional Relations and Finance.

The EFCC website, www.efcclm.eu, which was launched at the Euromedlab Congress in Innsbruck, is now in full operation.

The 1st European Joint Congress of EFCC and UEMS will be held in Lisbon, on 13-16 October 2010, entitled “Laboratory Medicine in Healthcare”. Everybody is warmly invited to participate. A video conference on accreditation, sponsored by BioRad similarly to the one held in Paris a year ago, will be linked to this Congress. This conference aims to be “special” by having sessions and speakers focusing on clinically oriented topics that highlight the importance of the interface between clinical and laboratory medicine. This aim is reflected in the conference slogan: “Laboratory Medicine at the Clinical Interface”. This conference intends to be “special” in other ways too, as we wish to learn the views and opinions of congress participants as well by making the majority of the sessions interactive. To achieve this, there will be “Pros and Cons” Sessions that present opposing views on contradictory topics and which are expected to generate professional debates in relation to the use of diagnostic tests in clinical practice. Educational Sessions and Interactive Case Discussions will provide opportunities for participants to express their views by voting. Details of the conference can be found on EFCC website and also at www.lisboncongress2010.org

Reports from Committees were presented which can be downloaded from the EFCC website:

**Education and Training Committee** by Pr A-M. Simundic, deputising for E. Topic. The Committee has two Working Groups, Congresses and Postgraduate Training and Distance Education and e-learning.

**Quality Management Committee.** The Committee has one active Working Group, WG Accreditation and ISO/CEN, chaired by W. Huisman, and a new one was established by the chair, Jean-Claude Libeer on IVDs.

**Professional Committee** chaired by Simone Zerah. The Committee has one working group that represents the interest of the profession at EU level and also operates the EC4 Register.

**Public and Professional Relations Committee** chaired by M. Klouche. The Committee looks after EFCC’s Newsletter and website and is responsible for promoting EFCC’s activities.

**Scientific Committee** chaired by Pr S. Sandberg. Several new working groups have been established on Biological Variation, Post-analytical External Quality Assessment, and on Test Evaluation for the assessment of the clinical impact of new diagnostic biomarkers. The SPIDIA project group is funded by EU grants.
EFCC awards:

- The **EFCC-Roche Scientific Award for Laboratory Medicine** for 2009 was most deservedly awarded to Rob Jansen.

- A new award, the **EFCC Labs are Vital Award for Excellence in Outcomes Research in Laboratory Medicine**, sponsored by Abbott, was announced the first time. Terms and conditions [can be found on the EFCC website](http://www.efcclm.eu).

The Treasurer presented the financial situation and the budget for 2010. He concluded that the financial foundation for EFCC was small but solid. Due to the global financial crisis EFCC has decided to reduce the number of meetings and use its resources to support the work of its committees and working groups. Working groups are asked to make use of internet communications as much as possible.

AR Horvath presented the results of a European survey on priorities for the strategic objectives and goals of EFCC. The final summary of responses received from 21 European countries, EDMA and all EFCC officers can be viewed on the EFCC website.

**Election of new EC4 Foundation Board for 2010-2012.** Five candidates were elected as members of the EC4 Foundation Board: Simone Zérah (FR), Janet McMurray (UK), Rob Jansen (NL), Damien Gruson (BE), Gerard Sanders (NL). The EFCC Treasurer Peter Schuff-Werner was appointed to the EC4 Foundation Board as an advisor.

More details about the EFCC General Assembly and the Strategic and Activity Plan of the organization can be found on [www.efcclm.eu](http://www.efcclm.eu).

The next General Assembly will be held during Euromedlab 2011 in Berlin.
2. EFCC Committee and Working Group activities

2.1. EFCC Initiates Webinar Activities
By Damien Gruson, Chair, EFCC-WG on Distance Learning, Brussels, BELGIUM

To stimulate distance-learning activities, EFCC has released on March 25 its first webinar. A webinar describes a specific type of Web conference. It is typically one-way, from the speaker to the audience with limited audience interaction. This EFCC webinar was collaborative and included question & answer sessions to allow full participation between the audience and the speakers. Around 300 participants, laboratory scientists and clinicians (Urologists, Laboratory Managers both private and public, Hospital Managers, and General Practitioners) from various European countries were registered to this first event, coorganized with Beckman Coulter, with the assistance of Anthony Newman, Publisher, *Clinica Chimica Acta* (CCA), Reed Elsevier.

The webinar was dedicated to latest innovation around prostate cancer detection. Around 301,500 cases of prostate cancer were diagnosed in the 25 member countries of the EU in 2006 and screening policies for this cancer remain challenging. The session coordinated by Alexandros Haliassos, MD. PhD, EFCC-WG on distance learning, included three presentations given by Prof. Fritz Schröder, M.D., Erasmus University Medical Center, Rotterdam, The Netherlands, on the „Challenges in prostate cancer detection.“ Prof. Bert-rand Tombal, M.D., Ph.D., St-Luc University Clinics, Catholic University of Louvain, Brussels, Belgium, discussed, Prostate Health Index (phi), a Solution to significantly Reduce the Occurrence of Negative Prostate Biopsies.“ And lastly, Prof. Marianne Philippe, PhD., St-Luc University Clinics, Catholic University of Louvain, Brussels, Belgium, presented, „Clinical Laboratory, a Key Contributor for the Implementation of Novel Prostate Cancer Screening Tool“ The webinar reviewed the current challenges in prostate cancer detection and addressed how a novel multimarker strategy can help to reduce the number of negative biopsies. Serum Prostate Health Index (phi) is a multivariate index incorporating PSA, free PSA and [-2]proPSA concentrations into one single result providing the probability of cancer in men aged 50 and older with total PSA = 2 to =10.0 ng/mL and a nonsuspicious digital rectal examination. [2]proPSA is a novel serum marker strongly associated with prostate cancer and delivers added specificity to PSA. As a result, phi contributes to reduce significantly the number of negative biopsies resulting from suspicious PSA or percent free PSA results. An archive of this webinar and its content will be shortly available on the EFCC website.

