

POCT at the Crossroads of Innovation and Successful Strategies

by Dr. Bernard Gouget

SFBC-EFLM Representative; IFCC Treasure;
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of Clinical Biology and Laboratory Medicine (FIFBCLM)

Diagnostic tests performed outside the central laboratory or decentralized testing is generally known as point-of-care (POC). Biosensors and new technologies for patient-proximal diagnostic products and the new attitudes of patients and healthcare providers and systems will transform the organization and the practice of laboratory medicine for more efficient medical service and economic perspective. Over the years, its use has increased over the past decades in response to pressures for cost-containment, faster results and smaller sample volumes. The drive toward centralized laboratory operations has catalyzed the value of point-of-care testing in hospitals. Now, with testing centralized in a core laboratory, point-of-care testing becomes a more viable option for many time-sensitive tests.

POCT has the potential to enhance clinical outcome. POCT encompasses a large variety of IVD products ranging from moderate sized instrumented diagnostic systems serving larger institutional uses to single-use, disposable tests for individual home use. Near patient tests, including those for blood glucose, pregnancy, fertility, coagulation, cholesterol, drugs, cardiovascular and infectious diseases, drugs of abuse, and various urine components, are in high demand as physicians and patients realize their potential for promoting improved healthcare in different segments: hospital sector, private practice, primary care settings, and home monitoring. Existing new technology areas such as protein sequencing, DNA sequencing, and the human project have to be placed into the context of their impact on rapid diagnosis new developments and forecasts in POCT. In addition, the drive for wellness and the attention surrounding healthcare reforms will focus on rapid diagnosis and prevention. However, there



are many challenges, which must be overcome for POCT to be fully utilized.

The value of immediate results is also evident in testing for chronic diseases where rapid diagnosis can limit the spread of disease and lead to prompt initiation of therapy in the increasing numbers of diagnosed diabetics, people with cardiovascular disease and other chronic conditions, or in people with infectious diseases. For serious diseases such as the human immunodeficiency virus (HIV), the ability to rapidly detect the virus in a single doctor visit is crucial in initiating therapy as quickly as possible and ensuring that patients are aware of their test results. In many countries studies demonstrated that 25%-35% of those tested for HIV, using nonrapid methods did not return for test results!

Factors driving growth are the increasing patient and physician demands for more efficient testing approaches, availability of new biosensors technologies for more effective diagnosis and triage, and reduction of healthcare costs. Although the benefits of POCT are clear, this industry is not without challenges. Tests performed on clinical laboratory analyzers continue to be perceived as superior to POCT. Companies entering the POCT market must demonstrate that their tests have more clinical utility than those performed in laboratories.

POC testing appears to be headed for an even bigger role in diagnosis and monitoring patient care and the world market for POC tests has

shown consistent growth, a trend that is expected to continue. The worldwide Point of Care Diagnostic testing sector (POCT) is the fastest growing sector of the worldwide diagnostic industry. The global testing POC market is around USD 14 billion. It will further grow to USD 16.5 billion in 2016 for a compound annual growth rate (CAGR) of 3.7% between 2011 and 2016. The glucose-monitoring segment of the POC market reached USD 7.5 billion in 2011. The blood chemistry and electrolyte segments of the POC market reached USD 2.2 billion in 2010 and will further grow to USD 2.8 billion in 2016 for a CAGR of 4.8% between 2011 and 2016. The fastest-growing segment, cardiac markers, is projected to increase at a CAGR of 14.4 percent, rising from USD 1 billion in 2011 to USD 2 billion in 2016. The infectious disease and tumor marker segments have the next highest projected growth rates, with both expected to increase at CAGR of more than 10%.

Globally, the diagnostic business is typified by intense competition and areas with high growth. The constant pressure to reduce healthcare spending is shifting healthcare utilization in favor of the medical laboratory, making it an ever more valuable part of the treatment plan. As hospital stays are shortened, contact between the physician and patient is reduced, which places a larger role on labs to gather, interpret, and deliver accurate information in a timely manner. POCT is a challenge for our professional maturity. Implementing POCT is complex and requires a cooperative effort at many levels. The specialist in lab med has the expertise; we should embrace and manage the POCT concept. Of course, Universal connectivity of POCT devices is the key to managing quality and accreditation, according to ISO 22870, which is a part for a successful POCT implementation. But the challenge to succeed in the task of establishing POCT must be met, so that in this 21st century medical laboratory science can exist for professionals who practice it.

