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International Federation of Clinical Chemistry and Laboratory Medicine





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#### **EDITORIAL**

#### Message from the eNews Editor

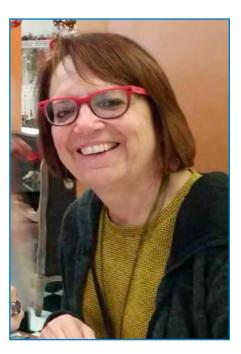
by Katherina Psarra eNews Editor

Summer is here and lots of lists of books for the beach are bombarding us. Take with you lots of books but take the IFCC eNews as well. Download the IFCC application on your smartphone and there they will be along with the eJIFCC, the eAcademy and the website.

The hottest topic nowadays seems to be the big data. Big data are produced in all areas of laboratory medicine. We have to take care of their analysis, and of their handling as well. We have to understand them and to make good use of them. Don't be afraid of them. We have the means to get as much information as possible.

Another hot topic in this issue of the eNews is point of care testing (POCT). IFCC working group is giving a lot of information to us regarding their use. And then accreditation and certification seems to stay to remain a very interesting point until all the labs in the world are accredited as they should.

Have great holidays my friends and enjoy the sun, the sand and don't forget to check on the news too.



#### Katherina Psarra

#### News from the IFCC Website



#### eJIFCC Vol 30 n°2 - June 2019

The June 2019 eJIFCC is now available. In this issue: Non-coding RNAs as potential laboratory biomarkers.

Since the discovery of non-coding RNAs, enormous information has been accumulated about the function of these molecules acting as fine-tuners of cellular processes in development, maintenance of homeostasis up to the generation of malignancies. Altered expression of non-coding RNAs have been implicated in the pathogenesis of diverse human diseases suggesting their potential to become diagnostic or prognostic molecular biomarkers in the near future. This special issue of the eJIFCC incorporates a series of manuscripts that discuss the possibilities and challenges in the use of non-coding RNAs as non-invasive biomarkers in various clinical conditions, especially focusing on cell-free miRNAs in different human diseases.

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#### THE VOICE OF IFCC

#### Update from the IFCC Committee on Point-of-Care Testing meeting in Barcelona



Adil Khan, IFCC C-PoCT Chair

Barcelona, the city of Antoni Gaudi, hosted, EuroMed-Lab 2019, the 23rd IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine.

It was also the venue for the meeting of members of the IFCC Committee on Point-of-Care Testing (C-POCT) - which comprises thirty-three members drawn from Canada, the Americas, Europe, Africa, the Middle East, Asia, Australia and New Zealand. Point-of-Care (POC) Testing, the testing of patient specimens at the bedside and outsides the confines of the clinical laboratory, and usually performed to improve patient management, is growing exponentially due to their "user-friendliness" and non-reliance on costly hospital infrastructure. But this explosion of POC tests poses a number of challenges. The C-POCT members look at different aspects of point-of-care testing and provides international leadership by developing the clinical practice guidelines or educational materials where none exist or there is lack of clear direction. Its members have devoted ten or more years of their careers to point-of-care testing and so they are well qualified to give guidance, and furthermore they have been nominated by their country's professional societies, so they are experts in their own right.

by Adil I. Khan IFCC C-PoCT Chair Director, Point-of-Care Testing & Clinical Chemistry Dept. of Pathology and Laboratory Medicine Lewis Katz School of Medicine Temple University, Philadelphia, USA



La Sagrada Familia

As issues are addressed the membership includes representation from companies such as Roche, Siemens, Nova Biomedical and Abbott Diagnostics to ensure opinions are balanced from both academic and industry perspectives.

The EUROMEDLAB 2019 congress hosted a symposium devoted to POC tests whose theme was "Pointof-Care Testing: From quality assurance strategies to clinical utility and patient outcomes." The speakers, were drawn from the C-POCT committee. Dr. Sverre Sandberg from Norway, gave the opening lecture titled, "Quality control and analytical performance specifications for different clinical POCT settings. Should they be different?" He discussed the importance of performing POC testing based on clinical outcomes, cost and setting and this would in turn determine their performance specifications. Furthermore, he went on to explain that since POCT is carried out in a different environment with different users and often with different performance specifications and different types on inbuilt controls, it is important to re-evaluate how and which types of quality control should be used. Dr. Paloma Oliver from Spain discussed her experience in her talk titled: "20 years' experience on quality assurance strategies of a large and ISO 22870 accredited POCT multiparameter network," highlighted the issues and complexities of POC testing service. She stressed the importance of creating a homogenous POCT network for all clinical settings, led by laboratory medicine and in accordance with the ISO 22870 requirements, that address three key areas: quality assurance, staff training and competency and continuous improvement. All of them are essential to

improve the management of POCT and consequently, patient care. Finally, Dr. Rajiv Erasmus from South Africa explained how POC testing for HIV is turning the tide in the fight to end this epidemic in Africa by 2030. In his talk: "How the use of POCT has changed the clinical pathways and outcome for patients with infectious diseases in Africa" he showed how the POC testing was the solution to the lack of infrastructure and highly skilled professionals in rural parts of Africa, that resulted in shorter treatment times and improved outcomes. The symposium ended with the "SensUs Student Competition: Global education and innovation in POCT" given by Marc Vives Enrich (GB), and Eliene Rutten (NL). This is an international student competition on biosensors for health and spurs innovation.

The IFCC Working Group on "How should Glucose Meters be Evaluated in Critical Care (WG-GMECC)," chaired by Dr. Cynthia Bowman, updated the C-POCT committee on their progress. This WG has completed a document on "How Should Glucose Meters Be Evaluated for Critical Care" that is available for download from the IFCC –C-POCT website. It addresses the clinical practice of using Blood Glucose Meters (BGM)



L-R: Masaru Yamamoto; Michel Vaubourdolle; Ellis Jacobs; Anne Skurup; Silvia Cardinale; Silvia Colli Lanzi; Paola Bramati; Paloma Oliver; Filiz Akbiyik; Laetitia Crouch; Alessandro Palese; Sean Cunningham; Adil Khan (Chair)

and what requirements they must fulfill in order to be used in critically ill patients and in Professional Healthcare Settings on patients in various states of health and patients receiving intensive medical intervention and therapy (http://www.ifcc.org/ifcc-education-division/emd-committees/taskforcepoct/wg-gmecc/). A second document addressing quality management and training and competency recommendations for BGM is under development.

Currently the C-POCT committee is working on a paper addressing the requirements for POC testing outside the hospital setting and includes direct-to-consumer testing. The POCT committee also discussed

the upcoming IFCC World Lab Congress in Seoul, 2020, where the C-POCT would hold a POC test mini-symposium, 'The Current status and Future Roles of Pointof-Care Testing." Finally, the Africa Federation of Clinical Chemistry (AFCC) Regional Conference will be held in Marrakech, Morocco from 25th to 28th September, 2019. A symposium on Point of Care Testing will be held. Professor Erasmus and Professor Sandberg both affiliated with the IFCC–POCT Committee will take part in this symposium.

For all updates, visit the C-PoCT webpage at: http:// www.ifcc.org/ifcc-education-division/emd-committees/c-poct/.