2.2. 10th EFCC Continuous Postgraduate Course in Clinical Chemistry, „NEW TRENDS IN CLASSIFICATION, DIAGNOSIS AND MANAGEMENT OF THROMBOPHILIA“, 23-24 October 2010 Dubrovnik, Croatia
By Assist. Prof. Ana-Maria Simundic, Deputy Chair, EFCC -C on Education and Training Assistant Editor, Biochemia Medica, Zagreb, CROATIA

EFCC is pleased to announce the 10th Continuous Postgraduate Course: „NEW TRENDS IN CLASSIFICATION, DIAGNOSIS AND MANAGEMENT OF THROMBOPHILIA“, to be
held in Dubrovnik, Croatia on 23-24 October 2010. Course organizers are EFCC, ETRO (European Thrombosis Research Organization), Croatian Society of Medical Biochemists, Slovenian.

Association for Clinical Chemistry and Inter-University Centre Dubrovnik. The official language of the Course is English. Course proceedings will be published as review articles in the Supplemental issue of the CCLM journal, which is the official journal of the EFCC.

Travel grants are available for a limited number of young course participants (under 40 years). Travel Grants Application deadline: June 15th, 2010. Please visit the course web page for all details about the course and complete course program: [http://www.efcclm.org/](http://www.efcclm.org/) (under Events and Meetings).

Course topics are:

- Platelets: structure and function / Hans Deckmyn (Belgium);
- Hypercoagulable states: pathophysiology, classification and epidemiology / Zrinka Alfirevic (Croatia);
- Diagnostic algorithm in thrombophilia screening / Sandra Margetic (Croatia);
- Genetic basis of thrombosis / Maurizio Margaglione (Italy);
- Antithrombin deficiency / László Muszbek (Hungary);
- Deficiency of Protein C, S / Zsuzsanna Bereczky (Hungary);
- FV Leiden and FII 20210 testing in thromboembolic disorders / Tadej Pajic (Slovenia);
- Antiphospholipid antibodies / Philip G. de Groot (Netherlands);
- Hyperhomocysteine and thrombophilia / Mojca Bozic Mijovski (Slovenia);
- Thrombosis and cancer / Maria Benedetta Donati (Italy);
- Pediatric thrombosis / Alenka Trampus Bakija (Slovenia);
- Thrombophilia screening: whom, why and when to test? / Mojca Stegnar (Slovenia);
- Genetic association studies in thrombophilia research / Ana-Maria Simundic (Croatia);
- Pharmacogenetics guided anticoagulation therapy / Christine Mannhalter (Austria).

We look forward to offering you an excellent opportunity to acquire new knowledge and exchange experience in the field, as well as a truly pleasant and unforgettable stay in Dubrovnik!
3. News from EFCC National Societies

3.1. New face of Laboratory Medicine in Romania
By Dr. Camelia Grigore, Member EFCC Professional and Public Relations Committee, National Representative IFCC, Sibiu, ROMANIA

During the last years laboratory medicine in Romania has changed tremendously. Its main goal was to reduce the gap that separated it from other European countries as fast and as efficiently as possible. Since 2007, as a member of EU, Romania’s laboratory medicine has had to satisfy the European standards in the field. The strategy to achieve this goal includes projects for the harmonization in the field of training professionals, the accreditation of laboratories following ISO 15189, and scientific cooperation for the advancement of laboratory medicine science.

Romanian laboratory professionals, represented in the EFCC by the Romanian Society of Laboratory Medicine (RSLM) attended last year’s all the important European conferences and meetings in order to join European projects in laboratory.

Since 2007, Romanian professionals are represented at the European Register of Laboratory Specialists EC4 and they fulfill the professional qualifications according to the European syllabus for the medical specialists (40% of laboratory specialists). The other 60% of laboratory specialists are scientists with no clinical training, so they do not qualify for the Eur Clin Chem title.

Accreditation of laboratories has started several years ago according to ISO 17025, and continues according to ISO 15189. About 20% of all medical laboratories (from a total of about 1,500 public and private laboratories) are accredited and the process is continuing, because the National Insurance House put as a reimbursement criteria the laboratory accreditation according ISO 15189 and wants to make it mandatory. In a market-based economy, a technology-dependent health care system is driven by its budget. Applied to laboratory medicine, it has become obvious that the amount of money a lab could allocate for its equipment ultimately defined the quality of services it can provide. There are many laboratories that cannot meet accreditation criteria because of the technical level and because of shortage of budget, a common condition for most of hospital laboratories in these days.

Another important European Project attended by the Romanian laboratory specialists together with the Romanian Association of Medical devices providers, is the launch of the Romanian version of the web site “labtestonline.ro,” planned to arrive next year. It will take much volunteer work to show patients that there is a lot of science and quite a bit of work
behind each lab test; increasing the public’s knowledge in lab medicine and consequently the visibility of laboratory specialists’ in their efforts to serve the public. Each year the Romanian Society of Laboratory Medicine has its Annual Conference, which provides an opportunity for the specialists to meet and discuss specific problems with colleagues from Romania and with foreign quests. This year’s meeting will take place in Targu Jiu, on September 8-12, 2010. We warmly invite you to take part, to study the complexities of Romanian laboratory medicine, and feel the Romanian spirit revealed in Brancusi’s Endless Column (Coloana fără sfârșit).

3.2. News from the Swiss Society of Clinical Chemistry (SSCC)
By Dr. Reto Savoca, President of the Scientific Board

The list of members of the different scientific working groups as well as the description of their goals was recently updated.

