№ 10 October 2023



International Federation of Clinical Chemistry and Laboratory Medicine



Communications and Publications Division (CPD) of the IFCC Editor: Katherina Psarra, MSc, PhD IFCC Office, Via C. Farini, 81 20159 Milano, Italy E-mail:<u>enews@ifcc.org</u>



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Editorial



Dear colleagues

It is already the 1st of October. The fall is here and most of us have begun forgetting their summer vacations.

It is a good time for IFCC because many more National societies are joining and even laboratory societies of different disciplines than purely Clinical Chemistry. You will find out a lot about these activities in the President's message, where you will also learn about the progress in the guidelines concerning several methods and the new Working Group created to support this activity.

And then, there is a very interesting interview of Prof. Christa Cobbaert, Chair of the IFCC Scientific Division. You will read about the activities and plans of the Scientific Division, a very important division, the backbone of all the events that take place, like the WorldLab to be held on May 2024 in Dubai. The history of the IFCC SD is there not to forget to mention its future.

The fall is here, dear colleagues, and I am sure that a lot of congresses take place in your countries, congresses of your national societies of Clinical Chemistry, as well as other laboratory societies. Have a look at the falling leaves of the trees, let the autumn mood relax you and write a report for the IFCC eNews. We are looking forward to them.

And don't forget to propose your candidates for the IFCC awards in Dubai. You can read about them in this issue also.

Choose the best of the best!

Katherina



Katherina Psarra, MSc, PhD, eNews Editor

The voice of IFCC

IFCC President's Message

October 2023 By Khosrow Adeli

My warmest greetings to everyone at IFCC. I hope you all are enjoying the arrival of the Fall season. To start, I am delighted to inform you that the IFCC Organization is experiencing significant growth in its membership base. We have received applications from several new societies and countries seeking to become full or affiliate members, and we have welcomed numerous new corporate members in just the past few months. Pending ratification by the IFCC Council, we anticipate having 98 national societies as full members, more than 20 affiliate members, and 58 corporate members. This remarkable achievement breaks all previous records across all membership categories, underscoring the heightened visibility, influence, and global reach of the IFCC organization. Later this year, we will be publishing a special feature article in the eNews, highlighting all the new IFCC national societies, affiliates, and corporate members that have joined IFCC over the past three years.

Additionally, there is a growing interest in IFCC membership from societies and entities in various specialties within laboratory medicine, extending beyond clinical chemistry. The IFCC Executive Board is enthusiastic about recommending an expansion of the IFCC's membership scope, aiming to encourage participation from all areas of clinical laboratory diagnostics and clinical laboratory medicine. To align with this vision, we will be proposing amendments to the IFCC statutes, facilitating the inclusion of other specialties within the IFCC organization. Furthermore, the IFCC Executive Board is advocating for changes in the election process for Executive Board members to foster a more inclusive opportunity for individuals within the IFCC community to contribute to the board. The proposed amendments suggest that no individual should serve in the same position on the Executive Board for more than six years in total. Additionally, individuals cannot be nominated for more than one position in the same year or election cycle. Stay tuned for forthcoming updates! A ballot will be initiated, and all IFCC Full Member Societies will be invited to vote on the proposed revisions to the IFCC statutes, ensuring the continued growth and success of the IFCC Organization.

I'm also thrilled to announce the **formal launch of the new IFCC initiative on Laboratory Medicine Practice Guidelines.** The IFCC Executive Board has granted approval for an innovative program aimed at encouraging IFCC functional units, including committees, taskforces, and working groups, to create and share best practice recommendations and guidelines across all facets of clinical laboratory medicine. This program is dedicated to facilitating the implementation of these recommendations in clinical laboratories worldwide. Under this program's umbrella, **the IFCC will develop various types of guidance documents, encompassing best practice recommendations, position papers, and comprehensive**



Prof. Khosrow Adeli PhD, FCACB, DABCC, FAACC

IFCC President's Message

evidence-based and graded practice guidelines. These documents will be made widely and freely available, serving as valuable resources for laboratory professionals. Their purpose is to provide guidance, establish standards, and promote best practices within the field of laboratory medicine. Undoubtedly, these resources will contribute significantly to enhancing the quality of laboratory practices worldwide, with a particular focus on benefiting developing countries. To oversee and drive this program forward, we are in the process of forming an IFCC Taskforce on Laboratory Medicine Practice Guidelines (TF-LMPG). This taskforce will serve as a steering group, providing program oversight, and will also act as a review panel to evaluate proposals submitted by various functional groups. Stay tuned for further updates and contributions from this exciting initiative.

Finally, in partnership with MZ Events, the Arab Federation of Clinical Biology, the Saudi Society of Clinical Chemistry, and the UAE Genetics Association, IFCC is diligently working on preparations for our upcoming flagship scientific event, the **IFCC WorldLab Congress**, scheduled to take place in the fabulous city of **Dubai from May 26 to May 30, 2024.** More information to follow in future editions of the eNews.

As always, feel free to email me at president@ifcc.org with your feedback, questions, or concerns.

Cheers,

Khosrow ©

VLP Report on 33rd MACB Annual Scientific Conference

By Dr. Merve Sibel Güngören , IFCC Clinical Laboratory Management Committee Member (C-CLM)

As members of IFCC Committee on Clinical Laboratory Management (C-CLM), we have been kindly invited to the 33rd Malaysian Association of Clinical Biochemists (MACB) Annual Scientific Conference "Paradigm Shift of Laboratory Medicine – Knowledge Engineering" which was held during 4th – 6th September 2023. We had lectures during the pre-conference workshop on the 4th of September and a symposium on the 5th September.