#### Introducing the IFCC Working Group on Volatolomics (WG-Vol)

by Larry Kricka

Professor of Pathology and Laboratory Medicine Department of Pathology & Lab. Medicine University of Pennsylvania Medical Center, Philadelphia, USA



Dr. Larry Kricka (Chair)



Dr. Paolo Fortina (Member)



Dr. Joesph Wiencek (Member)

The new Working Group on Volatolomics (WG-Vol) is part of the new Emerging Technology Division (ETD) that was ratified in 2017. It provides current awareness of emerging technologies likely to have important clinical diagnostic applications in the near future - one of those emerging technologies is volatolomics (*i.e.*, breath analysis). Members of the new WG-Vol are: Dr. Larry Kricka (Chair), Dr. Paolo Fortina (Member), and Dr. Joesph Wiencek (Member) and the terms of reference for the new working group are to develop a survey of the diagnostic applications of volatolomics (breath analysis) and to develop periodic updates of the volatolomics survey over the next 3 years. Breath analysis is not new and already has a few, but very specific applications (e.g., breath alcohol testing, <sup>13</sup>carbon/<sup>12</sup>carbon-based tests). One aspect of current work on volatolomics centers on finding diagnostic utility in the pattern or signature of volatile organic compounds (VOCs) in breath. Breath analysis is an attractive proposition because this type of testing is non-invasive, applicable to the point-of-care and offers the possibility of real-time clinical management. Already, there are more than 10 companies focused on the clinical diagnostic applications of volatolomics employing diverse analytical technologies (breath analysis analyzers are sometimes known as "electronic noses"). The broad scope of diagnostic applications under investigation and development ranges from breath glucose testing to testing for different types of cancer.

Volatolomic technologies are diverse and include different types of mass spectrometry [*e.g.*, gas isotope ratio mass spectrometry (GIRMS), selected ion flow tube mass spectrometry (SIFT-MS), field asymmetric ion-mobility spectrometry (FAIMS), secondary electro-spray ionization-MS], sensors and sensor arrays (*e.g.*, copper bromide-based sensor, colorimetric high

dimensional sensor array), gas chromatography (*e.g.*, GC SAW). Further notable aspects of breath analysis technologies are the use of artificial intelligence, cloud-based analysis of data and analyzers linked to a smartphone.

The survey will be published as a pdf on the WG-Vol website (https://www.ifcc.org/ifcc-emerging-technologiesdivision/etd-working-groups/wg-vol/) and will include:

- News items and opinion pieces from key researchers/opinion leaders about recent developments in the clinical diagnostic applications of volatolomics.
- A directory of companies active in the clinical diagnostic applications of volatolomics.
- Links to clinical trials involving volatolomic testing.
- Details of analyzers and regulatory approvals of clinical diagnostic products based on volatolomic testing.
- A literature survey updated quarterly designed to provide an educational resource and a snapshot of work since 2010.

#### IFCC Distinguished Awards for the IFCC WorldLab Congress - Seoul (KR) 2020

#### **Call for nominations**

#### *by Maurizio Ferrari Chair, IFCC Awards Committee*

As you are aware, the IFCC confers several Distinguished Awards to scientists and clinicians who work in clinical chemistry and laboratory medicine or related disciplines. These triennial awards are the highest honours that our Federation can bestow to colleagues worldwide in recognition of their outstanding achievements, to publicize their exceptional research and other contributions that have improved medical and healthcare, and to stimulate and encourage other scientists to accelerate their efforts in advancing clinical chemistry and laboratory medicine.

On behalf of IFCC and its Awards Committee, I am pleased to call for nominations for the following ten (10) IFCC Distinguished Awards for presentation at the IFCC Congress in May 2020, Seoul, Korea.

These awards for 2020 are listed below and a more detailed description of them, including the former honorees, can be found by clicking on this link.

Article continued on next page



- 1. IFCC Distinguished Clinical Chemist Award sponsored by Yashraj Biotechnology Ltd.
- 2. IFCC-Henry Wishinsky Award for Distinguished International Service since 1990 (IFCC Distinguished International Services Award 1981-1987) sponsored by Siemens Healthineers.
- 3. IFCC Award for Distinguished Contributions in Education sponsored by Abbott Laboratories.
- 4. IFCC Award for Significant Contributions in Molecular Diagnostics sponsored by Abbott Laboratories.
- 5. IFCC Distinguished Award for Laboratory Medicine and Patient Care sponsored by Sekisui Diagnostics.
- 6. IFCC-Robert Shaffer Award for Outstanding Achievements in the Development of Standards for Use in Laboratory Medicine sponsored by NIST CLSI.
- 7. IFCC Distinguished Award for Contributions to the Cardiovascular Diagnostics sponsored by HyTest.
- 8. IFCC-Gérard Siest Award Young Scientist Award for Distinguished Contributions in Pharmacogenetics sponsored by Biologie Prospective.
- 9. IFCC Distinguished Women Scientist Award for Contribution to In Vitro Diagnostics sponsored by Yashraj Biotechnology Ltd.
- 10. IFCC Young Investigator Award sponsored by IFCC.

Nominations are welcome from the President or National Representative of the nominees' national society, which should be a member of the IFCC.

#### Each nomination should contain:

- (1) a statement as to the reasons for nomination,
- (2) a full CV of the nominees including a bibliography, and
- (3) other letters of support (optional).

They should be sent to Silvia Colli-Lanzi of the IFCC Office (colli-lanzi@ifcc.org).

#### The closing date for receipt of nominations is 30 November 2019.

Please do not hesitate to write to Silvia Colli-Lanzi or to myself (president@ifcc.org) if you have any queries.

The IFCC Awards Committee 2018-2020

#### **IFCC Developing Quality Competence in Medical Laboratories (DQCML)**

#### Visit to Kazakhstan: April 19-20, 2019



by Egon Amann IFCC DQCML Chair Alexander Haliassos Lina Khorovskaya Annette Thomas DQCML Lecturers

The congress and workshop days were overshadowed by the tragic and untimely loss of IFCC President, Prof. Howard Morris.

This report is dedicated to his memory.

#### **INTRODUCTION:**

The Kazakhstan Association of Medical Laboratory Diagnostics (KAMLD), a Full Member of IFCC, is actively involved in IFCC conferences and meetings. KAMLD's current president is Prof. Mustafa Rysuly. ➡ Following initial discussions with Dr. Urazbayeva Dinara, at that time vice-president of KAMLD, the Application for IFCC DQCML program was submitted on February 19, 2019, to DQCML to organize a workshop. All initial discussions with KAMLD were language-assisted by Dr. Lina Khorovskaya of St. Petersburg, Russia, member of C-AQ.

The goals and objectives of the workshop that was requested by KAMLD were described as: "Establish professional relationships and improve their knowledge in the field of quality control of labora-



Kazakhstan DQCML speakers and organizers. From left to right: Dr Thomas is the second; Dr Khorovskaya is the third; Dr Amann is the seventh; and Dr Haliassos is the ninth.



Certificate ceremony of workshop participants (April 20, 2019)

tory service specialists in Kazakhstan".

The application was discussed and subsequently approved by the EMD EB.

Subsequently the dates of the workshop were fixed to be held on April 19 - 20, 2019, in Almaty, Kazakhstan. The workshop was intended as a satellite event of *the 7th International Laboratory Medicine Congress of the KAMLD*. This had the advantage that interested laboratory professionals visiting the congress were able to participate in the workshop. Moreover, members of the *Kazakhstan Public Association - Federation of Laboratory Medicine* (FLM; President Dr. Zhanar Nurlanovna), an IFCC Affiliate Member, also participated.

As the venue for the congress and for the workshop, the Best Western Atakent Park Hotel in Almaty was chosen.

The detailed planning phase started. The visiting team comprised Egon Amann (Chair DQCML), Annette Thomas (Chair C-AQ), Alexander Haliassos (Chair C-PT), and Lina Khorovskaya (Member of C-AQ).