- **Formation and FAMH Commission**, Dr. Jean-Luc Magnin (magninjl@hopcantfr.ch);
- **Molecular Diagnostics (web)**, Prof Dr. Beat Thöny (beat.thony@kispi.uzh.ch),
- **Medicaments**, PD Dr. Katharina Rentsch (katharina.rentsch@usz.ch),
- **Post Analytics**, Dr. Brigitte Walz (brigitte.walz@ksl.ch),
- **Internal Quality Control**, Dr. Reto Savoca (reto.savoca@kssh.ch),
- **Fähigkeitsausweis Praxislabor (FAPL)**, PD Dr. Lorenz Risch / Dr. Olivier Boulat (lorenzrisch@hotmail.com / olivier.boulat@chuv.hospvd.ch),
- **Pipette**, Prof. Dr. Andreas Huber (andreas.huber@ksa.ch),
- **Swiss Group for Inborn Errors of Metabolism (SGIEM)**, Prof. Dr Brian Fowler (brian.fowler@ukbb.ch)
- **DRG**, PD Dr. Heike (Freidank freidankh@uhbs.ch),
- **Mass Spectrometry**, Dr. Pierre-Alain Binz (pierre-alain.binz@isb-sib.ch)

The Mass Spectrometry (MS) working group is organising courses in mass spectrometry to share knowledge on the possibilities and use of the technology in Laboratory Medicine. The goals are to inform about the analyses processed in Switzerland that use Mass Spectrometry as analytical tool; a growing list of laboratories is made available on the website of the SSCC; and to keep contact and exchange experience with similar activities in other countries (see: [www.sscch.ch](http://www.sscch.ch)).

3.3. Association for Clinical Biochemistry (ACB):

The ACB officers have recently celebrated the meeting of Janet Smith's colleagues, past and present, in the old Eye Hospital in Birmingham. Indeed, this photo is believed to have been taken on the exact spot where the old laboratory was until it moved to Dudley Road in the 1980s. Janet recently retired from University Hospitals Birmingham. During her career, Janet worked tirelessly for the ACB, including being Chair of the Association, plus her huge efforts to take the Education Committee forward. Janet had a number of research interests and was particularly interested in improving the use of HbA1c in diabetic monitoring.
3.4. SFBC and the Transformation of Medical Biology in France: Benchmark for the EU?

By Dr. Bernard Gouget, SFBC-EFCC Representative; IFCC Executive Board Member
Secretary General, International Francophone Federation of Clinical Biology and Laboratory Medicine (FIFBCML)

Within the context of the HPST (hospital, patient, health, and territories) called “the Bachelot law” and under the leadership of M. Ballereau and A.M. Gallot, governmental experts, the new law (legislative order) reforming medical biology was published in the official journal of the French Republic on January 15, 2010. Medical biology tests are medical procedures in their own right: this is the central point upon which the reform of French medical biology is focused. This reform places medical biology fully at the heart of hospital professions and patient management, becoming a determining step in healthcare delivery for the diagnosis of most pathologies and treatment follow-up. This legislation modernizes the legal framework for medical laboratories (laboratoires de biologie médicale – LBM) laid down in 1975, to take into account medical and scientific innovations, which have occurred in the discipline since that time. It provides a uniform framework for the practice of the profession, and sets out to improve the quality of service through compulsory ISO 15189 accreditation for all laboratories, no later than the end of 2016.

The Order contains 11 articles and first gives a definition of medical biology testing, the conditions under which it is to be carried out, the duties incumbent on medical laboratories, and the role of medical biologist. It is a medical procedure, which contributes towards the prevention of disease, screening, diagnosis and evaluation of the risks of onset of pathological conditions, as well as part of the decision-making, therapeutic management, and the determination or followup of physiological or physiopathological conditions of the human being. In particular, the Order specifies the conditions for conducting medical biology tests outside the laboratory, and sets limits for the scope of this discipline (point-of-care testing, fast screening tests for use by clinicians and home tests for patients). The involvement of the medical biologist in the therapeutic education of patients is set out, notably for the new inspection of self-monitoring measurement devices. The reform reasserts the professional transformation of the discipline. No longer a technician, the medical biologist has a full medical role to play and is part of patient management. Together with the clinical practitioner, the medical biologist is now responsible for the entirety of the medical procedure henceforth called a medical biology examination. Medical biologist-clinical practitioner communication is reinforced: obtaining relevant clinical information, the right to “substitute” examinations having regard to rules of good practice for proper prescription. The responsibility of the medical biologist in the preanalysis phase is specified, for example, with respect to sampling procedures in public and private sectors and in different situations (laboratory, home, care institution). The converging points with pathological anatomy and cytology are specified. The medical biologist is a doctor or pharmacist holding a specialization diploma in Medical Biology. The rules authorizing the practicing of this discipline by other professionals, notably those trained in other countries are laid down. Should the professional qualification, as certified by training certificates issued by third party States and relevant professional experience indicate any substantial differences compared with required
qualifications in France, compensation measures are to be followed in the form of aptitude
tests or adaptation courses.

The Reform therefore sets out to harmonize the operating rules for clinical pathology
laboratories between the private sector and the public sector. It facilitates cooperation
between public institutions and the two sectors, notably through public health cooperation
groups. The Order further comprises measures intended to sustain the continuum of medical
biology services within one same public health territory. The Reform also sets out to achieve
the grouping of laboratories and to maintain territorial limits for medical laboratory activity.
Medical laboratories may be multisite (single laboratory in a hospital or hospital district
within the territory), but these sites must not be set up on more than three adjoining public
health territories, unless dispensation is given by the regional public health authority for
Pathology. The Reform sets up systems to guarantee a plurality of offer for medical
laboratory services within a public health territory by laying down so-called precautionary
rules. It is prohibited in particular for a person, whether legal or natural, to acquire shares
in companies operating a medical laboratory if the result of this acquisition would be to
enable such person to control a proportion, whether directly or indirectly, that is more than
“33% of the total quantity of medical laboratory examinations conducted” within one same
infra-regional public health territory. The Order also prohibits an interest in the share capital
of laboratories to be taken by legal or natural persons engaged in a health profession
authorized to prescribed pathology examinations, or engaged in the activity of supplier,
distributor or manufacturer of in vitro medical diagnosis devices, or employed by an insurance
company, or by provident, pension or social welfare bodies. The Order encourages the
professionalized inspection, i.e., with the imposed order and structure of examinations on
the basis of reference systems, published in particular by the national authority for health
(Haute Autorité de Santé – HAS) and introduces a financial penalty for any medical
laboratories conducting any examinations that are not warranted under the nomenclature
of medical biology procedures or under good practice recommendations in force.