IFCC C-CLM Workshop was titled as "Benchmarking Quality Performance in the Clinical Laboratory" and my lecture was about autoverification, titled as "The Concept and Framework of Autoverification". Our workshop was kindly moderated by MACB President, Dr. Raja Elina Aziddin who is also a member of IFCC C-CLM. This workshop was designed to include three main lectures about hot topics of analytical and postanalytical phases (analytical performance specifications, moving average and autoverification), each of them followed by studies presented by distinguished Malaysian colleagues. Presentations integrating conceptual and practical aspects of these important topics were enriched with constructive discussions. This workshop was a great opportunity for us to interact with our Malaysian colleagues, to observe the level of implementation of novel tools like moving average and autoverification and to learn about local details of clinical laboratory practice in Malaysia.

After the workshop, Prof. Yee Yean Chew, the president of the MACB 33rd Conference, was kind enough to take us to her laboratory at University Malaya Medical Center (UMMC) which holds an ISO 15189 accreditation. We were impressed by the testing capacity and variety.

IFCC C-CLM Symposium on Innovative Solutions in Laboratory Medicine was held on the 5th of September, as one of the morning sessions. My talk was on digital transformation strategies in clinical laboratories. The level of attendance and questions from the participants reflected the interest of Malaysian laboratory medicine community on this topic.

This visit to Kuala Lumpur as a representative of IFCC was an honour for me, as I was able to present my expertise to an audience from a different part of the world. In my opinion, VLP creates great opportunity both for us as speakers and the local participants of these events for networking, learning from each other and disseminating the vision of IFCC.

I stayed at Kuala Lumpur for five days and four nights. The venue of the event was Pullman Kuala Lumpur Bangsar Hotel which was converted shortly before the event into Wyndham Grand Bangsar Hotel. I would like to thank Dr. Raja Elina Aziddin, Dr. Yee Yean Chew and all members of MACB Organizing Committee and MACB Council members for this successful event.

MACB was established and registered in 1990 and has more than 500 members today. During the conference, there were around 250 participants including exhibitors. Compared to total number of members, I find the level of commitment very impressive. I have very positive impressions for Malaysian Clinical Biochemistry community. I think they need to have more interaction with global experts to benchmark their position and navigate their strategies for further planning.

Lastly, I would like to thank IFCC, Abbott, and IFCC-Abbott VLP Chair, Prof. Sedef Yenice for their support for this great visit.

VLP Report



Opening Ceremony of the 33rd Malaysian Association of Clinical Biochemists (MACB) Annual Scientific Conference



Dr. Raja Elina Aziddin, Malaysian Association of Clinical Biochemists (MACB) National Representative and IFCC C-CLM member, bestowing a certificate to Dr. Güngören.



Speakers and Audience of the Workshop ""Benchmarking Quality Performance in the Clinical Laboratory".



Dr. Güngören giving her presentation "The Concept and Framework of Autoverification".



Group photo in front of one Mural at University Malaya Medical Centre (UMMC)





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Troponin I Lp-PLA2 *hs-cTnl (STAT)

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Metabolism

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Pepsinogen II Gastrin-17

GH (hGH)

tPAIC

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Ferritin Folate (FA) EPO **RBC** Folate

IFCC Distinguished Awards for the IFCC WorldLab Congress

- Dubai (UAE) 2024 - 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 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 **IFCC Distinguished Awards** for presentation at the I**FCC Congress in May 2024, Dubai (UAE)**

- 1. IFCC Howard Morris Distinguished Clinical Chemist Award (since 2020) IFCC Distinguished Clinical Chemist Award (1967- 2017). sponsored by <u>Yashraj Biotechnology Ltd.</u>
- 2. IFCC Award for Significant Contributions in Molecular Diagnostics sponsored by <u>Abbott</u> <u>Laboratories.</u>
- 3. IFCC Distinguished Award for Laboratory Medicine and Patient Care.
- 4. IFCC Distinguished Award for Contributions to the Cardiovascular Diagnostics sponsored by <u>HyTest.</u>
- 5. IFCC-Gérard Siest Young Scientist Award for Distinguished Contributions in Pharmacogenetics (under 40 years of age) sponsored by <u>Biologie Prospective.</u>
- 6. IFCC Distinguished Women Scientist Award for Contribution to In Vitro Diagnostics sponsored by <u>Yashraj Biotechnology Ltd.</u>

Please note that each country/society can only nominate candidates for a **maximum of 2** awards. This rule allows a better distribution of awards to scientists from various regions around the world.

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),

4) Copy of ID as proof of age for the IFCC-Gèrard Siest Young Scientist Award.

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

A more detailed description of them, including the former honorees, can be found by <u>clicking on this</u> <u>link</u>.

For the 6 (six) Dubai Awards, the closing date for receipt of nominations is 31st December 2023.

IFCC Distinguished Awards



APFCB News 2023 Issue 2

Prof. Pradeep Kumar Dabla, Chief Editor, APFCB eNews says: "The APFCB is glad to present you the 2nd issue of APFCB eNews, 2023. The APFCB Committee-Communication & Publication has worked committedly to raise the communication standards and networking with the member societies & partners while updating addresses office bearers so that important information could reach all members within time. Though not limited, we plan to extend communication via social media platforms, automated e-mailing, and providing archived electronic information archived electronic information: webinars, educational videos, and other modern tools".

Click on the image to download your copy!

The painting on the cover, by Dr. Tan It Koon, Founding President of SACB and APFCB and Former IFCC Executive Board Member and WHO Member of Expert Committees, is titled "A Beautiful View of the Three Gorges in China".

News from the website





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IFCC: the people

IFCC Calls for Nominations



Communications and Publications Division (CPD)

<u>Committee on Public Relations (C-PR)</u> - 2 members positions <u>Working Group eJIFCC – eJIFCC Editor-in-Chief</u> position <u>CPD Executive Committee</u> (CPD-EC) Corporate Representative position

Nominations should be sent to the IFCC office (colli-lanzi@ifcc.org) by 31st October 2023

Task Force for Corporate Members (TF-CM)

3 Member positions: The open positions include (1) one new member position, (2) opportunity to serve as the secretary, and (3) opportunity to serve as chair.