Two major topics were listed in this application:

- I. Developing Quality Competence in Laboratory Medicine
- II. Implementation of External Quality Assurance in Kazakhstan

❑ In order to learn more about actual situation and issues in Kazakhstan's Clinical Chemistry labs, the visiting team initially considered to visit clinical laboratories (public hospital labs and private labs) after the workshop. However, due to time constraints of the visiting experts such lab visits had to be cancelled.

This document is a report of that visit jointly prepared for DQCML by Egon Amann, Alexander Haliassos, Lina Khorovskaya, and Annette Thomas.

#### **VISIT PROGRAM:**

The program for the visit was discussed in advance with the following people hosting it:

- Prof. Mustafa Rysuly, President KAMLD mrysuly@bk.ru
- Dr. Saken Rustemov, Executive Director KAMLD sa.rustem@bk.ru
- Madina Saparbaeva, Secretary of KAMLD kamld@medexpo.kz

#### DAY 1: ASSURING QUALITY IN THE CLINICAL LABORATORY (APRIL 19, 2019)

Day one was devoted to lectures and workshops. Since English language proficiency appeared to be rather low, lectures were translated into Russian. In turn, workshop group results, as summarized below, were presented in Russian and translated into English for the visitors. For the interactive workshop "What is the best strategy to achieve compliance with QMS- and QC-requirements in the clinical laboratory" the approximately 42 participants were divided into six groups.

The full text including the programme of the two days, along with the Summary of possible solutions for identified issues, are available on the IFCC Website at: http:// www.ifcc.org/ifcc-communications-publications-division-cpd/newsarchive-links/ifcc-enews-2019-issue-7-8/.

#### **IFCC: THE PEOPLE**

#### Maria Luisa Castillo de Sánchez, Treasurer † (IFCC Executive Board: 1985-1987)

#### by Francisco Xavier Sánchez Castillo Mexico



A woman, a professional, a devoted wife and mother of 10 children who gave her 13 grandchildren and 6 great-grand children. She lived a righteous and incorruptible life. Her parents inspired her not only to acquire knowledge but a purpose of excellence, dedication, breadth of vision and spirituality, as well as a love for the arts, sports and languages.

She got her Bachelor's degree in chemical-pharmaceutical biology in 1949 from the National Autonomous University of México. Soon after, she started working at the Mexican Institute of Social Security (IMSS) and the Institute of Social Security for State Workers (ISSSTE), in areas related to quality control in clinical laboratory and drug trials. During the next 17 years she was active in the labor union of the IMSS where she led a group of chemists to improve their labor conditions.

In 1966, she and her colleagues founded the Mexican Association of Clinical Biochemistry (AMBC). Her influence was conclusive for Mexico to become a

member of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). She represented Mexico at the IFCC from 1966 to 2005 and was the editor of the AMBC periodical-magazine *BIOQUIMIA* and coordinator of the AMBC National Congresses until her retirement in 2005.

Her aptitude and experience in congress organization served her well when called upon to organize the X<sup>th</sup> International Congress of Clinical Chemistry in Mexico City (1978), the first IFCC international congress in Latin-America. Maria Luisa later became the Chair of IFCC Congress and Conference Division (1979-1984) but having served as a member of that Committee since 1972. She became part of the IFCC Executive Board as Treasurer for the period 1985-1987. In 1990, she received the "Henry Wishinsky Award for Distinguished International Services", for her unique contribution to the promotion and understanding of clinical chemistry throughout Latin America. She was mainly responsible for the establishment of the Latin American Confederation of Clinical Biochemistry (COLABIOCLI). She played an important role as a consultant in the activities of the Pan-American Health Organization (PAHO) and World Health Organization (WHO) pertaining to clinical laboratory issues.

To date she is the only woman to have been honored with the IFCC Award.

As president of the COLABIOCLI (1993-1995), MLCS spear-headed the project "Continuous Quality Improvement and Total Quality Management in Clinical Laboratories in Latin American countries". As a part of this project, Maria Luisa and other collaborators produced a guide for the purpose of providing key elements required to produce highly reliable and trustworthy results for excellence in clinical trial performance in the Latin American Region. The project trained and mentored professional "Tutors" to in turn reproduce the project in their countries ("Cascade Teaching System"). The project was internationally recognized and sponsored by international organizations.

She practiced professionally until the age of 80 and throughout her career she was in successful *crescendo*, ascending to various relevant national and international positions that afforded her many satisfactory and unforgettable experiences.

She celebrated her 93<sup>rd</sup> birthday on the 20<sup>th</sup> of March 2019 and, in the early morning of the 27<sup>th</sup> of April, accompanied by her children, death of the just people found her in her sleep.



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The **6th** Congress of the African Federation of Clinical Chemistry and Laboratory Medicine The **19th** Moroccan Congress of Clinical Biology

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#### IFCC President 2019-2020

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Prof. Maurizio Ferrari

The results of the ballot for the substitution of the IFCC President, following the unfortunate death of Prof. Morris, was concluded, June 30.

The voting unanimously confirmed the Executive Board recommendation to appoint Prof. Maurizio Ferrari as President, beginning his term on July 1.

The President-Elect will transition into the role of President during the 2020 year at a date mutually agreed upon between the EB and the President-Elect.

In summary, 52 societies voted (out of 88 having the right to vote).

Full details of the ballot may be found from the independent company that conducted the ballot:

https://secure.electionbuddy.com/results/6EFTVWKVRNVV.

On behalf of the IFCC Executive Board, we congratulate Prof. Maurizio Ferrari in his role.



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International Consortium for Harmonization of Clinical Laboratory Results



Workshop Announcement

# Reference materials and regulations for global standardization / harmonization of clinical laboratory testing

## 29-30 May, 2020 - SEOUL, KOREA



Immediately following IFCC WorldLab 2020 - http://www.seoul2020.org/2020/home

This workshop will address the need to establish global metrological traceability of clinical laboratory methods using ISO standards with JCTLM certified reference materials, reference measurement procedures and harmonization protocols, rather than via country or region-specific reference materials or requirements.

Workshop topics will address technical and regulatory issues, impact of new biomarkers and technologies, approaches to prioritization of measurands for harmonization, and conclude with recommendations for improved approaches to achieving harmonization of results.

Information and registration: <a href="mailto:seoul@ifcc2020.org">seoul@ifcc2020.org</a>

Presented under the auspices of



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#### **IFCC: THE YOUNG SCIENTISTS**

News from IFCC Task Force Young Scientists: a Young Scientists session organized during the 33<sup>th</sup> Tunisian National Congress of Clinical Biology

#### by Dr. Manel Chaabane

Associate Professor of Hematology National Blood Transfusion Center of Tunisia General Secretary of the STBC National Corresponding member for IFCC TF YS

The 33<sup>th</sup> National Congress of the Tunisian Society of Clinical Biology (STBC) was held in the Mediterranean city of Hammamet between 25-27 April 2019. An IFCC Task Force Young Scientists session was organized by the STBC executive board (EB) in collaboration with Task Force for Young Scientists (TF YS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the IFCC EB, within the framework of the congress.

The session was entitled "Trends in medical laboratory science technology". Young scientists from India, Italy, Turkey and Tunisia participated in the session, which was chaired by young scientists from Tunisia.

The first conference entitled "IFCC TF YS: A short presentation" was presented by Dr. Manel Chaabane (TN) and was dedicated to the aim, objectives and activities of the IFCC TF YS. At the end of the presentation, Dr. Manel Chaabane recalled that the STBC EB is about to create the Tunisian Young Scientists Working Group in order to reinforce the contribution of Tunisian young professionals to the promotion of laboratory medicine at both national and international level.