The 12th EFLM Continuous Postgraduate Course in Clinical Chemistry

by Prof. Dr. Sc. Elizabeta Topic, chair EFLM Committee of Education and Training

Within the frame of EFLM the Croatian Society of Medical Biochemistry and Slovenian Association of Clinical Chemistry the 12th EFLM Continuous Postgraduate Course in Clinical Chemistry New Trends in Classification, Diagnosis and Management of Gastrointestinal Diseases, will be held at the Inter University Centre in Dubrovnik (Croatia), from November 10-11, 2012.

These courses have been launched in 2001 as postgraduate scientific courses of continuing education in clinical chemistry and laboratory medicine, organized within the frame of EFLM (former EFCC) at Inter University Centre Dubrovnik for members of the EFLM societies. The common title of the courses is EFLM Continuous Postgraduate Courses in Clinical Chemistry: New Trends in Classification, Diagnosis and Management, each of them dedicated to a particular medical entity such as Diabetes Mellitus (2001), Cardiovascular Diseases (2002), Neurological Diseases (2003), Tumour Diseases (2004), Auto-immune Diseases (2005), Metabolic Syndrome (2006), Molecular Diagnosis (2007), Kidney Diseases (2008), Thyroid diseases (2009), Thrombophilia (2010), and Inflammation (2011).

This year the Course is devoted to gastrointestinal diseases (<http://www.dubrovnik-course.org>).

Many renowned speakers from all over the

Europe will present their state of the art lectures in the field. The new classification, epidemiology and screening tests in gastrointestinal diseases will be presented. From oncological angle attention is made particularly on colorectal cancer and in gastrointestinal nutrition-related diseases to the malabsorption, anorexia, refeeding syndrome and obesity. Related to gastrointestinal diseases in children the cystic fibrosis, celiac disease and pancreas malfunction will be presented and the program will be finished with lectures in chronic gastrointestinal diseases.

Travel grants are available for young course participants (under 35 years), from European countries. (http://www.dubrovnik-course.org/travel_grants). Grant application deadline is 30 June, 2012.

Beside the course will offer an attractive scientific program designed to deliver a highly interactive and stimulating atmosphere, the participants will be able to take part in vivid discussions and exchange ideas with well known experts in the field. We hope that participants will enjoy this opportunity to acquire new knowledge and experience, while also making new friends and enjoy the beauties of Dubrovnik - city which beauty goes beyond words.

It is our pleasure to invite you to participate in this weekend course and look forward to offer a truly pleasant and unforgettable stay in Dubrovnik!

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The 5th SFBC International Symposium on Critical Care and Blood Gases

by Michel Vaubourdolle, SFBC-Chair Committee on accreditation, and Bernard Gouget, SFBC-EFLM representative

The triennial international symposium founded by Dr. Alain Feuillu (Rennes (FR)), was organized this year in Deauville (FR) on May 31 to June 1, 2012. Deauville is very well known for many reasons not only with the American film festival, but also with the horse races all year round, and its international horse auctions; as well as the annual polo competition, which brings together the world's best players. Deauville is the ideal setting for a cultural and scientific pause. This is one of the reasons why Dr. Michel Vaubourdolle, president of the International symposium, choose this wonderful place to discuss an important topic on critical care testing and blood gases. The symposium gathered 400 participants from more than 10 countries in presence of Ian Watson, EFLM president, Greg Miller, AACC president, Nader Rifai, editor in chief Clinical Chemistry, Philippe Gillery, Joelle Goudable, and Roselyne Garnotel, representing the SFBC and Bernard Gouget, who was representing Graham Beastall IFCC president.

POCT concept is at a crossroads: the technologies to make rapid testing a reality have arrived, but are we ready? This was the debate in Deauville. During the two-day symposium, organized in four sessions, it was possible to better understand the latest trends in innovation and projections for future applications. Paul Holloway presented the benefits and expectations of POCT devices. The benefits of bringing diagnostic testing closer to the patient and reducing TAT are self-evident but include the potential for more rapid clinical decision making, triaging, monitoring, identifying dangerous pathogens and reducing the financial and clinical costs of patient care. The extension of POCT to pathogen recognition and treatment sensitivity is gaining momentum, enhanced by drives to improve medical care at scenes of disaster and terrorist injuries, and along with that is a strong impetus for improved sepsis biomarkers. Pr. B Carbonne and Agnès Mailloux presented the benefit of POC in neonatology using POCT device for bilirubin, Dr. JL Daban the new approaches in intensive care units, and Dr. Petra Wilk the impact of POCT on ward organization. During his talk, Pr. P Toulon focused on the significant increase of POCT in hemostasis in both the spectrum of tests available and the advantages of the physician.