Nominations should be sent to the IFCC office (paola.bramati@ifcc.org) by 31st October 2023

Emerging Technologies Division (ETD)

<u>ETD Executive Committee (ETD-EC)</u>: 3 members + 1 corporate member. <u>Committee for Emerging Technologies in Pediatric Laboratory Medicine (C-ETPLM)</u>: 3 members <u>Committee on Mobile Health and Bioengineering in Laboratory Medicine (C-MHBLM</u>): 1 member

Nominations should be sent to the IFCC office (colli-lanzi@ifcc.org) by 15th November 2023

Task Force on Ethics (TF-E)

1 Member position

Nominations should be sent to the IFCC office (colli-lanzi@ifcc.org) by 15th November 2023

Education and Management Division (EMD) Committee on Clinical Laboratory Management (C-CLM) - 1 member

Nominations should be sent to the IFCC office (cardinale@ifcc.org) by 3 December 2023

For any further information on nominations, please refer to your National or Corporate Representative - contacts are available <u>here.</u>

Report and Interview to Prof. Christa Cobbaert

Chair of the IFCC Scientific Division

By María Pasquel-Moxley, Member C-PR WG-IANT/RIA/, eJIFCC





Prof. Christa Cobbaert, Chair of the IFCC Scientific Division (SD)

Dr. BQF. María Pasquel-Moxley interviewer

Summary of professional activities, Prof. Christa Cobbaert.

Christa Cobbaert is heading the Clinical Chemistry and Laboratory Medicine Department at the Leiden University Medical Centre (LUMC) in Leiden, the Netherlands. Her scientific research in the domains of Cardiovascular Risk Management, Kidney Disease and Cancer Biomarkers, has a major focus on Precision Diagnostics using next generation protein diagnostics based on mass spectrometry. Mass spectrometry allows to revisit old biomarkers and to select emerging molecular defined biomarkers, for the sake of personalized patient management/ outcome. Mass spectrometry also allows protein standardization at the molecular level. In her research group promising biomarkers which have the potential to fulfil unmet clinical needs in the clinical care pathways of the mentioned research domains are selected, multiplexed into protein panels, and quantified at the molecular level using mass spectrometry-based proteomics, a generally accepted alternative for replacing flawed and hardly standardized immunoassays. Finally, her research group uses quantitative MS-based bottom up proteomics also as a platform for establishing global Reference Measurement Procedures and Reference Measurement Systems for e.g. serum apolipoprotein standardization, through certification of IVD-manufacturers.

Professor Cobbaert is currently the chair of the IFCC Scientific Division EC, involved with metrology and standardization of medical tests (http://www.ifcc.org/ifcc-scientific-division/) and a member of ISO TC 212 working group 2 on reference systems. She is representing EFLM in the IVD subgroup of the Medical Device Coordination Group during meetings with the European Commission on the interpretation of the IVDR 2017/746. In this capacity she chairs the EFLM Task Force on European Regulatory Affairs (https://www.eflm.eu/site/page/a/1650). Her work resulted in ~230 original publications, multiple lectures/webinars and several appointments at (inter)national positions because of her expertise on metrological traceability of test results.

Interview:

History of the IFCC Scientific Division:

A Committee on Standards was established in 1966 "to instigate and promote theoretical and practical developments in the field of standards and standardization in clinical chemistry - in its broadest sense". Following a Council decision in 1978, efforts have been made to extend its work to include more subjects of interest both to clinicians and clinical chemists and laboratorians. Accordingly, the name of the Committee was changed to the Scientific Committee and later to the Scientific Division.

The Scientific Division (SD) is a functional unit of the IFCC and its activities are managed by an Executive Committee (EC). This EC is responsible for (1) developing the mission statement, (2) developing strategy and tactics, (3) initiating and managing standardization/harmonization projects of prioritized medical tests, and (4) generating and adhering to its Terms of Reference. The **mission of the SD** is to advance the science of Clinical Chemistry and Laboratory Medicine and to apply it to the practice of Clinical Laboratory Science. SD's **major focus** is on **implementing the metrological traceability concept for global test standardization / harmonization** by establishing working groups (task oriented) or committees (theme oriented) who develop ISO-compliant reference measurement procedures, reference materials and reference measurement systems.

Dear Dr. Christa Cobbaert, with this introduction taken from the IFCC website <u>Scientific Division</u>, please answer the following questions:

1. Do you think that this mission can be expanded or generate other working groups or committees within the SD with the rapid advance of artificial intelligence in laboratory medicine?

Indeed, the IFCC SD faces challenging times as the evolution in technology, metrology, (data) science already impacts the way how we establish working groups (WGs) and define objectives. A good example is the neonatal bilirubin working group which is a joint WG of the IFCC SD and the IFCC Emerging Technology Division (ETD). A joint WG was considered to be essential for test standardization of conventional central lab methods measuring neonatal bilirubin but also for new non-invasive transcutaneous devices and biosensors used by pediatricians at the point-of-care. Ultimately, irrespective of the methods used appropriately standardized tests and exchangeable test results should be the norm in order not to confuse medical doctors and not to harm neonates.

With the rapid advance of artificial intelligence (AI) the need for valid and well standardized data that can be pooled among trials and healthcare institutions is ever increasing. Especially if AI becomes part of e.g. -omics applications in medical labs and gets integrated in our Laboratory Information Management Systems, it becomes part of the medical test process. Consequently, a more holistic approach for evidence-based test evaluation and standardization will be needed, as well as an intensified collaboration among the four IFCC divisions (Education and Management respectively Communications and Publications Divisions are the other two) in order to keep pace with all developments. Finally, from a regulatory perspective AI will be considered an IVD test, its risk classification being dependent on its intended use. To handle all these opportunities, partnerships, consortia and/or alliances are needed between IFCC and IVD-industry, professional societies, the metrology world, and other collaborators such as ICHCLR and the JCTLM committee. There is no room anymore for working in silos.

2. The second objective of the IFCC SD is developing strategies and tactics. Considering that we live in such a changing and different world, how do you consider these tactics? Can strategies be used in the different realities of science and technology in developing, as compared to developed countries?