Dr. Giulia Sancesario (IT), IFCC TF YS member and coordinator of the Young Scientists Working Group of the Italian Society of Clinical Chemistry and Molecular Biology (SIBioC), presented a lecture about "New technology in pre-analytical phase", which focused on the importance of standardization and monitoring of this phase for laboratory efficiency and for operational costs reduction.



Dr. Giulia Sancesario (IT)



Dr. Sedat Abuşoğlu (TR)



Dr. Manel Chaabane (TN)

Article continued on next page



#### "WHAT'S NEW IN POST-ANALYTICAL PHASE"

Dr. Pradeep Kumar Dabla MD, PGDHA, PGDBA

Chair, IFCC Task Force for Young Scientists (TFYS)

NABL Assessor ISO 15189:2012

Programme des XXXIIIèmes Journées Nationales de Biologie Clinique IFCC -Task Force Young Scientists session: Trends in medical laboratory scienc technology

#### Dr. Pradeep K. Dabla (IN), lecturing via video conference from Delhi



Moderators: Dr. Nabila Ben Rejeb (TN), Dr. Aida El Argoubi (TN) and Dr. Mouna Sassi (TN)



Participants to the IFCC TF YS session "Trends in medical laboratory science"



Dr. Khalil Ben Abdalllah (STBC EB), Dr. Giulia Sancesario, Dr. Sedat Abuşoğlu, Dr. Manel Chaabane (STBC EB)

The advances in analytical phase were presented by Dr. Sedat Abuşoğlu (TR) who highlighted the role of nanomaterials and mass spectrometry technology in the improvement of diagnostic tools. The role of point of care testing (POCT) devices in the development of the interaction between the patient and the clinician was also raised.

Dr. Pradeep Kumar Dabla (IN), chair of IFCC TF YS, attended the session via video conference from Delhi and gave a lecture about advances in post analytical phase. He provided substantial information about the requirements of the ISO15189 standards, reference limits and laboratory quality indicators defined by the IFCC working group on laboratory errors and patient safety.

An interesting debate chaired by Dr. Nabila Ben Rejeb (Associate Professor of Biochemistry), Dr. Mouna Sassi (Associate Professor of Hematology) and Dr. Aida El Argoubi (Associate Professor of Virology) followed each presentation and new issues were raised in relation to limited resources at the disposal of developing countries, the controversial role of POCT etc.

The session was attended by more than ninety participants. They found the lectures very informative and they were very interested in the activities of the IFCC TF YS.

This event was one of the most successful collaborations established at the occasion of the young scientists meeting during the 1st IFCC Conference "Laboratory Medicine: Meeting the needs of Mediterranean Nations", which was held in Rome, Italy, between 2-4 July 2018.

We hope that more important links will be created between Tunisian young scientists, IFCC TF YS and national young scientists working groups in order to share experience and promote innovation.

by Dr. Bernard Gouget

#### **Contribute to the IFCC eNews**

#### The data tsunami and bioethics: keeping the human rights at the centre



**Bernard Gouget** 

Chair, IFCC Committee on Mobile Health and Bioengineering in Laboratory Medicine (C-MHBLM) Past-Chair, IFCC Nominations Committee (NC) SFBC-International Committee EB member of the International Francophone Federation of Clinical Biology and Laboratory Medicine (FIFBCML) President - Healthcare Division Committee - Comité Français d'accréditation (Cofrac)

The digital revolution extends into many sectors and across multiple health disciplines. Digital technologies and the accumulation of Big Data have developed very quickly and already govern multiple aspects of our daily lives (information, documentation, localization, communication, commercial transactions, industrial process management, forecasting and decision support). The Conseil Consultatif National d'Ethique Français [CCNE-French National Consultative Ethics Committee] has just published an opinion on "Big Data and Health". It emphasizes how the massive accumulation of

data from individuals and the processing of this data must be discussed in the light of ethics.

The term Big Data designates the availability of a large number of data, that only digital tools, ranging from algorithms to the calculating power of computers, can process effectively. The information that data initially contain, regardless of the origin thereof (scientific, administrative, personal or other), is considerably enriched by the connections that can be made among them. These data can have a connection with health or well-being. They can arise from biological measurements, such as genomics, environmental and behavioral data grouped into large cohorts and collected occasionally or repeatedly from medical records as well as from individuals themselves, via social networks and other means of communication.

It is necessary to change the scale in view of the number of data available and our capacity to analyze them. The CCNE points out that once collected, data can be copied infinitely, without loss of quality, and stored in databanks. Data can be transferred and used very widely, including for usages different from those for which they were initially provided or captured. Their distribution has no borders. Algorithmic processing may seem sufficient to guide human reasoning, but it is not a substitute for it.

These disruptive technologies lead to specific ethical questions. The information delivered to the individual and their consent for the collection and use of personal data has become more complex since data can be easily duplicated and reused for purposes that are not initially defined and the processing thereof will give rise to secondary data, often more sensitive than the initial data.

Cross-referencing information often allows very precisely identifying individuals and the initial data anonymization efforts may no longer be a sufficient guarantee to protect individual rights. A very precise understanding of the predispositions of each individual could lead to individualized risk management and penalize individuals. Thus, there is a need for explanations and information on the routing of digital data and the exploitation of the data collected. The laboratory medicine specialist-patient-physician relationship relies on a human rapport founded on trust, responsiveness, observation, the use of physiological indicators and experience. This relationship cannot help being profoundly changed by the role of this approach in aiding a decision based on algorithmic data exploitation. Care must be taken that the development of digital tools does not cause a loss in the singular human relationship, ultimately leading to a risk that medical decisions will be imposed in an impersonal manner by the digital tool. In contrast, the automation of certain tasks should be used to free time to focus on human relationships and counseling.

The parameters that influence health and well-being become measurable with connected devices and applications. Individuals are therefore increasingly induced to take control of their physical condition themselves and to get together to understand the results of medical research related to the illness that concerns them. Thus, new actors become involved, some of whom may exploit the health market for commercial purposes. We should be wary of the fate of data and the risk of malicious exploitation, particularly with regard to vulnerable people.

Any primary information taken in isolation, apparently innocuous, must now be considered as being able to contribute to information about health by cross-referencing it in another context with other data which are not related to this information. This processing reveals new information. This information is saved and may be used without the knowledge of the owners of the original data and be exploited positively or in a harmful way, since this information can lend itself to both beneficial and possibly harmful uses.

Data are collected in multiple situations by individuals themselves, whether they are aware of it or not, or collected as part of care or by researchers to supply databases, registries and cohorts, not to forget administrative data. The use of this raw material is sought by operators whose origin, motivations and values are very varied (care, new tests or devices, improvement of knowledge, health economics efficiency, public health, protection of privacy, etc.). As a result, it becomes more complicated to characterize a piece of data as sensitive and therefore provide it with specific protection.

The digital revolution opens up immense prospects, but the speed of technological change disrupts our precedents and reveals new risks. We can only follow CCNE recommendations on the importance of vigilance for the protection of fundamental individual rights and freedoms when Big Data is used in health. They are at the nexus of the individual and the community, the deeply personal and the general, the public and the private. There are situations in health of poor quality or inappropriateness of care that can be compensated for by a wider use of digital technology and data processing, which will most certainly be a factor for diagnostic and therapeutic improvement. The fast evolution of digital technology has already led to important innovations for patient management and organization of care. This will be even truer in the future, given the major and irreversible reality of this evolution. Still, it is necessary that this progress benefits everyone, given that equality of access to care is only very imperfectly assured. Is it possible, through the use of Big Data, to create another form of relationship and solidarity for the benefit of the community and society?