Pr. Ph Gillery and C Dukas demonstrated the value in blood Glucose and HbA1C monitoring in order to establish more tight blood glucose control in diabetes patients.

The afternoon session focused on the new biosensors beyond the traditional applications of electrochemical biosensors. Pr. M.E. Meyerhoff described the recent efforts to use simple electrochemical biosensors for the measurements of polyionic drugs and associated contaminants, including the anticoagulant heparin, low molecular weight heparins, and OSCS contaminants in biomedical grade heparin preparations. Several presentations discussed how new technologies would change diagnosis screening, testing paradigms, and provided an analysis of potential new POC applications in the clinical sector and emphasized the potential benefit of POC for various sectors of the medical and scientific community, capillary glycemia by Dr. Ph DERACHE, and the recent developments in microbiology based on molecular techniques by Pr. P.Y. Levy. At the end of the first day, it was possible to have a comprehensive overview on the importance of the connectivity, remote data management and IT by Dr. M Boisson, and how to reduce preanalytical errors using RFID in the blood gas process.

The second day saw Nader Rifai report on recent advances in technology that revolutionized the research and discovery capabilities for scientific information, and discussed the experience with Clinical Chemistry in the dissemination of scientific information.

With the new French regulation, many presentations described the strategies for the implementation of the accreditation for POCT. An experience from APHM Marseille by Pr. H Portugal, and the second one by P Vernet, CHU St Antoine, APHP, before a lively round table discussed the new challenge posed by the compulsory accreditation for all French medical laboratories before end of 2016 under the coordination of Michel Ballereau and Anne Marie Gallot, the initiator of the French reform for medical laboratories.

The last session was organized by the AACC critical care and POCT division with three presentations J.A. Dubois who reported on POCT as a growing, connected market segment with increased wireless capabilities where POC communication standards ensure fulfillment of the critical



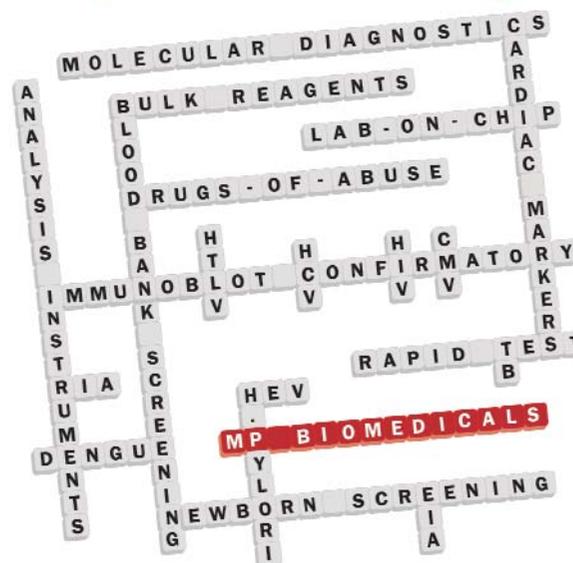
Photo: (From left to right) Michel Vaubourdolle (SFBC-Chair Committee on accreditation), Nader Rifai (Editor in chief Clinical Chemistry), Greg Miller (AACC president), Ian Watson (EFLM president), Bernard Gouget (SFBC-EFLM representative)

user requirements of bidirectionality, device connection commonality, commercial software interoperability, security and QC/regulatory compliance. Pr. S Ehrmeyer presented CLIA'88 quality-management system model to ensure quality of POCT in comparison with the worldwide ISO 15189/22870 norms and J.Nichols described the changing US regulations with new development in proficiency testing and quality control based on risk management.

Since the movie "A Man and a woman," Deauville is under the inter-

national spotlight, forever connecting the town to romanticism, and we can sing "Chaba-daba-da" (theme music from the Claude Lelouch film "Un homme et une femme."). We enjoyed the gala dinner with the red carpet at the entrance and the interactive Quiz Movies. This congress will be also an opportunity to interact with colleagues, young scientists, friends, to meet new ones and to build long-term professional relationship. Thanks also to the corporate companies who supported this project: IL, Radiometer, Roche, and Siemens.