The availability and accessibility to metrological traceable test results differs among developing and developed countries. Once the metrological traceability concept has been adopted and implemented for prioritized tests by the IVD-industry test results become traceable to higher order reference materials/ reference measurement procedures. In an ideal world there should be commitment from the IVD-industry, especially those manufacturers with a global span, to produce these state-of-the-art reagents unmodified also for markets in developing countries. Unfortunately, this is not always the case and essential ingredients may be left out.

Also, as developing countries may use open analyzer systems and self-developed applications, there is an enhanced risk that the metrological traceability of these test results is hampered. In addition, the burden of proving safety and effectiveness of **in-house** tests is then the responsibility of the individual healthcare institution. This situation is experienced as a double-edged sword for low- and medium-income countries.

3. Point three indicates that SD is responsible for managing projects! Do you have a project in mind to develop, or are you already doing so? Can you, please, share the projects with our readers?

IFCC SD EC manages standardization/harmonization projects of 20 task oriented working groups (see <u>SD Working Groups - IFCC</u>) and 6 theme oriented committees (see <u>SD Committees</u> - <u>IFCC</u>). The Committee on Bone Metabolism works on the standardization of PTH assays, bone marker assays, and vitamin D metabolite assays. The IFCC WG on Apolipoproteins by Mass Spectrometry has established a reference measurement procedure (RMP) for standardization of 7 apolipoproteins [apo(a) in Lp (a), apo A-I, apo B, apo CI, CII, CIII and E] for more refined cardiovascular risk management, beyond lipid profiling. As Lp (a) is a genetically determined risk factor which accelerates ASCVD and aortic stenosis, it is now recommended to be measured once in a lifetime by the European Atherosclerosis Society expert committee. Note that the RMP is mass spectrometry-based with bottom-up proteomics. It detects and measures apolipoproteins at the molecular level. The highly heterogeneous apo(a) in Lp(a), one of the most misunderstood metrics in clinical chemistry so far. It will be standardized in two steps: firstly, by making Lp(a) test results traceable to SRM2B and expressing them in molar units, and secondly by making the results SI-traceable in the nearby future.

Another example is the PT/INR working group, a collaboration between the IFCC and the International Society of Thrombosis and Hemostasis (ISTH) which develops a sustainable metrologically traceable calibration hierarchy for INR based on an internal protocol for value assignment with a single primary reference thromboplastin and the harmonized manual tilt tube method for clotting time determination. Intermethod variability of PT results in commercial tests is about 40% among manufacturers but by establishing this reference measurement system it is anticipated that the intermethod variability will be reduced to < 10% among manufacturers once the RMS is adopted. Both POCT-devices and wet chemistry tests can then be standardized.

4. Is SD planning something? For example, regarding the POCTs that are now regulated and are part of ISO 15189:2022?

POCT tests should be evaluated and standardized like central lab tests in a similar way. So, there is no need to have a separate ISO-standard for POC tests. The goal should also be that both POC and central lab test results do not confuse caregivers and are exchangeable. In the end it comes down to implementing the metrological traceability concept and establishing a calibration hierarchy compliant with ISO 17511:2020 in collaboration with all relevant stakeholders. For the

PT/INR handheld meters used on wards in hospitals and by patients in the home situation, the testing takes place in capillary fingerprick blood. The calibration of a manufacturer's POC test against a (secondary) reference thromboplastin is therefore performed with split plasma samples.

5. Finally, there are any messages that you can give to the thousands of colleagues who read this magazine, and especially to young scientists who face a very big challenge in terms of technological development and the forward leaps in laboratory medicine.

The young generation is invited to become actively involved in the IFCC and its activities for building the future of laboratory medicine. Be(come) part of this impactful non-political professional organization and contribute to implementing the metrological traceability concept for proper test standardization, or select other topics that interest you and contribute to safer and more effective diagnostics and healthcare.

Dear Prof. Dr. Christa Cobbaert, we appreciate your time, effort and dedication in leading this Division.

You are a brilliant professional who works very hard for the development of science in laboratory medicine.

We congratulate you and thank you for taking the time to write this report.

Sincerely,

Dr. BQF. María del C. Pasquel - Moxley Interviewer



The current IFCC SD (Rome 2023), chair Prof. Christa Cobbaert.

Report and Interview to Prof. Christa Cobbaert



Visiting lecture tour end of August at the occasion of the IPCLM in Palestine.



Visiting lecture tour end of August at the occasion of the IPCLM in Palestine. Prof. Christa Cobbaert and authorities.

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> MICHAEL DOWLING President and CEO, Northwell Health, USA



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QUINT STUDER Co-Founder, Healthcare Plus Solutions Group, USA



"We have opportunities to develop appropriate clinical algorithms that can help ensure that patients get the care that they need"

OCTAVIA PECK-PALMER Division Director, Clinical Chemistry, Associate Professor of Pathology, University of Pittsburgh School of Medicine, USA



"Many of us have the ideas, the plans and the scientific knowledge, but we need to be able to ensure that it aligns with what people are able to do."

YIN LING WOO Professor of Obstetrics and Gynaecology, Consultant Gynaecological Oncologist, University of Malaya, University Malaya Medical Centre, Malaysia



"Every voice matters as we collaborate to improve the health of individuals and populations around the world."

CHRISTINA CARABALLO Vice President, Informatics, HIMSS, USA



"We have to completely reimagine what is the role of the clinical lab, not at a test level, but in the longitudinal way of data that gives us a meaningful way to predict risk."

KHOSROW SHOTORBANI President, Executive Director, Project Santa Fe Foundation, USA Founder and CEO, Lab 2.0 Strategic Services, USA "Together, we can address diagnostic error which the NASEM reports to not only be possible, but a moral, professional, and public health impe<u>rative."</u>

> **PAUL EPNER** Vice-Chair, Sepsis Alliance, USA



"Through the use of a new biomarker, multiple health systems were able to save and mitigate downstream costs while improving health for the entire ecosystem."