#### NEWS FROM REGIONAL FEDERATIONS AND MEMBER SOCIETIES



News from Serbia (SMBS)

15<sup>th</sup> Belgrade Symposium for Balkan Region

#### Laboratory Medicine Management: Leadership Skills for Effective Laboratory Group

#### by Dr. Snežana Jovičić

Society of Medical Biochemists of Serbia Liaison Member of the IFCC eNews Working Group

The Belgrade Symposium organized by the Society of Medical Biochemists of Serbia, held on 11 and 12 April, continued the fourteen years long tradition of EFLM Symposiums for Balkan Region. The 15<sup>th</sup> Belgrade Symposium for Balkan Region continued tradition of gathering laboratory medicine professionals from the Balkan countries in order to share experience and discuss topics of mutual interest, therefore the new title of the Symposium was "Neighboring Countries: the Same Professional Aim". However, the borders of the Symposium expanded beyond the Balkans, and this regional meeting had also speakers from Italy, Austria, Slovenia, Croatia, Hungary, Cyprus, and Israel. The Symposium was organized under the auspices of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), European Federation of Clinical Chemistry and Laboratory Medicine (EFLM), Balkan Clinical Laboratory Federation (BCLF), Ministry of Education, Science and Technological Development of Serbia and Ministry of Health of Serbia.

During two days and within eight sessions, eminent foreign and local experts introduced participants to the latest developments in laboratory medicine planning and organization, type of medical laboratory and strategy, laboratory medicine management, leadership skills, accreditation and competencies, laboratory standards in Balkan countries, as well as challenges in laboratory medicine that we meet today.

After the opening ceremony and welcome addresses of the EFLM President-Elect, prof. Ana-Maria Šimundić; EFLM Secretary, prof. Guiseppe Lippi; BCLF

Article continued on next page



Chairs of the Opening Session: Dr. Bernard Gouget (France) and Dr. Snežana Jovičić (Serbia)



Speakers and chairs of the 15th Belgrade Symposium for Balkan region



Speaker's dinner

President, Dr. Jozo Ćorić, and prof. Vesna Matović, the President of the Pharmaceutical Association of Serbia, the Symposium was opened with the session hosted by the IFCC Emerging Technologies Division. Professors Bernard Gouget and Damien Gruson presented how we can use e-health tools in medical laboratories to obtain better outcomes, as well as the benefits of digital tools and machine learning in laboratory medicine. The Symposium continued with the inspiring session dealing with leadership skills. The characteristics and skills necessary for a leader in laboratory medicine, all the aspects of project management important in laboratory medicine practice, and the importance of communication between the clinical laboratory and its users were presented by professors Ana-Maria Šimundić, Giuseppe Lippi, and Graham Beastall.

The central part of the Symposium was sharing experiences between regional countries in implementing laboratory standards, harmonization, and teaching and training in laboratory medicine. Experiences from Slovenia, Croatia, Serbia, Bosnia and Herzegovina, Montenegro, Albania, North Macedonia, and Bulgaria were presented by Evgenija Homšak, Jasna Leniček-Krleža, Svetlana Ignjatović, Ermin Begović, Najdana Gligorović-Barhanović, Anyla Bulo Kasneci, Danica Labudovic, and Margaritka Bončeva.

The second day of the Symposium was opened by two sessions dedicated to laboratory organization and planning. Very important and provocative issue of management of laboratory tests demands through personal experience was presented by professor Dunja Rogić. Prof. Nataša Bogavac-Stanojević presented her work where she showed through cost-effectiveness analysis that the increase in laboratory use could actually decrease hospital costs. The use of six sigma for risk management and the optimal design of analytical quality control in clinical laboratory practice was presented by Adriana Unić. Also, the current views on measurement uncertainty in everyday practice were presented by Dr. Neda Milinković. Laboratory role in accreditation of healthcare institutions by the Agency for Accreditation of Healthcare Institutions in Serbia was presented from two points of view, of a surveyor (prof. Zorica Šumarac) and a chief of accredited laboratory (dr Vera Lukić).

The challenges met in laboratory medicine covered evolving regulatory challenges in in vitro diagnostics, presented by prof. Tomris Ozben. Prof. Marielle Kaplan presented the efforts in national harmonization program of critical values communication in Israel. We were introduced with the assessment of medical residents' skills in choosing appropriate laboratory request and subsequent interpretation of laboratory tests results in a Romanian university center by prof. Ioana Brudaşcă. Dr. Dragana Pap presented the challenges and perspectives of QMS, and the road map for achieving standardization in laboratory medicine.

The final sessions dealt with specific areas of laboratory medicine, namely current positions in laboratory testing in hemostasis, laboratory drug management, and latest results in endocrine disruptor research. About the latest protocols in laboratory diagnostics of anticoagulation, laboratory testing of lupus anticoagulant using different aPTT reagents, and assessment of hipercoagulable state in normal pregnancy and preeclampsia using global haemostatic assays talked prof. Andrea Griesmaher, prof. Violeta Dopsaj, and Sanja Lalić-Ćosić. The contribution of laboratory to therapeutic drug monitoring, challenges, and perspectives, integration of pharmacogenomics in clinical practice, as well as the latest research results in pharmacogenomics of the antidepressants of the SSRI group were presented by Prof. Nicholas Papgeorgakis, Angela Melpidou, Andriani Grigoratou, and prof. Vesna Pešić. The Symposium was closed with the presentation of the latest research results on endocrine disrupting chemicals inducing oxidative stress, their effect on organisms, and particularly the influence of di-2-ethylhexyl phtalate on the oxidative stress tissue damage and on the fatty acids composition, by Prof. Nuriye Nuray Ulusu and Dr. Duygu Aydemir.

The two day Symposium, with over 250 participants, pointed out the same issues and problems that laboratory medicine professionals in this region meet in their every day work and practice, provoking discussions and exchange of opinion. The positive impressions of all the participants demonstrated that these local meetings addressing the practical issues that we are all facing and exchanging experience are necessary in laboratory medicine practice, and that the local problems are rather common to all than local.



Speakers and chairs of the 15th Belgrade Symposium for Balkan Region



#### News from Tunisia (STBC)

#### STBC 2019: Leading Lab Medicine in Disruptive times



*by Prof. Taïeb Messaoud* President STBC *Prof. A Hedhili* AFCB-EB Reg. Representative *Dr. Bernard Gouget* President, Healthcare Division Committee-Comité Français d'accréditation (Cofrac) Chair, IFCC-Committee on Mobile Health and Bioengineering in Laboratory Medicine (C-MHBLM)

The Royal Hotel and Convention center hosted the Société Tunisienne de Biologie Clinique (STBC) 2019 national congress at the Hammamet's Yasmine district. This place, well-kept secret, is a haven of tranquility, reflecting the Tunisian culture in a peaceful, uncluttered fashion.

Just arriving, luckily enough we got fresh lemonade from Tunisian-grown lemons, courtesy of the friendly organizers, before satisfying our thirst of knowledge attending the XXXIII National Days of Medical Biology (XXXIII Journées Nationales de Biologie Clinique (JNBC)), organized under the auspices of Madame Sonia Ben Cheikh, Minister of Public Health. The three days meeting gathered 800 participants and 15 IVD distributors providing an environment in which experts coming from Tunisia and abroad shared the most recent breakthroughs in medical diagnostic in a highly focused atmosphere.

