MADRID
XII General Conference

Feeding the future of IFCC now!

Chair: Bernard Gouget

Hotel Auditorium-Marriott, Madrid, Spain
19-21 March 2016
### General Conference Session 1:
**Chair:** Sergio Bernardini

<table>
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<tr>
<th>Time</th>
<th>Session</th>
<th>Chair</th>
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<tbody>
<tr>
<td>08.30</td>
<td>Welcome</td>
<td>Bernard Gouget</td>
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<td>Opening of the General Conference</td>
<td>Sergio Bernardini</td>
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<td>08.45</td>
<td>The IFCC Executive Board:</td>
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<td>08.45</td>
<td>Strategic Plan (2016-2017)</td>
<td>Maurizio Ferrari</td>
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<tr>
<td>09.15</td>
<td>Treasurer’s report</td>
<td>Tomris Ozben</td>
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<td>09.45</td>
<td>Corporate Members’ report</td>
<td>Rolf Hinzmann</td>
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<tr>
<td>10.15</td>
<td>Discussion</td>
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<td>10.30</td>
<td>Coffee Break</td>
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<tr>
<td>11.00</td>
<td>IFCC Federations’ Report</td>
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<td>11.00</td>
<td>AFCB</td>
<td>Mohammed Assan Kamil</td>
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<td>11.15</td>
<td>AFCC</td>
<td>Adekunle B. Okesina</td>
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<td>11.30</td>
<td>APFCB</td>
<td>Leslie Lai</td>
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<tr>
<td>11.45</td>
<td>COLABIOCLI</td>
<td>Q. F. Graciela Queiruga</td>
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<td>12.00</td>
<td>EFLM</td>
<td>Mauro Panteghini</td>
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<td>12.15</td>
<td>NAFCC</td>
<td>David Kinniburgh</td>
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<td>12.30</td>
<td>Discussion</td>
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<td>13.00</td>
<td>Lunch (seat assigned by drawing lot)</td>
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### General Conference Session 2:
**Chair:** Leslie Lai

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<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>14.00</td>
<td>EMD Executive Summary</td>
<td>Leslie Lai</td>
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<td>14.15</td>
<td>Mentoring Programme</td>
<td>Donald Young</td>
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<td>Developing Quality Competence in Medical Laboratories (DQCM)</td>
<td>Michael Thomas</td>
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<td></td>
<td>Cancer Genomics: Revolution in Medical Practice</td>
<td>Jason Park, Paolo Fortina</td>
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<td>15.00</td>
<td>Crossing science and education: HbA1c analysis:</td>
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<td>Understanding what is measured fundamental to interpretation</td>
<td>Garry John</td>
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<td>15.30</td>
<td>Discussion</td>
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<td>15.45</td>
<td>EMD-CPD Joint Interactive Session:</td>
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<td>IFCC eAcademy: “The new tool for Implementation of Distance Learning Programs in Laboratory Medicine”</td>
<td>Janet Smith, Peter Vervaart</td>
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<td>16.15</td>
<td>Coffee break</td>
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16.35-18.20 General Conference Session 3: Chair: Khosrow Adeli

16.35 CPD Executive Summary Khosrow Adeli
16.45 IFCC PR Activities: “Facing the Digital Future of IFCC Communications” Edgard Delvin
17.05 Value and Impact of Laboratory Medicine in Healthcare: An IFCC Taskforce Report Khosrow Adeli
17.25 IFCC Website: A Guided Tour Janine Grant
17.45 Digital Publishing in Academia: Recent Advances Tahir Pillay
18.05 Discussion

19.45-22.00 Dinner with keynote address and discussion Moderator: Damien Gruson
“The protective role of Mediterranean diet on cardiovascular disease, risk in the Environmental Health Perspectives” Invited Speaker: Prof. Demosthenes Panagiotakos, Harakopio University, Athens

08.00-09.00 Continuation of the EB/Divs (Cs+WG) closed meetings

09.00-10.30 General Conference Session 4: Chair: Rolf Hinzmann

09.00 Corporate Members - Introduction Rolf Hinzmann
09.15 Strengthening partnership between IFCC and its Corporate Members Graham Beastall
09.30 Keynote Lecture: Serving patients, physicians and payers, Challenges for the IVD industry in a rapidly changing environment Patrick Bugeon
10.10 Discussion

10.30-11.00 Coffee Break

11.00-12.30 General Conference Session 5: Chair: Ian Young

11.00 SD Executive Summary Ian Young
11.15 Standardization of laboratory tests - why it is needed Graham Beastall
11.35 Standardization of laboratory tests - how to do it Greg Miller
11.55 Standardization - the example of thyroid function tests Linda Thienpont
12.15 Discussion