TRICIA RAVALICO Director, Scientific Leadership and Education, Core Diagnostics, Abbott, USA

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Contribute to IFCC eNews

Getting to zero harm in controlled substance prescribing: Increasing the accuracy of prescription compliance monitoring through enhanced drug testing support

The opioid epidemic is a serious public health crisis, with a growing need to find new ways to help support both patients and providers to improve overall outcomes. The Centers for Disease Control and Prevention (CDC) estimate that over 100,000 deaths in 2021 were a result of drug overdoses, a 15% increase from 2020, with opioids accounting for a disproportionate number of those deaths. Thus, while many efforts have been made, opportunities exist in the opioid epidemic to help improve patient outcomes.

A key component to battling the opioid epidemic is utilizing laboratory medicine to inform clinical decision-making, enhance monitoring and reduce overdoses. As part of the University Hospitals (UH) Pain Management Institute and Department of Pathology's response, an integrated clinical care team involving clinical, laboratory, and risk management leaders, sought to effectively use urine drug testing as a key component to their safe controlled substance prescribing. This team aimed to enhance opioid monitoring by improving physician confidence and accuracy of ordering and interpreting lab testing for controlled substance monitoring.

This process was multi-faceted and included newly designed and inclusive drug test panels, accompanied by intuitive naming, built-in reflexes between screening and confirmatory testing, and a comprehensive analytic method to detect commonly prescribed opioids and benzodiazepines. Guidance and educational materials were also strategically rolled-out to provide guidance to clinical stakeholders and users. Lastly, laboratory medicine was integrated into the clinical process through a new laboratory toxicology consultation service. Through this new process, UH has increased



Pictured from left to right: Jaime Noguez, Christine Schmotzer, Sean Hoynes, Heidi DelVecchio, Jeanne Lackamp

compliance to appropriate follow-up of presumptive positive drug screens with >98% compliance, while decreasing drug testing costs by 25%. This change corresponds to a 35% increase in clinician compliance with the testing guidelines and has increased clinical confidence related to drug testing. For their efforts and outcomes, this integrated clinical care team was awarded the 2022 UNIVANTS of Healthcare Excellence award recognition of Distinction. Congratulations to Jaime Noguez, Director, Clinical Chemistry & Toxicology, Christine Schmotzer, Vice Chair, UH System Pathology Operations, Sean Hoynes, Director, Risk Management at UH Primary Care Institute, Heidi DelVecchio, Senior Risk Management Officer, Jeanne Lackamp, Director, UH Pain Management Institute.

For more information on this best practice and others, please visit <u>www.univantsHCE.com</u>. To learn about educational opportunities associated with UNIVANTS, please visit <u>www.HealthcareELX.com</u>.

Satellite Meeting





SATURDAY 25TH MAY 2024

INTERNATIONAL CONGRESS OF PEDIATRIC LABORATORY MEDICINE

Topics

Immunodeficiencies

Immuno-flow cytometry in pediatric laboratory medicine

Genomics vs Mass spectrometry in pediatric laboratory medicine

Newborn Screening for SCIDs

NGS in diagnosing undiagnosed diseases



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Investigator Initiated Studies: An Opportunity for

Collaboration with Industry

By Jean-Sebastien Blanchet, Director Medical and Scientific Affairs, Beckman Coulter Nadav Kaufman, Senior Director, Global Marketing, QuidelOrtho Anne Skurup, Senior Medical Advisor, Radiometer Medical, ApS

This article was developed in support and with endorsement from the IFCC Task Force Corporate Members (TF-CM). It is not however all encompassing with general trends and recommendations and is not necessarily representative of the positions of the companies employing the authors.

What are Investigator Initiated Studies (IIS)?

Investigator Initiated Studies (IIS) are defined as studies conceived and led independently by investigator(s). IIS are proposed and managed by external researchers who are not employed by a product manufacturer and may be supported and/or have associations/partnerships with one or more manufacturers.

Some diagnostic manufacturers may be readily interested in supporting investigator-initiated studies as a valued way to expand the knowledge base supporting a specific product. Such independent evaluations may also support mandatory post market surveillance needs performed by manufacturers.

When companies initiate clinical studies, internal teams define the study aims, protocols, statistical analysis plan, expected publication, and many other details. Clinical studies required for product registration as part of the IVDR regulation in Europe or FDA submission in the US are usually entirely managed by companies' clinical and regulatory affairs departments, following strict execution processes and well-defined quality standards.

IIS are different, as they are initiated from an unsolicited proposal by an independent investigator, who then maintains control of the study. As such, most supporting companies leave a large degree of freedom to investigator(s) for most aspects of the study, so long as minimum expectations are met to ensure high quality standards, good business practices and legal, ethical and regulatory compliance.

Why propose an IIS?

Investigators may propose IIS to manufacturers to address a wide variety of scientific objectives, including:

- To evaluate analytical and/or clinical performance of an assay in specific patient populations, in the context of local standard of care or specific therapies, including real-world evidence.
- To perform reference interval studies: either to confirm the manufacturer's proposed ranges or to add ranges for specific patient populations.
- To address the potential clinical impact of an intervention in preanalytical, analytical or postanalytical phases to improve laboratory workflow, time to first result and patient outcomes, leading to the demonstration of clinical utility and potentially to the development of institution's policies.
- To demonstrate the health economics benefits of an IVD assay in routine clinical practice.

Steps to Propose an IIS:

Companies typically evaluate IIS proposals through a formal review process, which often includes a scientific review, as well as compliance assessment. These reviews assess the scientific and clinical relevance of the proposal, robustness, as well as the appropriateness of the requested support. This review process can be lengthy, depending upon the various teams involved, and may take between two and twelve weeks to decide if and how support for the study is possible.

1. Identify the research question.

To propose an IIS, first identify an area of interest and determine what scientific question(s) you seek to answer. Innovative and novel studies are preferred by some companies, but studies which seek to confirm previous conclusions also have relevance, as they reinforce scientific understanding.