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What's in a Name?

by Michael Thomas,
Association of Clinical Biochemists (ACB) President

What's in a name? "That which we call a rose by any other name would smell as sweet." Says Shakespeare's Juliet,

implying in her words that the names we ascribe to objects have an element of arbitrariness and are a mere matter of convention. But is this really so? Is there more to it than mere convention? In 2005, the Association of Clinical Biochemists became the Association for Clinical Biochemistry. This was a small change in name but a significant change in that it recognized the desires of the membership to promote a greater inclusivity towards all those with an interest in the specialty and within the wider discipline of medicine. It formally extended the membership to all individuals interested in clinical biochemistry, and as a consequence, many biomedical scientists and industrial colleagues are now members of the ACB.

More fitting for the Articles Mergers with first, the Association of Clinical Scientists in Immunology,

and more recently the Association for Clinical Microbiology, has further broadened the range of the Association's membership outside the traditional boundaries of Clinical Biochemistry. Two years ago, my predecessor, Julian Barth, wrote in ACB News (No. 563, March 2010) that this "does not quite fit our present Association articles, which permit membership to any ... health professional with an interest in clinical biochemistry in the UK or Ireland." And, "nor would our Association name fit the bill." Changes in the by-laws do now reflect that our members may have an "interest in clinical biochemistry and/or laboratory medicine." However, the Association's name stubbornly remains that of "Clinical Biochemistry" alone and fails to recognize the wider constituency of our membership. We recognize that it is time to reconsider the Association's name and ACB Council would endorse this after consultation with the membership. It is therefore our intention to canvass members through an electronic survey on a further change in name, and Laboratory Medicine Executive Officers will recommend that the Association's name becomes the

"Association for Clinical Biochemistry and Laboratory Medicine." This title would be consistent with those of international bodies who have also embraced a wider membership such as the International Federation of Clinical Chemistry and Laboratory Medicine and the American Association for Clinical Chemistry and Laboratory Medicine, both of whom continue to use their trademark names and logos of IFCC and AACCC, respectively. We believe it is essential to retain our accepted trademark of ACB. Having been known by this abbreviation for almost 60 years, it is recognized nationally and internationally and also sits well against the proposed change in name. "A rose is a rose is a rose," said Gertrude Stein, often interpreted as emphasizing that things are what they are. But there are benefits for the ACB in changing our name at this time. A professional association such as ours has strength in numbers and in breadth. Moreover, a wider membership fits with the changing pattern of delivery of laboratory medicine away from the old disciplines to that of a more integrated service. I sincerely hope that members will participate in the electronic survey and they will be persuaded of the benefits of changing the name of the Association to encourage membership across all branches of laboratory medicine, without losing the trademark "ACB."

UK Biobank Opens Its Data to Researchers

The massive health data resource UK Biobank (www.ukbiobank.ac.uk) recruited 500,000 people aged between 40-69 years from 2006-2010 from across the United Kingdom to undergo various measures, providing blood, urine and saliva samples for future analysis, as well as detailed information about themselves. Now, the databank is opening its resources to researchers. Scientists from the UK and from overseas, hailing from academia, industry, charity, or government-funded projects, will be able to use data after confirmation that research is health-related and in the public interest. Information provided to researchers will be anonymized. Applications to use the resource can be made online.

News from the Croatian Society of Medical Biochemists (CSMB)

by Dr. Jasenka Wagner, President of the CSMB committee for public relations

During the past year, Croatian Society of Medical Biochemists (CSMB) organised two national meetings and one international meeting. The first meeting, "22nd Symposium of the Croatian Society of Medical Biochemists," was held in Zagreb in June 2011. This meeting is organized annually with different topics covered each year. This year's topics were Novel markers of gastrointestinal diseases. About 200 participants attended the meeting, with abstracts from the symposium being published in *Biochemia Medica* (2011;21(2):A21-A30).

Recently organized for the first time (2010), but already becoming a successful tradition, "2nd Croatian Predictive Medicine Symposium with International Participation" was held in Zagreb, in November 2011. About 150 participants attended this meeting dedicated to the role of laboratory medicine in predictive medicine. This year's lectures were oncology based. The abstracts of the Symposium were published in *Biochemia Medica* (2012;22(1):A1-A16).

The traditional meeting in the frame of EFLM, "11th EFCC Continuous Postgraduate Course in Clinical Chemistry: New trends in Classification,

Diagnosis and Management of Inflammation" in cooperation with Slovenian Association for Clinical Chemistry and Inter-University Center Dubrovnik CSMB was organized in October 2011 in Dubrovnik. Course proceedings were published in *Biochemia Medica* (2011;21(3)) as review articles. About 120 participants from Croatia and surrounding countries attended the Course.