12.30-14.00 Lunch
### 14.00-15.20  Continuation of General Conference Session 5:  
**Chair: Philippe Gillery**

- **14.00**  
  Keynote address: Emerging and disruptive technologies  
  Larry Kricka
- **14.20**  
  Measurement and clinical utility of CSF proteins  
  Kaj Blennow
- **14.40**  
  Standardization of autoimmune tests: successes and challenges  
  Joanna Sheldon
- **15.00**  
  Discussion

### 15.20-15.45  Coffee Break

### 15.45-18.00  General Conference Session 6:  
**Coordinator: Vanessa Steenkamp**

**SPANISH ROOMS (mezzanine floor)**

Simultaneous interactive workshops suggested by IFCC Functional Units, National Societies and Regions.

Each topic will be presented 3 times, as per below schedule:

- **15.45-16.25**
- **16.25-17.05**
- **17.05-17.45**

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<tr>
<th>UNITS</th>
<th>TITLES</th>
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<tbody>
<tr>
<td>TF-CB</td>
<td>Rationale use of contemporary and high-sensitivity cardiac troponin assays</td>
<td>J. Ordoñez-Llanos</td>
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<td>TF-PG</td>
<td>Precision, Personalized and Stratified Medicine: the central role of Lab Medicine in its development and clinical use. Where do we stand, where can we go?</td>
<td>R. van Schaik</td>
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<td>TF-PLM</td>
<td>Critical Values for Use in Children</td>
<td>S. Geaghan, V. Grey</td>
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<td>TF-YS</td>
<td>Research as a career – A Perspective From Young Scientist</td>
<td>P. Dabla</td>
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<td>C-AQ-C-CLM</td>
<td>What is the best strategy to achieve compliance with QMS- and QC-requirements in the clinical laboratory?</td>
<td>E. Amann, S. Yenice</td>
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<td>CLMA/IFCC Project</td>
<td>Increasing Clinical Effectiveness (ICE)</td>
<td>G. Beastall</td>
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<td>AACB (AU)</td>
<td>Demonstrating the value of Laboratory Medicine</td>
<td>H. Morris, A. St John</td>
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<td>ACB (UK)</td>
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<td>AACC (US)</td>
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<td>Turkish Biochemical Society (TBS)</td>
<td>1. Biological variation and patient safety. How should clinicians interpret laboratory results?</td>
<td>A. Coskun</td>
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<td>2. Worldwide standardized education and training in clinical chemistry and laboratory medicine</td>
<td>D. Aslan</td>
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<td>Radio “El Microscopio”</td>
<td>Biochemistry 2.0</td>
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<td>Biochemistry Knowledge Management - Knowledge economy</td>
<td>H. Fares-Taie, S. Fares-Taie</td>
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<td>Improving the use and interpretation (value) of Biochemistry Information.</td>
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<td>TF-POCT</td>
<td>POCT: Tackling the Current Issues and Planning for Future Ones</td>
<td>A. Khan</td>
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<tr>
<td>TF-PT</td>
<td>Meeting the clients with the producers on Proficiency Testing of rare analytes</td>
<td>A. Haliassos</td>
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17.45 Open meeting with all IFCC National Representatives and Representatives from Iberoamerican countries

Rosa Sierra Amor, Jose Queraltó
Participation at IFCC activities, and sharing experiences: interactive discussion

19.30-20.00 Aperitif and Concert
20.00-22.00 Gala Dinner

MONDAY 21 MARCH 2016

08.00-09.00 Continuation of the EB/Divs (Cs+WG) closed meetings

09.00-10.30 General Conference Session 7: Chair: Tomáš Zima

09.00 C-CC Executive Summary
The emergent hybrid Lab Med Conferences: future vision of IFCC congresses and meetings

Tomáš Zima

09.30 Evolution of the IVD Industry’s ongoing support for congresses according the business ethics codes

Peng Yin

09.50 The forthcoming IFCC congresses presented by the Congress Presidents

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<thead>
<tr>
<th>IFCC/Event</th>
<th>Location</th>
<th>Dates</th>
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<tbody>
<tr>
<td>XIV APFCB</td>
<td>Taipei, TW</td>
<td>(Nov 26-29, 2016)</td>
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<td>XXIII COLABLIOCLI Congress 2017</td>
<td>Punta del Este, UY</td>
<td>(Sept 17-22, 2017)</td>
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<td>XXIII IFCC WorldLab 2017</td>
<td>Durban, ZA</td>
<td>(Oct 22-25, 2017)</td>
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<td>XXIII IFCC-EFLM EuroMedLab 2019</td>
<td>Barcelona, ES</td>
<td>(May 19-23, 2019)</td>
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10.20 Discussion