2. Design the protocol.

Once the research question is well defined, identify the appropriate study design to answer the question. Develop a detailed protocol describing the study. It is important to keep in mind that for IIS the protocol should be provided by the investigator. However, companies may offer suggestions to the protocol after an initial review to ensure the quality of the study.

3. Estimate the budget.

Based on the protocol, an assessment of the required support will be defined and requested from the sponsoring company(ies). The support may range from simply seeking no-cost reagents/ consumables, to much broader support such as provision of an analyzer, on-site support and training, or technical resources. Companies may also provide financial support to fund statistical analysis, testing labor, and writing of results. An agreement on the study outcomes, timelines and the final publication of the data shall be reached as well between the investigator and the supporting company.

4. Establish the contract.

The company will conduct an internal review of the proposal to ensure scientific quality, but also to validate that the company support matches a fair market value, in compliance with legislations. Following a positive internal review, a contract will be established between the company and the investigator institution. The study can only begin after approved contract(s) are in place.

Some companies may choose to follow up on study progress on regular basis, and provide financial support based on milestones.

How to contact the company?

To propose an investigator-initiated study, simply directly contact the target company and/or companies via their web sites for scientific and medical affairs support or through your local company contact.

Investigator Initiated Studies



Jean-Sebastien Blanchet, Director Medical and Scientific Affairs, Beckman Coulter



Nadav Kaufman, Senior Director, Global Marketing, QuidelOrtho



Anne Skurup, Senior Medical Advisor, Radiometer Medical, ApS

News from Regional Federations and Member Societies

Rare Links: Launch of the Rare Registry

Report from Pakistan



By Dr Sibtain Ahmed, (Aga Khan University, Karachi, Pakistan)

The "Rare Links" webinar series, hosted by Aga Khan University, successfully organized a hybrid education session titled "Embarking on a Pioneering Journey: The Launch of the Rare Registry" on August 31, 2023. This event brought together national and international experts to share insights and experiences related to the launch of the RARE DISEASES REGISTRY by the section of Chemical Pathology, Department of Pathology and Laboratory Medicine. This registry is a milestone for the newborn screening and diagnostics of inherited metabolic disorders (IMDs) in Pakistan. The webinar aimed to educate participants about the importance of a Rare Registry in enhancing patient care and research for IMDs, explore strategies for the sustained operation of the registry, and highlight the crucial role of accurate data collection within it.

The event commenced with opening remarks by Professor Imran Siddiqui (Professor Chemical Pathology and Dean of the Faculty of Chemical Pathology at CPSP). Dr. Lena Jafri (Section Head of Chemical Pathology) then unveiled the details of the Rare Registry through a comprehensive and thought-provoking presentation.

This was followed by a panel discussion, titled "Rare Dialogue Expedition," moderated by Dr. Hafsa Majid (Assistant Professor in Chemical Pathology). The panellists included esteemed experts such as Dr. Aysha Habib Khan (Professor Chemical Pathology, Dr. Bushra Afroze (Associate Professor, Paediatrics & Child Health), Ms. Azeema Jamil (In charge NBS Iab), Dr. Muhammad Bilal (Genetic specialist), Mr Shahnawaz Yunus (Data entry operator), and Dr. Ayesha Niaz Shaikh (Young physician).

Dr. Sibtain Ahmed, an Assistant Professor in Chemical Pathology, led an engaging session on the roadmap for the sustainability of the Rare Registry, using a Padlet activity to encourage interactive participation from the attendees.

The event concluded with closing remarks by Dr. Erum Khan, Professor and Chair of the Department of Pathology & Laboratory Medicine, underlining the significance of collaborative efforts in advancing research and healthcare in the field of rare diseases.

The webinar attracted a diverse audience including pathologists, paediatricians, physicians, residents, laboratory professionals, nurses, and geneticists. More than 50 participants actively engaged in the event through the Zoom platform, while a significant number of attendees were present at the Peer Learning Space at Aga Khan University, Karachi.

In a country like Pakistan, where the prevalence of rare diseases often goes unnoticed due to limited resources and awareness, the establishment of a Rare Disease Registry holds immense significance. Such a registry provides a centralized repository of data related to rare diseases, enabling better patient care through early diagnosis, informed treatment decisions, and the identification of potential research avenues. Additionally, the Rare Registry will facilitate collaboration among healthcare professionals, researchers, and policymakers, fostering a comprehensive approach towards addressing the unique healthcare challenges posed by rare diseases in the region.

Overall, the "Embarking on a Pioneering Journey: The Launch of the Rare Registry" webinar played a pivotal role in raising awareness, fostering collaboration, and initiating crucial discussions around rare diseases and IMDs diagnostics in Pakistan.

Glimpses from Rare Links-CME Session:



Group photo of participants.



Dr Hafsa Majid moderating the panel discussion



Dr Imran Siddiqui giving the welcome address



Dr Lena Jafri unveiling the details of the Rare Registry.



Dr Sibtain Ahmed leading the Padlet activity.



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XXIII National Congress of Clinical

Chemistry and Laboratory Medicine



®EXPOLAB Veracruz 2023 (Mexico)

By QC Maria Yolanda Larrazolo Ramos, Coordinadora de Publicidad del XXIII Congreso Nacional de

Química Clínica y Medicina de Laboratorio® EXPOLAB Veracruz 2023 - Federación Nacional de Colegios

de la Química Clínica AC (FENACQC - MX).