With a deep sorrow, Prof. A. Hedhili, paid a vibrant tribute to the work of the IFCC President who dramatically passed away in mid-April 2019. Howard Morris has been a dynamic President, totally oriented toward the future of IFCC and very attentive to the Arab world which is at a critical juncture, with ambitious economic, social and health reforms bringing great promise to the region.

During the last IFCC-EB meeting, held last February 2019 at the Medina Hammamet center, he inspired discussions to unlock the creativity of the STBC, the Arab federation and young fellows to accelerate the progress toward an innovation-driven scientific model in order to create productive and widespread opportunities of collaborations to broaden new horizons and realize their potential of expertise within IFCC. Everyone will also remember him for his contagious laugh, his generosity in praise and concerns. Howard's spirit was present and his memory was persistent to a very extraordinary degree during the whole congress.

JNBC 2019 welcomed international speakers from France, Italy, Turkey. The XI pre-course on molecular biology has become a tradition. It was devoted to PCR-RFLP typing and DNA sequencing. On the first day, three workshops were organized on quality control on hemostasis chaired by Prof. N Kaabachi and Brahim Nsiri; Prof. Joseph Henny presented the recommended protocols for establishing reference values, and Prof. Tarek Barhoumi and Nabil Saklu on the data analysis with SPSS software.

For the first time, an IFCC TF-YS workshop on innovation in pre-analytical phase and advances in analytical and post analytical phases was planned with the collaboration of Prof. Pradeep Kumar Dabla, Maulana Azad Medical college, Delhi (IN) and chaired by Prof. Manel Chaabane, Faculty Pharmacy Monastir.

Article continued on next page

The inaugural conference on Thrombopathia and Constitutional thrombocytopenia was delivered by Prof. Remi Favier (CHU Trousseau, APHP, FR), the second plenary lecture by Prof. Jean-Jacques Boffa (CHU Tenon, APHP, FR) on Diabetic kidney disease and the third by Prof. Marc Delpech (CHU Cochin, APHP, FR) on diagnosis and treatment of hereditary or genetic diseases.

During two days, the topics of parallel sessions included: hemostasis and pregnancy, parasitosis and mycosis in ophthalmology; resistance to antibiotics, food allergies, new biomarkers, drug addictions. A debate on the new nomenclature, protection of personal data, privacy protection and GDPR compliance took place in presence of F. Blanchecotte, President, Union of private French Biologists (SDB).

Awards were delivered to the following scientists:

- Haouami Yosra received the "Abderraouf Mebazaa Award 2019" for the study of cytokine and transcriptional biomarkers during renal allograft.
- A "fundamental research in clinical biology" best poster award was given to Moslah Bilel for the comparison of two metabolomic approaches to estimate community drug abuse.

 Ben Dhaou Khouloud received the first best poster award in medical biology for the evaluation of carbapenemase detection tests and the second best poster was awarded to Mahdi Abdelkarim for the use of exopolysaccharides issues from probiotics to overcome antibiotic resistance

The 2019 program reflected a shortlist of some of the new developments in laboratory medicine—a glimpse into its future evolution. It is always a challenge to perceive which tests or techniques will have the biggest potential for use in everyday laboratory practices.

Free from their professional activities at the hospital or at their private laboratory, the Tunisian specialists of lab medicine were able to prioritize their own learning and to absorb the most recent information which they may later bring home to their colleagues. Peerto-peer interactions and interactions with thought leaders from the International Francophony Federation (FIFBCML) were important initiatives to stay updated in lab medicine in their fields of specialty.

No place is better for such interactions than the annual STBC live meeting, where Tunisian, international speakers and attendees are gathered together to discuss breaking data, biological, clinical challenges and future directions for patient care.



The STBC Executive Board L-R: Pr. Asma Ghariani, Pr. Farouk Barguellil, Pr. Brahim Nsiri, Pr. Taieb Ben Messaoud, Dr. Khalil Ben Abdallah, Pr. Manel Chaabene, Pr. Amina Bibi, Pr. Khalthoum Kallel



#### News from Italy (SIBioc)

#### SIBioc - ELAS 2019: Emerging visions in LabMed innovation and digital health

#### by Dr. Bernard Gouget

Chair IFCC C-MHLM, President-Healthcare Division Committee-Comité Français d'accréditation (Cofrac) **Prof. Damien Gruson** EC-Member IFCC-ETD **Prof. Sergio Bernardini** Chair-IFCC-ETD

Italian and international "tenors" from SiBioc, IFCC-ETD, IFCC-MHBLM and EFLM-EB members were welcomed the first day of the conference entitled «Expectations of Lab Medicine in the 2020's» at the «College San Carlo Foundation», prestigious complex, located in the historic center of Modena, in a baroque palace from the XVII century. This foundation is active in the field of philosophy, the humanities and the social and religious sciences. All settings successfully met to highlight the challenges and innovation in medical diagnostic and clinical lab medicine!

The morning session was chaired by Tomris Ozben, Tomas Zima and Mario Plebani. Graham Beastall, great well-known lecturer, inspiration to many, faithful friend, helped us to understand the added value of Lab medicine and its central role in healthcare. He presented the mnemonic added value 'SCIENCE' tool which is covering seven domains: standardization and harmonization; clinical effectiveness; innovation; evidence-based practice; novel applications; cost-effectiveness; and education of others. This assessment includes three dimensions: operational efficiency; patient management; and patient behaviors. "Leadership is required at international, national and local level," he said, "the time is now right to look outside the laboratory". Andrew St John, from the Australasian Association of Clinical Biochemists (AACB) defined the concept of a "Value Proposition for Medical Testing" as the provision of information to enable clinicians and other stakeholders to make better decisions about the care of individual patients.





#### Pavarotti Statue in Modena

The SIbioC-ELAS (European Ligand Assay Society) Conference in 2019, was organized between May 6-8 in Modena (IT), a city declared a «Unesco World Heritage site» since 1997. It is the second most populated area in the Emilia-Romagna Region, just after the neighboring capital Bologna. Modena has a famous University dated from 1175 which is the fifth oldest one in the world! This concept relies on better translation of global evidence into local and effective implementation of a test and requires a new skill set for the profession such as understanding economic modelling. Khosrow Adeli illustrated the critical need for innovative IFCC e-communication strategies like electronic chat rooms, fully Online e-Conferences, WebCasts/Webinars, and expansion of distance education with the addition of the e-Academy.

A new generation of technology is changing our lives and profession, from the everyday use of satnavs and smartphones through the profound ability of genomics helping us to develop precision medicine. A large part of the conference was dedicated to the discussion of the current topics at excellence in Lab Med and in digital health, the e-technologies, AI, m-Health and eHealth as well as to the development of the IF-CC-ETD strategic vision.

Artificial intelligence is currently the hottest topic in both technology and in medicine at large. Hardly a day goes by without promising research papers and studies being published on how to apply machine and deep learning methods to medical problems. The mention of A.I. makes companies prospects better on any market, hyping and overmarketing what an algorithm can do, is an everyday phenomenon. It is not an easy task to separate the wheat from the chaff. As Jean Christophe Mestres, (GIS Healthcare) said: "Only digital health can bring healthcare into the 21st century and make patients the point-of-care". AI is likely to transform all areas of health and medicine towards clinical decision-making. Our role is to prepare everyone for the adoption of innovative, disruptive and smart technologies while keeping the human touch. Al in healthcare and medicine could organize patient routes, intelligent disease monitoring or treatment plans better, and provide health professionals with literally all the information they need to make a good decision. More communication to the general public about the potential advantages and risks of using AI in medicine is needed, it is the only way to bring the promise of science fiction into reality and turn AI into «the stethoscope of the 21st century».