The Order sets up a compulsory accreditation scheme for medical laboratories, the deadline
of which is November 1, 2016, with an interim date of November 1, 2013, when evidence
must be provided that they have taken steps to obtain this accreditation. This accreditation
concerns all laboratories, private and public, university and non-university, to reinforce the
quality and safety of testing. The French accreditation committee (Comité français
d’accréditation - COFRAC) is the sole body granting this accreditation based on standards
NF EN ISO 15189 and 22870. Decisions given by the COFRAC are to be transmitted to
the national authority for health (HAS), to the French health products safety agency (Agence
française de sécurité sanitaire des produits de santé - AFSSAPS), to the Biomedicine
Agency (ABM) and to the Regional Health Agency (ARS). The Order also redefines the
National Quality Control of medical biology test results, to be ensured by AFSSAPS, and
additionally an obligation of external quality evaluation is introduced for all medical biology
tests. The Order also specifies the conditions for inspections to be carried out by inspection
officers and their relations with COFRAC. Administrative, disciplinary, and criminal penalties
are determined. The Order describes the conditions under which medical laboratory
technicians must practice their profession i.e., medical biology, or cytopathological anatomy. This particular article enables laboratory technicians to enter into the category of health professionals. France is at the forefront in setting up compulsory accreditation. Taking part in a clinical research trial has become a challenge if a medical laboratory is not accredited. Accreditation contains the word “credit,” i.e., confidence. Etymologically, therefore, the purpose is to reinforce trust. Regulatory restrictions are the evincing of changes in context, and a response to our citizens’ expectations with regard to public health, and indeed the expectations of the international scientific community.

Having regard to the critical nature of this undertaking, the IFCC, EFCC, and the ILAC (International Laboratory Accreditation Cooperation) are soon to sign a memorandum of mutual understanding not only to strengthen the credibility and trust in clinical pathology in line with internationally recognized rules, but also to support the community of clinical pathologists in the face of these cultural changes.

3.5. The 18th Meeting of the Balkan Clinical Laboratory Federation is organized under the auspices of the EFCC and IFCC
By Anyla BULO, ASoLaM (Albanian Society of Clinical Biochemistry & Laboratory Medicine)
Website: www.bclf-2010.org

On behalf of the Organizing Committee and the Albanian Society of Clinical Biochemistry & Laboratory Medicine it’s a great pleasure and honour for me inviting you to participate to the 18th Meeting of the Balkan Clinical Laboratory Federation and 3rd Albanian National Conference of Clinical Biochemistry and Laboratory Medicine, which will be held on 22-25 September, 2010 in Tirana, Albania.

Fast technological changes in laboratory medicine have also brought an important change in the way of thinking for the patient’s care. The tight cooperation between laboratory medicine specialists and clinicians nowadays are empowering this multidimensional field. This important scientific Balkan event organized successfully every year, offers an excellent scientific and professional level. It brings us closer with the trends and achievements in technology and scientific research. Tirana is the ideal setting for such an important event. Tirana is a symbol of urban culture between the sea and the mountains, preserving Illyrian, Roman, Byzantine culture in an Oriental atmosphere… between European elements and those typical Mediterranean’ and Balkan’ ones. Nowadays, Tirana city and the metropolitan area nearby, is a typical and complex example of a city in constant evolution. It incorporates a mixture of structures and historical events, transforming Tirana in one of the most dynamic cities in Europe.

The 18th BCLF Meeting in Tirana will offer an exciting social programme which will enable you to understand Tirana history, tradition, culture and discover the many amusements this city offers to you. Joining together with delegates and industrial partners, meeting fellow colleagues from across Europe will strengthen our friendship and professional communication. I look forward to welcoming you to the 18th BCLF Meeting in Tirana
3.6. Sweden: Evidence based laboratory medicine  
By Anders Kallner, Karolinska University Hospital, Stockholm, SWEDEN

In the beginning of March the 12th IFCC-Roche Bergmeyer conference and expert discussion focussed on „Novel Biomarkers“. In the proceedings, published as a supplement to the Scandinavian Journal of Clinical and Laboratory Investigation, which have just become freely downloadable at http://informahealthcare.com/toc/clb/70/s242, 23 authors publish their contributions. It gives some food for thoughts regarding evidence of rational thinking in laboratory medicine and clinical diagnosis.

3.7. France (SFBC) hands the Presidency of the Francophonie over to Tunisia(STBC) during the 1st Congress of the FIFBCML in Hammamet  
By Alain Legrand, SFBC and FIFBCML Past President

The 24th National Meeting of Clinical Biology (JNBC) of the Tunisian Society for Clinical Biology (STBC) were held in Hammamet, Tunisia, from 28 April to 1 May. This year, they were particularly in the spotlight, as this event also constituted the 1st Congress of the International Francophone Federation of Clinical Biology and Laboratory Medicine (FIFBCML).