On April 28, 2023, the XXIII National Congress of Clinical Chemistry and Laboratory Medicine ®EXPOLAB Veracruz 2023 was held, being hosted by the College of Laboratory Medicine Professionals of the Veracruz region, where some up-to date topics in the area of clinical chemistry were reviewed in order to encourage continuous study in our profession. Beginning on April 28 and ending on April 30, renowned national and international speakers shared scientific advances and experiences in the different areas discussed. The event was held at the facilities of the Hotel "Galleria Veracruz Square". Among the activities of the congress, the Diploma Award Ceremony for Chemists from the different affiliated Colleges and associations, that accessed the 2023 Professional Certification process, was held. During the closing ceremony, awards and recognition were given to the winners of the "Dr. Manuel A. Rodríguez Quintanilla" and to the commercial house that won the Technological Innovation Award, which on this occasion was the LICON commercial house. The attendees were thanked for their presence and invited to the XXIV National Congress of Clinical Chemistry and Laboratory Medicine ®EXPOLAB Playa del Carmen.



Attendees XXIII National Congress of Clinical Chemistry and Laboratory Medicine - ®Expolab Veracruz 2023



EXPOLAB Veracruz 2023



Young Scientists at the Free Works Competition



Inauguration ®Expolab Veracruz 2023



Organizing Committee XXIII National Congress of Clinical Chemistry and Laboratory Medicine - ®Expolab Veracruz 2023



Certified Chemicals 2023

40th Anniversary of the Hong Kong Society

of Clinical Chemistry



By Dr Iris CHAN, IFCC National Representative HKSCC, Department of Chemical Pathology, Prince of

Wales Hospital, Shatin, HONG KONG

The year 2023 is the 40th Anniversary of HKSCC. It was started with the Annual Scientific Meeting (ASM) held on 7 January 2023. This was the first physical ASM of the society since the COVID-19 pandemic. The theme of the ASM was "Current Advances in Clinical Investigation and Management". There were two presentations by invited speakers: (1) " Development of Robotic Surgical System for Clinical Application - from Laparoscopic to Endoscopic Surgery" by Professor Philip WY CHIU, Head of Division of Upper GI & Metabolic Surgery, Department of Surgery; Associate Dean (External Affairs), Faculty of Medicine, The Chinese University of Hong Kong; and (2) " Therapeutic Drug Monitoring of 5-fluorouracil to improve Patient Safety and Drug Efficacy" by Dr Felix CK WONG, Consultant, Division of Chemical Pathology, Department of Pathology, Queen Mary Hospital. These were followed by five industrial presentations by Beckman Coulter Hong Kong Limited, Bio-Rad Pacific Limited, Ortho Clinical Diagnostics and Roche Diagnostics (Hong Kong) Limited, Waters Corporation. The ASM was well attended by 139 HKSCC members and guests. There were also fifteen industrial partners participating in the industrial exhibition.



Group photo of HKSCC Council Members (Term 2022 – 2023) with Industrial Partners in HKSCC 40th Anniversary Celebration



ASM 2023 (7 Jan 2023): Prof Philip WY CHIU



ASM 2023 (7 Jan 2023): Dr Felix CK WONG

40th Anniversary Hong kong Society of Clinical Chemistry

A dinner lecture was held on 18th May 2023 jointly by Hong Kong Society of Clinical Chemistry and Thermo Fisher Scientific (Hong Kong) Limited. There were two presentations by invited speakers: 'New Insights of Biomarkers in Clinical Application' by Ms KH CHONG, Product Manager (Biomarkers) APAC, Thermo Fisher Scientific, and 'Bringing the Power of Rapid NGS to Rare Diseases and Oncology' by Dr Amy LAM, Field Application Scientist, Genetic Science Group, Thermo Fisher Scientific, Hong Kong. The lecture was attended by 120 members and guests.





Ms KH CHONG

Dr Amy LAM

Highlight of the year was the dinner lecture held on 25th August 2023. Professor Dennis YM LO, Li Ka Shing Professor of Medicine, The Chinese University of Hong Kong was invited to present a topic on 'Creating Paradigm Shifts in Molecular Diagnostics'. The lecture was well attended by 158 members and guests.



Prof. Dennis YM LO during his presentation

EFLM's New Corporate Membership Status:

Strengthening Bonds with IVD Companies

By Tomris Ozben, EFLM President

Individual IVD, biomedical, and pharmaceutical companies, corporate entities, as well as research establishments, play a significant role in the field of Laboratory Medicine. For this reason, it is imperative to establish robust connections with these entities to ensure alignment in decisionmaking processes, foster effective communication, and promote collaboration between industry professionals and laboratory experts.

This rationale has led the EFLM Executive Board to introduce a new membership status specifically tailored for Corporate Members. This project proposal underwent thorough and meticulous discussion during the EFLM Executive Board meeting held in Rome on May 21, 2023. It received unanimous approval, highlighting its potential to create valuable communication channels between EFLM and the IVD industry. Subsequently, the proposal was presented to the EFLM General Meeting, the governing body of EFLM, which convened in an extraordinary meeting on September 7, 2023. This meeting included 35 Full National Societies Members and 4 Affiliate National Societies Members (the latter having observer status). An unanimous and affirmative vote was cast in favour of incorporating the new Corporate Membership status into EFLM and amending the EFLM Articles of Association to accommodate the necessary changes.

On behalf of the EFLM Executive Board and EFLM National Societies, I am pleased to share this new EFLM initiative with the IFCC and its members. We have initiated a recruitment campaign for IVD companies and related entities interested in participating in the EFLM Corporate Membership program. Those wishing to become part of this initiative can ensure their inclusion by contacting the EFLM Office at <u>eflm@eflm.eu</u> through Silvia and Terry.



New IFCC Members

IFCC WELCOMES A NEW FULL MEMBER: ARMENIA

The IFCC welcomes the Association of Medical Laboratory Diagnostics Specialists (AMLA) – Armenia.

The "Association of Medical Laboratory Diagnostics Specialists - Armenia" is now the 96th Full Member within the IFCC.

Best wishes for a long and fruitful participation into IFCC activities and projects for advancing excellence in laboratory medicine for better healthcare worldwide.