Damien Gruson stressed the fact that digital technologies will impact organization and lab workforce. The convergence of genomics, biosensors, electronic medical records, smartphone apps, and robotics will change the role and functions of the laboratory staff. Technological innovations will increasingly shift the balance of care toward more centralized care and decentralized less specialized care.

The presence of the EFLM President, Michael Neumaier, offered knowledge about the latest advances in immunology, to understand the existing paradigm of the bipartisan immune system and to get information on immune receptors from myeloid cells and models for functional studies. Then, Maurizio Ferrari, provided an overview of the applications of NGS in diagnostic. The scale and efficiency of high–throughput DNA sequencing technologies that can now be achieved is providing unprecedented progress in areas from the analysis of genomes themselves to how proteins interact with nucleic acids. He highlighted the breadth of next–generation sequencing applications and the importance of the insights that are being gained through these methods in various biological fields.



Prof. Michael Neumaier and wife; Dr. Khosrow Adeli and wife

As an introduction to the Round table, chaired by Bernard Gouget, Tricia Ravalico, IFCC CPD-CM, presented the «Univants of Health care excellence Award» which is recognizing integrated clinical care teams that are driving measurably better healthcare performance. The use of automation, robotics, has become widespread in clinical laboratories. Representatives from the industry reported their latest innovations. Michael Frandsen presented the transport pipeline «Tempus 600» designed to transport quickly blood and other small clinical samples and save crucial time. Andrea Pedrazzini (Impeco) spoke about the leading-edge systems to automate the entire diagnostic cycle for the perfect total testing process. A video, by Health tech Fly Ltd, explained the advantages of the use of drones in healthcare, illustrated by the Naples experience to deliver, blood, vaccines, tubes, organs, and other medical supplies. The drones can reach rural areas and provide the ability to assist victims who require immediate medical attention within minutes, which in some cases could mean the difference between life and death. They can also be used within hospital walls and courier blood between hospital buildings.

At the end of the day, everyone, according to their wishes, had the opportunity to visit the Duomo, International masterpiece of the Romanesque style, the plaza Grande, to buy parmesan cheese and the traditional balsamic vinegar at the Albinelli Covered Market or to take a rest listening Luciano Pavarotti, most famous tenor of the 20th century. At dinner, we were delighted by the typical Modenese cuisine (salami, zampone, cotechino sausages) and the so famous Lambrusco wine. On the second day, at the Maserati headquarters, we followed the entire production process, subject to numerous automated checks that ensured total quality, at very impressive high standards!



News from Pakistan (PSCP)

A Symposia on 'Overview of Laboratory Accreditation: ISO 15189 and CAP guidelines'

#### by Dr. Fatima Z. Kanani

Section Head and Consultant Chemical Pathology The Indus Hospital, Pakistan

Laboratory accreditation is a formal process by which a recognized body assesses and recognizes that a certain clinical laboratory meets the predetermined standards. This process ensures that the laboratory tests or service are accurate and reliable. So creating awareness amongst laboratorians regarding the laboratory accreditation process is important. To achieve this object a half day symposium on "An Overview of Laboratory Accreditation: ISO 15189 and CAP Guidelines" was held at The Indus Hospital, Karachi on May 2<sup>nd</sup>, 2019. The seminar was conducted by the Section of Chemical Pathology, The Indus Hospital, under the auspices of International Federation of Clinical Chemistry and Pakistan Society of Chemical Pathologists. The Seminar was accredited for two CME credit hours by PSCP, and was attended by above 70 participants

from 12 different institutions of Karachi, Pakistan, including consultant chemical pathologists, hematologists, microbiologists, histopathologists, laboratory managers, supervisors and laboratory technologists.

The first talk of the symposium was given by Dr. Usman Ali, Consultant Chemical Pathologist at the Ziauddin University on the differences between certification and accreditation, importance of accreditation and the overall process and requirements of ISO 15189:2012 accreditation. He talked about the relevance of documentation and formulation of standard operating procedures, and their implementation.

Following this, a talk was given by Dr. Sahar Iqbal, Associate Professor Pathology and Consultant Chemical Pathologist at the Dow University of Health Sciences. She spoke about the auditing process and clauses of ISO 15189, various challenges encountered in the process and ways to mitigate them. She also highlighted the significance of evidence and record keeping at every juncture.

The next part of the symposia was composed on laboratory accreditation requirements of College of American Pathologist. Dr. Lena Jafri, Assistant Professor and Consultant Chemical Pathologist at the Aga Khan University Hospital, addressed the key elements of CAP accreditation process. She focused on the significance of team work when undergoing such a major task. The detailed understanding of the CAP checklists,



Presenter delivering a talk on ISO: 15189 Laboratory Accreditation

implementation of the same, gap analysis, proficiency testing requirements etc. were all addressed at length.

These talks were followed by a discussion with an expert panel and an extensive question and answer session, led by the panelists comprising of the presenters and Dr. Aysha Habib Khan, Assistant Professor, Aga Khan University Hospital and Dr. Fatima Zehra Kanani, Section Head and Consultant Chemical Pathologist at The Indus Hospital. Overall, the session proved to be a great learning activity for the participants and was highly appreciated by them. Participants further encouraged the organizers to organize more such activities in the future.



Participants attending the symposia



Panel of Experts responding to queries raised by laboratorians



AND LABORATORY MEDICINE

#### **EFLM Biological Variation Database**





The database, produced by the EFLM WG "Biological Variation" (Chair: Aasne Karine Aarsand) and the EFLM TG "Biological Variation Database" (Chair: Sverre Sandberg) was launched at the EuroMedLab Congress in Barcelona.

The database, available via EFLM homepage or directly at https://biologicalvariation.eu, delivers updated evidence-based biological variation (BV) estimates to users worldwide.

#### PROJECT'S BACKGROUND

BV data are reference data that have many applications in laboratory medicine. The data describe the variability of clinically important measurands around homeostatic set points within subjects (CVI) and between subjects (CVG). The availability of well characterised data enables the interpretation of laboratory results in clinical settings and can be used to define analytical performance specifications (APS) and other applications. The literature describing studies of BV stretches back over 45 years. Reviews of BV data identify widely varying estimates for many measurands, calling for a new approach to deliver robust BV estimates for safe clinical application.

On this background, the Working Group on BV and the Task Group on the Biological Variation Database have developed a standard for evaluating studies on BV; the Biological Variation Data Critical Appraisal Checklist (BIVAC), a Minimum Dataset for BV studies and a meta-analysis approach for delivery of global BV estimates. These tools are used to populate the EFLM Biological Variation Database. To read more

Below are publications related to the EFLM Biological Variation Database. Additional publications from the WG-BV can be found here.

The Biological Variation Data Critical Appraisal Checklist: a Standard for Evaluating Studies on Biological Variation. Aarsand AK, et al. - Clin Chem 2018;64:501-14 Click here to access the abstract

Biological variation data for lipid cardiovascular risk assessment biomarkers. A systematic review applying the biological variation data critical appraisal checklist (BIVAC) Díaz-Garzón J, et al.- Clin Chim Acta 2019 doi:10.1016/j.cca.2019.05.013 Click here to access the abstract

Systematic review of the biological variation data for diabetes related analytes González-Lao E, et al. - Clin Chim Acta 2019;488:61-7 Click here to access the abstract

Harmonization initiatives in the generation, reporting and application of biological variation data Aarsand AK, et al. - Clin Chem Lab Med 2018;56:1629-36 Click here to access the paper

European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)

Silvia Cattaneo - Via Carlo Farini, 81 - 20159 Milano - Italy Tel: +39 389 5320051- e-mail: eflm@eflm.eu - website: www.eflm.eu

#### News from the IFCC Website



#### **DIAGNÓSTICO IN VITRO - Junio 2019**

Enjoy the contents of the new DIV June issue.