This 1st Congress of the FIFBCML made it possible to enhance the presence of the JNBC on the international stage, with over 1,100 participants and over 19 countries represented. Three years ago, in Hammamet, during the 21st national meeting of the STBC, the International Francophone Federation was instituted. On this occasion, five founding members signed the Charter of Commitment for the creation of the FIFBCML: the Algerian Association of Clinical Laboratories (ALAM), the Syndicate of Lebanese Biologists (SDBL), the Moroccan Society of Clinical Biology (SMBC), the Tunisian Society of Clinical Biology (STBC) and the French Society of Clinical Biology (SFBC). The honour of ensuring the First Presidency of the FIFBCML fell to the SFBC and to its President Alain Legrand. In 2008, the Association for Immunoanalysis and Specialised Biology (IBS-CORATA) joined our Federation. The most important original objective of the Francophone Federation is to work for the promotion of the Francophonie and the use of the French language by those working in the medical biology laboratory and in the in vitro diagnostic industry, notably during national and international congresses through the organisation of sessions in French.

In the last few years, each of the founding members has organised Francophone meetings or sessions during which the various partners met. Three Francophone Days were organised, the 1st ones in Morocco (Fés, April 2008), the 2nd ones in Algeria (Alger, May 2009) and the 3rd ones in Lebanon (Beirut, October 2009). Francophone sessions, under the aegis of the FIFBCML, were also regularly held during the International Biology Days (JIB-Paris, November 2007, 2008 and 2009), the Tunisian national meetings (Hammamet, May 2008; Sousse, May 2009) and the national Moroccan meeting (Casablanca, March 2009). Lastly, during international congresses or symposiums, the FIFBCML organised sessions held in

All of these events held in the last three years under the aegis of the FIFBCML led to closer relations among the Societies of the member states, and to a better dissemination of knowledge and scientific advances. Our means of dissemination were called upon and also contributed to their coming together. Through all of these events and actions, collaboration networks among scientific teams were formed, consolidated and/or gave rise to new networks. In this way, several opportunities for exchange among practitioners working on the same themes, in terms of both training and research, were created.

All of this has contributed to the FIFBCML now being recognised as a driving force for other international learned societies, namely the Arab Federation of Clinical Biochemistry (AFCB) and the IFCC/EFCC, with which partnerships were formed during recent Congresses.

By holding its 1st Congress during the 24th national meeting of the STBC, the FIFBCML wished to strongly assert its existence by reminding us of the origins of its creation, consolidate the international positioning it acquired during other past events and develop new partnerships by getting other French-speaking countries to join. In addition to the representatives of the founding states, participants from other countries such as Switzerland, Canada, Belgium, Madagascar, Sudan, Mauritania, Cameroon, Côte d’Ivoire and Senegal were invited to attend the meeting in Paris and asked to take part in the works of the FIFBCML. This 1st Congress of the FIFBCML was an opportunity to elect its second President, Prof A HEDILI, the president of the STBC. The representatives and officers of the Arab Federation of Clinical Biology (AFCB) and of the International Federation of Clinical Chemistry (IFCC), along with its President Graham Beastall, congratulated the entire team of the FIFBCML on its actions and work, which consolidate regional collaborations through language cultures and enhance their profile in the international Federation. We send our best wishes to the new team.
4. Lab Tests Online News

4.1. Lab Tests Online-Germany Awarded Prize
EDMA, the European Diagnostic Manufacturers Association, is proud to announce that the German version of Lab Tests Online (LTO), the noncommercial multilingual information portal on laboratory testing, has been awarded a prize as one of the best German health websites. The German LTO website, which was launched in April 2007 by the German Society for Clinical Chemistry and Laboratory Medicine (DGKL) and the German Association of the Diagnostic Industry (VDGH), has been awarded a prize and will be highlighted in the 2010 edition of the well-known German online directory “Web-Adressbuch für Deutschland.” LTO was awarded the prize in the health category, and was especially commended by the jurors for the site’s commitment to improving the quality of life of patients and sharing best practices. LTO meets a public need and provides the highest quality standard on reliable health information, and has therefore been certified with the Health on the Net (HON) code and linked on the EU-Health Portal of the European Commission. LTO offers clear and easy-to-understand information to citizens and physicians about the diverse and advantageous contributions of laboratory medicine to health protection and care. Users can thereby inform themselves about the tests they have been prescribed, the conditions usually related to the assays, and how the success of the treatment is evaluated. Initially developed by the American Association for Clinical Chemistry (AACC) in the US, LTO is a global project with websites in the UK, Australia, and China. EDMA coordinates the project of localizing LTO in continental Europe where the peer-reviewed, patient-centered, and noncommercial website is already available in English, Czech, French, German, Greek, Hungarian, Italian, Spanish and Polish. The Romanian and Portuguese versions will be available soon.

4.2. French Version of Lab Tests Online Introduced

By Prof. Jean-Pierre Bali, General Secretary SFBC and Dr. Véronique Ducros, Co-Chair Scientific Division SFBC

EDMA, the European Diagnostic Manufacturers Association is proud to announce that Lab Tests Online, the noncommercial multilingual information portal on laboratory testing, is now available in French (www.LabTestsOnline.fr). The launch of the French website took place on Friday, November 6, 2009, at the 54th JIB-International Biology Days in Paris.
Initially developed by the American Association for Clinical Chemistry (AACC) in the U.S., Lab Tests Online is a global project with websites in U.K. and Australia as well. EDMA coordinates the project of localizing Lab Tests Online in continental Europe. The peer-reviewed, patient-centered, and noncommercial website is already available in Italian, Czech, German, Spanish, Greek, Hungarian, and Polish.

The General Secretary of French Society of Clinical Biology and Laboratory Medicine (SFBC), Jean-Pierre Bali, on behalf Alain Legrand, SFBC President, thanked all of those who attended the event, in particular his counterparts from the U.S. and other European countries who had effectively implemented the website in the past, as well as his colleagues (Mariam Klouche (DE), Stephen Halloran (UK), Alexander Halliassos (GR), Véronique Ducros, Damien Gruson, and Bernard Gouget (FR) on the French Lab Tests Online Committee. He also welcomed representatives of the French High Health Authority and the State Health Insurance Office, who provided encouragement in the progress and promotion of the website.