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26th International Congress of Clinical Chemistry and Laboratory Medicine

17th Congress of Arab Federation of Clinical Biology

10th Saudi Society for Clinical Chemistry Annual Meeting

8th International and UAE Genetic Disorders Conference

DEADLINES

15 January 2024 Deadline for poster abstract submission

15 March 2024 Deadline for reduced registration fees

Dubai World Trade Centre (DWTC)

News from the IFCC Website



The IFCC webinar: "Laboratory medicine - a critical role for patients in disease diagnosis and monitoring" took place on September 13, 2023.

The laboratory tests evaluate the clinical status, confirm the diagnosis, and allow medical doctors to assess if the treatment is efficient. Also, laboratory medicine gives the possibility to evaluate the patient and choose which is the best method or methods of personalized diagnosis for the patient, being integral to prevention, screening, diagnosis, treatment, and monitoring.

This webinar comprised of three following presentations of 20 min each:

Chair: Dr. Mirela Ahmadi

Talk 1 - "Assessing the specific tumoral markers, inflammatory status, and vitamin D metabolism before and after the first chemotherapy cycle for lung cancer patients" - Ms. Andreea Crintea Talk 2 - "The importance of molecular diagnosis of tuberculosis" - Dr. Mirela Ahmadi Talk 3 - "The association between the PLIN1 rs2304795 gene and Metabolic Syndrome in obese patients" Ms. Stanislav Alexandra Alina

News from the IFCC Website



Click here for registering

The 10th October webinar on "**Interference on high sensitivity troponin assays**" will give an overview of analytical and biological interference affecting troponin assays, the analytical methods needed to detect interference and further discuss the clinical consequences of troponin interference and discuss a and potential biological meaning of detecting such results. It will comprise of three following presentations of 20 min each

Moderator: Dr. Kristin Moberg Aakre (Norway)

Talk 1: Analytical and biological interferences for cardiac troponin assays; what should we look out for and when? **Dr. Pete Kavsak (Canada)**

Talk 2: Detecting troponin interferences; recommendations for the routine laboratory **Prof. Ola Hammarsten (Romania)**

Talk 3: When clinically can macrotroponins be confounding? Dr. Allan S. Jaffe (USA)

News from the IFCC Website



Waste from a Clinical Analysis laboratory can cause contamination and illness if not handled properly. Infectious waste, especially sharps, presents a risk to those who may come into contact with it. Many of diseases due to occupational exposure among health personnel correspond to hepatitis B infections and HIV infections. Laboratories also generate chemical, pharmaceutical and radioactive waste, which requires special handling, and large amounts of common waste. In some countries all this waste is mixed and burned in incinerators and this incineration generates large amounts of polluting substances. These substances can be transported polluting the environment not only where they are burned but also over long distances. If laboratory waste is not treated properly and is disposed of together with common waste, those who handle this waste also face a danger. It is important to promote the reduction of the entry of hazardous substances to the waste stream. There are alternatives that are safer and cleaner than incineration and are equally effective in rendering waste harmless. Being aware of the risks of poor handling of laboratory waste is very important and seeing how to implement measures to minimize these risks is essential.

This webinar comprises of three following presentations of 20 min each

Moderator: Dr. Ana Maria Lena

Talk 1: Adequate disposal of waste in the Clinical Analysis Laboratory - Lic. **Xavier Solans** Talk 2: Adequate disposal of waste in the Clinical Analysis Laboratory - Chemist **Carlos Alberto Severiche Sierra**

Talk 3: Impact on health due to inadequate handling of hazardous waste - Biochemist **Gustavo** Adolfo Velasco

IFCC's Calendar of Congresses, Conferences & Events

IFCC and Regiona Events	l Federation		
Date		Title	Place
Oct 10, 2023	EXAMPLE Live Series 2023	Interference on high sensitivity. troponin assays	Live webinar
Dec 4,- Dec 5 2023	Accurate results for patient care	2023 JCTLM Workshop on: 'EQA schemes elucidating the clinical suitability of laboratory results'	Sèvres, FR
Jan 25, - Jan 26 2024		AFCC CONGRESS 2024	Cairo, EG
May 25, 2024	Energing technologies in Pediatric Laboratory Medicine	XVII ICPLM - INTERNATIONAL CONGRESS OF PEDIATRIC LABORATORY MEDICINE	Dubai, UAE
May 26 - Jun 30, 2024	WORLDLAE DUBAI 2024	XXVI IFCC WORLDLAB - Dubai 2024	Dubai, UAE
May 26, - Jun 30 2024	ARAB FEDERATION OF CLINICAL BIOLOGY	AFCB Congress in conjunction with the XXVI IFCC WorldLab Dubai 2024 Congress	Dubai, UAE
Oct 3 - 6, 2024		XXVI COLABIOCLI 2024	Cartagena, CO
October 31 - Nov 3, 2024	APFCB	APFCB 2024 Sydney	Sidney, AU
May 18 - 22, 2025	BRUSSELS 2025 May 18-22, 2025	XXVI IFCC-EFLM EUROMEDLAB 2025	Brussels, BE

Date	Title	Place
Nov 18, 2023	Inter-QC Topics	Quality Academics, online, MX
Other events with IFCC auspices		





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- and Laboratory Medicine (APFCB) European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)
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France: French National Network of Accredited Laboratories of Medical Biology (LABAC)

India: Association of Medical Biochemists of India (AMBI) Iran: Iranian Association of Clinical Laboratory Doctors (IACLD) Jordan: Society for Medical Technology & Laboratories (SMTL) Kazakhstan: Public Association - Federation of Laboratory Medicine (FLM)

Mexico: Federación Nacional de Químicos Clínicos (CONAQUIC A.C.)

Mexico: Colegio Nacional de Químicos Clínicos en Medicina de

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Spain: Asociación Española de Biopatología Médica - Medicina de Laboratorio (AEBM-ML)

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United Arab Emirates: Genetic Diseases Association (UAEGDA)

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The Communications and Publications Division publishes ten editions of the e-News per year, including two double issues.

Editor

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The eNews is distributed to all IFCC members registered on-line to receive it and to all IFCC sponsors.

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