Publishing activities of CSMB are related to CSMB's scientific journal *Biochemia Medica* (www.biochemia-medica.com). We are proud to announce that, since October 2011, *Biochemia Medica* is indexed in Medline. With its international Editorial and Advisory Board it continues to publish articles by Croatian and international authors dedicated to professionals from laboratory medicine and various fields of biomedicine that share the same interests. Papers are published in English with abstracts in English and Croatian. BM is indexed in Medline, SCIE, JCR, Thomson Reuters, EMBASE/Excerpta Medica, Scopus, CAS, EBSCO/Academic Search Complete and DOAJ. The journal's impact factor for 2010 was 1.085.

Task and Finish Group on Critical Results (TFG-CR) - 2012-2014

EFLM has established a new Task and Finish Group on Critical Results (TFG-CR) under the WG-PEQAS

Aim: To perform a European survey on what critical result management procedures and policies laboratories have and how critical values are established and used in European laboratories.

Deliverables: To publish at least one scientific paper about the subject and to give a presentation or poster at EuroMedLab or other EFLM and/or AACB-related conference or symposium.

Members: Éva Ajzner, Chair, County's Teaching

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The SFBC Promoting the Accreditation ISO 15189 in Euro-Mediterranean Countries

by Michel Vaubourdolle, CHU St Antoine, APHP France, chair SFBC committee on accreditation

Dr. Michel Vaubourdolle, supported by a IFCC visiting Lecturer program, was invited to Morocco, to speak on the ISO 15189 accreditation for medical labs. The 13th Arab Congress of Clinical Biology, joined with the 12th Moroccan Congress of Clinical Chemistry and Laboratory Medicine, designed as ArabMedLab 2012, was held May 2- 5, 2012, in Marrakech, Morocco. This meeting was organized by the Moroccan Society of Clinical Chemistry and Laboratory Medicine (SMCC) and the Arab Federation of Clinical Biology (AFCB), under the auspices of International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).

Marrakech was and is the hub of a great civilization that grew from a melting pot of people from the four corners of the world, drawn here by the prosperity of a capital that has not ceased to exert its influence across the world. African, Saharan, Muslims, Arab and other civilizations have blended harmoniously to produce an explosion of creativity and special appreciation of traditional arts, architecture, science, and the ways of life. With the 13 ARABMEDLAB Congress/12 SMCC, we got a good example of the creativity and of the dynamism of our Moroccan colleagues to explore and to drive

the future of lab medicine.

The audience was important and representative of African and Mediterranean areas with 900 attendees and 40 countries represented. More than 60 speakers, recognized specialists, from many IFCC/EFLML countries as well as IFCC CPD, and SD representatives were present and contributed to 10 plenary sessions, 6 parallel sessions, and 7 industrial workshops.

Scientific topics concerned all biological specialties and actuality reviews, such as the value of laboratory medicine, pharmacogenomics, molecular genetics, biomarkers of Alzheimer disease, decision limits and reference intervals, vitamin B12 deficiency, cancer biomarkers, personalized medicine, hemophilia, vitamin D, highly contagious bacteria, quality management, viral hepatitis, autoimmune diseases, emerging antibiotic resistance. Some sessions were focused on African-Mediterranean aspects of the biological themes such as hemoglobinopathies in the Arab world.

The session "Proficiency Testing, Quality Management and Accreditation in the Arabic and Euro-Mediterranean Environment" was held Saturday May 5, 2012, in the morning. It was coordinated by Bernard GOUGET (IFCC Treasurer,

Paris, France) and Saif El Islam Slimani (President of CSB; Rabat, Morocco).

Various aspects and experiences about the accreditation process and quality assurance were presented. Fouad Harb (Damascus, Syria), Ghassan Shannan (Damascus, Syria) spoke on Quality management in the AFCB region, Present and future; The Road Map of quality management in Clinical Laboratories of Lebanon was done by Adel Mastori; Analysis of the Moroccan GBEA in comparison to the ISO 15189 was discussed by Nadia Charrat (LRAM; Rabat, Morocco); Anne Vassault (Paris, France) presented the Quality controls Tools for Clinical lab management in the AFCB region.