Lab Tests Online meets both a public need, and the highest quality standards on health information. Both values also appreciated by the European Commission, which has approved the inclusion of the European Lab Tests Online websites on the EUHealth Portal http://ec.europa.eu/health-eu/index_en.htm. Lab Tests Online offers clear and easy to understand information to citizens and physicians about the diverse and advantageous contributions of laboratory medicine to health protection and care. Therefore, users can inform themselves about the tests they have been prescribed, the conditions usually related to the assays and how the success of the treatment is evaluated. To get a better understanding of the project, please visit the website Lab Test Online www.labtestsonline.info, where one can access all the national sites.
5. EFCC-Labs are Vital Award

EFCC-Labs are Vital Award for Excellence in Outcomes Research in Laboratory Medicine

By Katharina Stiefel, Abbott and Sverre Sandberg, Chair of EFCC Science Committee

EFCC and Labs are Vital™ are pleased to announce the EFCC-Labs Are Vital Award for Excellence in Outcomes Research in Laboratory Medicine, sponsored by Abbott. The Award will be given to the best published paper, as judged by an independent panel of experts, which demonstrated improved outcomes (clinical and/or economic) arising out of the application or improved utilisation of an in-vitro diagnostics test.

The award was launched at Euromedlab 2009 in Innsbruck, and will be presented for the first time at IFCC/Euromedlab 2011 in Berlin. Thereafter it will be awarded every two years at an EFCC conference. The Award will consist of a certificate and the sum of 15,000 Euros.

For criteria and submission procedure please visit: www.efcclm.eu/about_efcc/downloads/efcc-lavaward.pdf

Applications for the Award must be submitted by one of the named authors of the paper, and must be accompanied by

- Reprint of the publication or (in the case of publications in press), a manuscript copy and a copy of the editor’s letter indicating final acceptance for publication
- Short CV of the submitting author
- Statement signed by all authors of the publication consenting to submission of the paper for the Award and to the conditions of entry.

All entries must be validated studies demonstrating improved outcomes (clinical and/or economic) arising out of the application or improved utilisation of an in-vitro diagnostic test. Entries must have been published or finally accepted for publication between 1 February 2009 and 1 February 2011. Entries must be published in English in a peer-reviewed medical, scientific or health economics journal. Entries must have been produced by an individual or group working wholly or mainly within Europe (as defined by WHO – www.euro.who). The submitting author must be located in Europe. It is a condition of entry that applicants agree to the use of the data and conclusions presented in the paper for purposes of promotion of laboratory medicine by EFCC and in campaigns and materials associated with Labs Are Vital. Only conclusions specifically presented in the paper will be used in such materials, and authors will be acknowledged in and have the right of review of any materials produced.

Applications, clearly marked “EFCC-Labs Are Vital Award” should be submitted to the EFCC Office, Via Carlo Farini 81, 20159 Milano, Italy, by the closing date of 1 February 2011. Applications will be judged by a panel of judges appointed by the EFCC Scientific...
Committee and selected to include expertise in clinical medicine, evidence-based medicine, health economics and clinical laboratory science. The Award (15,000 Euro and a framed certificate) will be presented at an EFCC conference in the year of the Award. The Award will be presented to the submitting author, who is responsible for division of the award among his/her co-authors.

For further information on the submission processes please contact the Chair of the EFCC Scientific Committee, Prof. Sverre Sandberg: sverre.sandberg@isf.uib.no.
6. News from EFCC partner organizations

6.1. Collaboration between Clinical Chemistry and Laboratory Medicine and EFCC.
By Ana-Maria Šimundic, EFCC representative in the CCLM Editorial board

In February this year the Agreement on mutual cooperation between the European Federation of Clinical Chemistry and Laboratory Medicine (EFCC) and the Journal *Clinical Chemistry and Laboratory Medicine* (CCLM) has been renewed for the duration of another 4 years. As an outcome of this agreement, the members of EFCC societies are offered special discounted CCLM subscription rates. The Publisher has also granted the availability of free access to the full online version of CCLM to one representative per National Society associated with EFCC; the members of the EFCC Executive Board and all EFCC Committee chairs. The letter with detailed information has been sent out to all EFCC Member societies.

Another benefit of this agreement is that EFCC has the right to publish all Approved Recommendations, Position Papers and Official Guidelines in CCLM. The Publisher further grants EFCC the right to publish News, special editions of CCLM, abstracts of EFCC conferences and other EFCC documents in CCLM.

Moreover, as of this agreement, CCLM grants all EFCC member societies the possibility to publish the conference abstracts of their annual meetings.

Lastly, in the context of the interaction between EFCC and CCLM, one officer of EFCC (Ana-Maria Šimundic, Croatia) has been elected as a CCLM Editorial Board member.

CCLM is the official journal of seven EFCC member societies already, and other EFCC societies are invited to join this group of societies, to intensify their contacts and cooperation with CCLM.

6.2. Collaboration between AACC’s Journal, Clinical Chemistry and EFCC.
By Ana-Maria Šimundic, Deputy Chair, EFCC Committee of Education and Training

In April this year, EFCC has signed the memorandum of mutual agreement on collaboration between AACC’s Journal, *Clinical Chemistry* (CC) and the European Federation of Clinical Chemistry and Laboratory Medicine (EFCC). As furthering the education of laboratory scientists is a mission shared by both the EFCC and Clinical Chemistry; the EFCC has agreed to help disseminate several free educational features published by Clinical Chemistry (Clinical Case Studies, Clinical Chemistry Guide to Scientific Writing, Podcasts and some other). EFCC shall support this educational program through links on the EFCC website, announcements in EFCC Newsletter, distribution of promotional leaflets provided by Clinical Chemistry, and circulating the information about the program through the mailbase of European society presidents and national representatives, and the EC4 Register.