Empezamos el número de la revista electrónica DIV en memoria del Prof. Howard Morris, Presidente de IFCC (2016-2019). Expresamos nuestra profunda consternación y tristeza por la repentina pérdida. Otros artículos son: Novedades y Noticias, Artículos Científicos y la Sección para Jóvenes Científicos de IFCC que busca promover y contribuir con el cuidado de la salud en el mundo entero. También hayará en este número una entrevista completa realizada por "El Microscopio". With DIV, the IFCC WG-IANT confirms its commitment to advance excellence in laboratory medicine for better healthcare worldwide in Latin America.

#### Read more

www.seoul2020.org



# IFCC WorldLab SEOUL 2020

24<sup>th</sup> INTERNATIONAL CONGRESS OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE



#### **NEW IFCC MEMBERS**

IFCC welcomes two new corporate members

#### **ET Healthcare Inc.**

**ETHealthcare** 

ET Healthcare Inc. is an IVD Company initially focusing on the China clinical market. We offer a POCT/near patient system, Pylon, for cardiac and inflammation markers.

Website: www.ethealthcare.com.cn

#### **Immunodiagnostic Systems - IDS**

immunodiagnosticsystems

IDS is a leading in-vitro diagnostic solution provider to the clinical laboratory market. We develop, manufacture and market innovative immunoassays and automated immunoanalyser technologies to provide improved diagnostic outcomes for patients. Our immunoassay portfolio is a combination of an endocrinology specialty testing menu and assay panels in complementary fields. The portfolio is available as a combination of tests available for use on our fully-automated systems, or as stand-alone test kits. This complete offering meets the needs of both clinical and research laboratories of all types and sizes, with their diagnostic testing requirements. Our IDS heritage within certain endocrinology fields, including vitamin D testing, offers a solid

platform on which to develop a market-leading endocrinology menu for Bone Metabolism, Calcium Metabolism, CKD-MBD (Chronic Kidney Disease & Mineral Bone Disorders), Fertility, Growth Disorders and Hypertension. Through partnership, we develop a broader complementary menu, extending into other clinical areas such as Allergy, Autoimmunity and Infectious Disease.

Website: www.idsplc.com

#### IFCC'S CALENDAR OF CONGRESSES, CONFERENCES & EVENTS

Calendar of IFCC Congresses/Conferences and Regional Federations' Congresses			
Sep 10 - 13, 2019	COLABIOCLI	COLABIOCLI Regional Congress 2019	Panama, PA
Sep 26 - 28, 2019	A statement of clinical case	AFCC Regional Congress	Marrakesh, MA
Nov 17 - 20, 2019	15 <sup>th</sup> APFCB 2019	APFCB Regional Congress 2019	Jaipur, IN
May 24 - 28, 2020	Figure County of Landowsky Indexes	XXIV IFCC WorldLab Seoul 2020	Seoul, KR
May 29 - 30, 2020	International Federation of Clinical Chemistry and Laboratory Medicine	IFCC - ICHCLR Workshop on reference materials and regulations for global standard- ization of clinical laboratory testing	Seoul, KR
May 16 - 20, 2021	EUROMEDLAB 2021 MUNICH	XXIV IFCC - EFLM EuroMedLab Munich 2021	Munich, DE

May 21 - 25, 2023



XXV IFCC - EFLM WorldLab EuroMedLab - Rome 2023

Rome, IT

#### Calendar of events with IFCC auspices

Feb 25 - Dec 31, 2019	Bolivian Continuing Education Program (PROBOECO) of the Bolivian Society of Clinical Biochemistry	Different cities, BO
Jun 3 - Oct 30, 2019	Distance Training Workshop for University Teachers	Online Event
Jun 5 - Dec 24, 2019	Postgraduate course of analytical quality in the clinical laboratory	Online event
Aug 20 - 23, 2019	73º Congreso Argentino de Bioquímica	Buenos Aires, AR
Sep 9 - 14, 2019	XLIII Congreso Nacional de Químicos Clinicos y Expoquim	Mexico City, MX
Sep 11 - 13, 2019	XXIV Congreso Latinoamericano de Bioquímica Clínica (COLABIOCLI) and XIV Congreso Nacional de Laboratoristas Clínicos de Panamá	Panama City, PA
Sep 22 - 24, 2019	XIV Congress of Czech Society of Clinical Biochemistry	Plzen, CZ
Sep 24 - 26, 2019	Cardiac Biomarkers Symposium - High Sensitive Troponin: Present and Future	Tel Aviv, IL
Sep 25 - 27, 2019	Congreso Nacional Bioquímico CUBRA XV 2019	Chaco, AR
Sept 25 - 29, 2019	16th Annual Meeting of the DGKL e. V.	Magdeburg, DE
Sept 26 - 28, 2019	LMCE 2019 and KSLM 60th Annual Meeting	Busan, KR
Sep 28 - Oct 1, 2019	10th Santorini Conference "Systems medicine and personalized health and therapy" – "The odyssey from hope to practice: Patient first – Keeps Ithaca always in your mind"	Santorini, GR
Oct 1, 2019	41st Conference LABAC	Paris, FR
Oct 2 - 5, 2019	4th Advances in Circulatory Tumour Cells (ACTC) Meeting, Liquid Biopsy: Latest Advances and Future Challenges	Corfù, GR

Oct 3 - 4, 2019	CELME 2019	Prague, CZ
Oct 3 - 5, 2019	XII Congress of Clinical Biochemistry	Montevideo, UY
Oct 8 - 10, 2019	5th National Congress SIPMeL – The Centrality of Laboratory Medicine in the Diagnostic Process	Riva del Garda, IT
Oct 16 - 18, 2019	5th ESPT Congress – Precision Medicine and Personalized Health	Seville, ES
Oct 23, 2019	From Bench to Diagnostic-Therapeutic Pathways - Symposium dedicated to the memory of Professor Angelo Burlina	Padua, IT
Oct 23 - 25, 2019	20th Congreso Chileno de Quimica Clinica y Ciencias del Laboratorio	Santiago, CL
Oct 27 - 31, 2019	The Joint Congress of 27th Balkan Clinical Laboratory Federation (BCLF) Congress and 30th National Biochemistry Congress (NBC) of TBS	Antalya, TR
Nov 1 - 4, 2019	19 International Congress of the Colegio Nacional de Bacteriologia, CNB Colombia	Bogotà, CO
Nov 6 - 8, 2019	3èmes Journées Francophones de Biologie Médicale	Monaco, MC
Nov 7 - 9, 2019	The Value of Laboratory Medicine into Clinical Medicine	Erice, IT
Nov 21 - 22, 2019	Journées de l'innovation en biologie (JIB 2019)	Paris, FR
Nov 28, 2019	CIRME - 13th International Scientific Meeting - - The Internal Quality Control in the Traceability Era	Milan, IT
Nov 28 - 30, 2019	XIX National Congress of Clinical Laboratory Professionals: Scientific Perspectives to the Technological Advances of the 21st Century	Santo Domingo, DO
Dec 6 - 7, 2019	53e JBP, Journées de Biologie Praticienne	Paris, FR
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