Comparisons between countries in the Arabic and Euro-Mediterranean areas were very interesting to discuss during a roundtable in the presence of Daniel Pierre, past president of ILAC and international accreditation bodies representatives.

In addition, this congress gives us the opportunity to meet the general secretary of the Marrakech University Hospital Mohammed VI and to initiate future collaborations between the University Hospital Mohammed VI and IFCC, SMCC, SFBC, and the French hospital organization.

Finally, this congress had also a convivial moment and met the IFCC executive board members in Marrakech for the board meeting and the International Francophone Federation of clinical biology and Lab medicine board members.

In conclusion, this meeting was very exciting and interesting, due to a real and useful mix between Arabic, Francophone, European and international delegates.

20th Meeting of the Balkan Clinical Laboratory Federation to Be Held in Belgrade, on September 18-22, 2012

by Prof. Dr. Nada Majkic-Singh, President, Society of Medical Biochemists of Serbia

The Society of Medical Biochemists of Belgrade has the pleasure of inviting you to the 20th Meeting of the Balkan Clinical Laboratory Federation to be held in Belgrade, on September 18-22, 2012, joined together with the 8th EFCC Symposium for the Balkan Region and 18th Congress of Medical Biochemists of Serbia.

This is the third time that the Society of Medical Biochemists of Serbia acts as the organizer of the BCLF Meetings. The Fourth Meeting of the Balkan Clinical Laboratory Federation was held in Budva in 1996, and the 11th BCLF 2003 Meeting was organized in Belgrade, under the auspices of the International Federation of Clinical Chemistry (IFCC) and the Forum of the European Societies of Clinical Chemistry (FESCC). More than 500 scientists from all over the world and all the Balkan countries were present. It has been generally agreed that the meeting fulfilled the expectations and was a success.

The Serbian capital Belgrade, the host of the Meetings, is an ancient city. No one knows when the first settlers inhabited the area of present-day Belgrade. During the prehistoric era, the city surroundings were already

densely populated. In those times, land and river caravans traveling along some of the oldest trade routes were meeting on its territory.

The ancient peoples who lived on this land were changing by turns from the Illyrian tribe of Autariats, through Dacians, Celtic Scordians, to Thracian Sings, etc. Belgrade's many names include: Singidunum, Alba Bulgaricam, Nandorfejervar, Alban Andor, Wiessenburg, Griechisch Weissenburg, Alba Graeca, Castel bianco, and Beograd (Belgrade). It is believed that the first inhabitants of Belgrade were the Sings, one of the Thracian-Illyrian tribes. They are mentioned by Herodotus, the father of European history. The city's first name recorded in history was Singidunum, most probably of Celtic origin, and can be found in the works of ancient authors and antique inscriptions. It was derived from the name of the Thracian tribe of Sinnings and the Celtic word Dunum, meaning "town." In historic documents, the city appeared under the Slavic name Belograd or Beograd in the 9th century.

Belgrade lies at the mouth of two rivers, the Danube and the Sava, under the Mountains of Avala, the silent witnesses of a long and bloody

history of the city that has always risen from ashes, like the phoenix, each time bigger and more beautiful.

The 20th BCLF Meeting in Belgrade will continue with its successful progress of the previous years, aiming to focus on the new data in the field of laboratory medicine. The intention is also to increase the participation of clinical chemists from all the Balkan countries, as well as from the neighboring states.

We hope that we will have the pleasure of your presence, and speaking on behalf of the Society of Medical Biochemists of Serbia, we look forward to your active participation in the works of the 20th Balkan Clinical Laboratory Federation Meeting and 8th Symposium for the Balkan Region, as well as the 18th Serbian National Congress of Medical Biochemistry and Laboratory Medicine.

The European Commission's New Health in Europe: Information and Data Interface (HEIDI) Tool Includes a Section for Rare Diseases

Heidi (Health in Europe: Information and Data Interface) is a recently developed internet-based wiki tool specifically designed for European health information and data. Emerging from two former EC Public Health Program projects (the Eugloreh report and EUPhix), Heidi offers articles and data on health status, diseases, determinants, health systems and policies, trends, institutional and policy aspects, and more.

There is a special section for rare

diseases available via the Contents tab. Data can be accessed by employing either search or browse functions. The information contained in Heidi, presented in the form of texts, tables, graphs, charts, and maps, is provided by various health professionals. Experts are called upon to contribute their expertise by becoming editors for Heidi. It is hoped that this new information tool can help develop evidence-based policies to improve the health of Europeans.