As a result of this new collaboration, *Clinical Chemistry* has kindly provided EFCC with 10 free individual subscriptions per annum for the duration of the agreement. EFCC has decided
to grant these free subscriptions to young scientists in some less advantaged regions in Europe according to officially published data on per capita GDP. National societies of 20 European countries (Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Macedonia, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Turkey, Ukraine) have received the invitation to nominate one candidate on behalf of their Society to receive this free annual subscription to Clinical Chemistry for the year of 2011. Call for applications is still open (deadline is **15 June 2010**). Applications should be sent by email to Ana-Maria Simundic (am.simundic@gmail.com), member of the Working Group for Postgraduate Education of the Education and Training Committee of EFCC.

All applications received by the deadline will be ranked by three members of the Committee and successful recipients will be notified and their names will be passed on to the editorial office of Clinical Chemistry.

Applicants will be informed by e-mail about the results of their application no later than 1 July 2010. Successful candidates, eligible for these subscriptions, will receive their login information from Clinical Chemistry directly. The first free subscription period will start from July 2010 and last until December 2011. The duration of all subsequent free subscriptions will be one calendar year.

This opportunity is offered to National Societies annually until the expiry and revision date of this mutual agreement of EFCC and Clinical Chemistry (January 1st, 2013). The next call will be announced in October 2011.
7. EFCC events in collaboration with corporate partners

7.1. Second Symposium on Quality Management in Laboratory Medicine in Lisbon, Portugal

By Claude Giroud, Bio-Rad

After the success of its first edition, last year, in Paris, Bio-Rad Laboratories is organizing 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. This Symposium, organized in duplex with Prague (Czech Republic) is under the auspices of EFCC and IFCC. The aim of this Symposium is to focus on various aspects of quality management, willing to increase awareness, development and implementation of them in laboratory medicine in Europe. The program includes 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 will be done by Jorge Nunes Oliveira for Portugal, and Tomas Zima - in duplex from Prague - for Czech Republic. Technical subjects will be developed by Mario Plebani (pre-analytics), Graham White (Measurement Uncertainty) and Michel Vaubourdolle (accreditation technical requirements).

A broad audience of medical laboratory and healthcare professionals is forecasted to attend. For more information see: www.lisboncongress2010.org/manufacturers-symposiae
8. EDMA News

EDMA Welcomes Parliament Vote on New Commission

EDMA, the European Diagnostic Manufacturers Association, welcomes this afternoon’s vote by the European Parliament on the new European Commission. The vote, which took place in Strasbourg, saw MEPs elect a Commissioner from each of the EU Member States with 488 votes in favour, 137 against, and 72 abstentions. The work of the new Commission, under President José Manuel Barroso, will begin February 10, 2010. The “Barroso II” Commission holds a number of important changes for EDMA. The new Commissioner for Health and Consumers, John Dalli, is a former Maltese Minister and MP, with a background in health and social affairs. He impressed MEPs in his January hearing before the European Parliament’s Committee on Environment, Public Health and Food Safety, and showed confidence and familiarity with the topics he will face throughout his mandate. In his hearing, he made clear that his work would focus on the idea that “prevention is better than cure.” In previous Commissions, the work of the In Vitro Diagnostic industry came under the remit of the European Commissioner for Enterprise and Industry. With the restructuring of the Commission, EDMA will be affected by the move of the Cosmetics and Medical Devices Unit from DG Enterprise and Industry to DG Health and Consumers, and thus under the portfolio of Commissioner Dalli. Christine Tarrajat, EDMA Director General, commented that EDMA looks forward to a fruitful cooperation with the Commission over the next five years, especially in light of the recent outcome of the “Exploratory Process on the Future of the Medical Devices Sector.”
9. EFCC and European projects

9.1. EFCC Supports the EU Project SPIDIA in the Standardization of the Pre-analytical Phase.
By M. Pazzagli, F. Malentacchi, L. Simi, S. Gelmini, University of Florence, ITALY

INTRODUCTION TO THE SPIDIA PROJECT

Recent discoveries have revealed that RNA, DNA or proteins, in tissue samples or released into the blood from pathological sites, like tumour cells or Alzheimer's disease (AD) brain lesions, can serve as biomarkers for early and reliable molecular diagnosis of such debilitating diseases. Further discoveries however have shown that the profiles of these molecules in clinical samples can change during transport and storage thus making clinical assay results and pharmaceutical research unreliable or even impossible. It will therefore be a decisive prerequisite for future and current diagnostic assays to develop standards and new technologies, tools and devices that eliminate the error in the pre-analytical steps. At this crucial moment in the development of molecular diagnostics, the project SPIDIA was launched as a 4-years project (2008-2012), having a total budget of 13 million Euros and funded by the European Union FP7 programme. SPIDIA (Full Title: Standardisation and improvement of generic pre-analytical tools and procedures for in-vitro diagnostic: website www.spidia.eu) is coordinated by QIAGEN GmbH and reunites 7 private research companies (including 4 SMEs), 1 private research institute and 6 public research organisms, including universities, hospitals and biobanks, one management SME and an official European Standards Organisation (CEN). The proposed research and standardisation activities of SPIDIA cover all steps from creation of evidence-based guidelines to creation of tools for the pre-analytical phase to testing and optimisation of these tools through the development of novel assays and biomarkers.

SPECIFIC AIMS OF SPIDIA FOR THE STANDARDIZATION OF THE PRE-ANALYTICAL PHASE OF BLOOD SAMPLES

One WorkPackage of the SPIDIA Project is focused both on the standardisation of existing pre-analytical procedures for blood samples and on the identification of critical steps in the pre-analytical procedure that need further development and improvement.

In order to reach these goals, it was planned an experimental model briefly described below.

Development of 3 ring trials:

1) SPIDIA-DNA- evaluation of DNA quality/quantity/integrity from a WHOLE BLOOD
sample
2) SPIDIA-DNAplas – evaluation of DNA quality/quantity/integrity from a WHOLE BLOOD sample plus the evaluation of DNA quality/quantity/integrity from a PLASMA sample
3) SPIDIA-RNA – evaluation of RNA quality/quantity/stability from a WHOLE BLOOD Sample

Collection of applications:
EFCC invites Laboratories performing Molecular Diagnostics to participate “for free” to one or more of the planned SPIDIA trials. EFCC has developed a specific area within the EFCC website to collect applications and support information about the SPIDIA Project and aims.

Execution of the SPIDIA ring trials: First step:
SPIDIA sends the (same) sample/s (whole blood, plasma) to the participants and asks them to perform the extraction procedure using their own protocol and reagents. Participants then send back the extracted DNA/RNA to SPIDIA for further analysis, plus details about reagents and protocols used for the extraction phase. At SPIDIA facilities, the extracted samples are investigated for quality/quantity/integrity and stability and then the participants receive a “report” and the “score” which includes the comparison of the performance of the single Laboratory with that of its peers.

Training activities
All the Participants will be invited to join in further SPIDIA activities which include participation to SPIDIA training courses, in order to discuss the performance of the laboratory and to revise the critical aspects that can affect the pre-analytical phase.

Execution of the SPIDIA ring trials: Second step
SPIDIA Participants are then invited to perform the ring trials for the second time taking into consideration alternative procedures/reagents that should be able to improve the “score”.

Data analysis and perspectives for standardization of the pre-analytical phase
Results of the first and second trial will be used to monitor the expected improvement of the performance of the pre-analytical phase. On the basis of the information and the data produced during the trials, SPIDIA will propose to the Scientific Community “evidence-based” guidelines for the pre-analytical phase in blood specimens. Availability of these data can serve also as a basis for officially recognized standardisation activities by CEN (European Committee for Standardization), one of the partners of the Consortium.
EFCC'S ROLE IN DISSEMINATING THE AIMS OF SPIDIA

EFCC has played an active role in the SPIDIA project by inviting Presidents and National representatives of the European community of clinical chemistry laboratories. Moreover EFCC and SPIDIA have collaborated in the development of the Web Pages for collection of Applications at the www.efcclm.org web site. At this moment of the project (by the closing date of February 5, 2010) 322 applications have been received from 219 Laboratories of 30 different European countries. A summary of the applications collected for the three ring trials is reported in Table 1 and the country distribution of the applications in Figure 1. Finally, during the application process, we have asked participating laboratories interested in the SPIDIA-RNA ring trial, to give some details about the collecting tube used for RNA expression studies in blood. The results of this survey are reported in Figure 2.

CONCLUSIONS

The aims of the EU Project SPIDIA, focusing on the standardization of the pre-analytical phase, can have relevant impact in future molecular diagnostic applications. SPIDIA is now running towards the planned objectives and the results of this project will be presented as they become available. The expected impact of the SPIDIA Project for the standardization of the pre-analytical phase of blood samples is the identification of critical steps in the pre-analytical procedure that need further development and improvement. Moreover the data collected during the two planned steps of the ring trials should support the preparation of new practice recommendations which could guide laboratories when using new reagents or devices. Finally the analysis of the entire process can be the basis of a standardization process in collaboration with the official European Standards Organisation (CEN).

The important role of EFCC in the implementation of the activities of SPIDIA and the close collaboration between the Scientific Society of EFCC and the EU granted project SPIDIA can represent a new model for planning future EFCC activities in the field of Laboratory Medicine.

Table 1. Number of applications collected at the www.efcclm.eu web site for the DNA, DNAplas and RNA trials planned within the EU SPIDIA Project.

<table>
<thead>
<tr>
<th>SPIDIA Programmes</th>
<th>TOTAL Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>DNA</td>
<td>131</td>
</tr>
<tr>
<td>DNAplas</td>
<td>67</td>
</tr>
<tr>
<td>RNA</td>
<td>24</td>
</tr>
<tr>
<td>Total applications</td>
<td>322</td>
</tr>
<tr>
<td>Total Labs</td>
<td>219</td>
</tr>
</tbody>
</table>

Figure 1. Country Distribution of European Laboratories performing the three SPIDIA programmes
Figure 2.
Distribution of SPIDIA-RNA applications (n=124) on the basis of the selected protocol relative to blood collection.
10. EFCC, EU Health agencies and Public Health
ECDC – First European Reference Laboratory Network for Tuberculosis Launched

The European Center of Disease Prevention and Control (ECDC) was established in 2005. It is an EU agency with aim to strengthen Europe’s defenses against infectious diseases. It is seated in Stockholm, Sweden. ECDC’s mission is to identify, assess, and communicate current and emerging threats to human health posed by infectious diseases. In order to achieve this mission, ECDC works in partnership with national health protection bodies across Europe to strengthen and develop continent-wide disease surveillance and early warning systems. By working with experts throughout Europe, ECDC pools Europe’s health knowledge, to develop authoritative scientific opinions about the risks posed by current and emerging infectious diseases. ECDC hosted the launch of the European Reference Laboratory Network for Tuberculosis (ERLN-TB) on January 25, 2010, at its first annual meeting in Stockholm, Sweden. Reference laboratories representatives from EU/EEA Member States and candidate countries will engage in an unprecedented initiative in the field of tuberculosis control in the EU. Recognizing laboratory function as one of the pillars of optimal tuberculosis control, the network will aim at strengthening the diagnosis of the disease at EU level, in line with the objectives of the Framework action plan to fight tuberculosis in the European Union. Under ECDC coordination, the ERLN-TB will pursue concerted action in capacity building, quality assurance, scientific advice, and support. For more information see: http://ecdc.europa.eu.