10.30-10.40 Coffee break
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<th>Time</th>
<th>Event</th>
<th>Details</th>
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<tbody>
<tr>
<td>10.40-11.30</td>
<td>TF-Ethics: Pearls along with three complete “Pearls”</td>
<td>Chair: Ann Gronowski</td>
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<td>Ethics in Laboratory Medicine: Using “Pearls” as an innovative teaching method</td>
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<td>11.30-12.00</td>
<td>Closing remarks</td>
<td>Maurizio Ferrari</td>
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<td></td>
<td>Outcome of Madrid General Conference and new perspectives for IFCC</td>
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<td>12.30-13.45</td>
<td>Lunch</td>
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<td>14.00-15.30</td>
<td>Regional Federations’ closed meetings</td>
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<td>15.30-18.30</td>
<td>Free afternoon: City tour sponsored by Sociedad Española de Bioquímica Clínica y Patología Molecular (SEQC)</td>
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<td>20.00-22.00</td>
<td>Dinner</td>
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Dear Colleagues,

The XII IFCC General Conference will be held in Madrid, Spain (19-21 March 2016) during the second year of the term of Prof. Maurizio Ferrari, IFCC President and his executive board (2015-2017). More than 250 participants will come together to celebrate innovation, imagination and inspiration and their passion for a better in health and lab medicine. The IFCC General Conference is the triennial closed meeting for the IFCC Functional Units. Its aim it to convene all the IFCC functional units at one time and location and to bridge the many scientific projects where relevant research takes place, to plan and to decide on future actions of the federation.

IFCC is a dynamic organisation that evolves constantly. Besides the presentation of the Strategic Plan and Finance, the GC Madrid 2016 program is designed to provide an innovative and comprehensive overview of the latest IFCC developments. Also, we directly asked the chairs of the Divisions, in coordination with the chairs of Committees, Working Groups and Task forces to select the topics and to present the most recent activities and projects as well as their vision on the future of laboratory medicine in the 21st Century.

The IFCC brings together more than 90 full and 12 affiliate members organized in six regions. That’s why it is essential to convene a round table with the Presidents of six IFCC regional partners who established formal relationships to discuss the interrelation between regions and how it can be developed in the future in a spirit of solidarity, efficiency and respect for the specific characteristics of each of them. The floor is also given to the 46 Corporate Members to express the IVD industry challenges and opportunities to capitalize on their strengths in line with the needs of the market in collaborating with IFCC scientists. Young scientists bring new blood and new ideas. A large international and Spanish delegation will be present. They will certainly stimulate debate around the future of the lab medicine community. The General conference is an ideal opportunity to further extend the IFCC leadership position and to meet its goal through discussion in an atmosphere of collegiality and a spirit of optimism. We are confident that the meeting will further strengthen international interdisciplinary cooperation.

We would like to express our thanks to the Societad Espanola de Bioquimica Clinica y Pathologica Molecular (SEQC) for welcoming us to Madrid, a beautiful and passionate city that boasts art, culture, science and sports; this makes the perfect place to celebrate the XII IFCC General conference.

Many thanks to the IFCC office, the MZ Congressi and the Madrid Convention Bureau for their invaluable collaboration and assistance.

Yours sincerely,

Bernard GOUGET
Chair, IFCC GC Madrid 2016

Sergio BERNARDINI
IFCC Secretary
First of all it is my great pleasure to welcome you at the General Conference in Madrid. This is the right moment to meet all members of IFCC coming from all over the world to gather and exchange ideas. The organization of the General Conference is already completed. I am certain the organizing did an outstanding job in delivering a programme of high quality and interest containing innovative ideas and of direct relevance to modern laboratory medicine and for the future of IFCC. These are exciting times in the world of Laboratory Medicine. Therefore, laboratory medicine specialists and the diagnostic industry have a responsibility to work together to convert data into knowledge which can be used to add value to patients’ health.

To reach this goal I’m supported by a team as talented as the Executive Board and IFCC Office and I know that we can look forward with confidence.

In writing this article I decided to focus the presentation on the future of IFCC, particularly looking to the opportunities that lie ahead for laboratory medicine for the specialists and corporates in our profession and for IFCC. For this reason, I start to describe some of the IFCC achievements of the past year in a single paragraph: here are a few headlines:

- Empowerment of the IFCC Regional Federations (new NAFCC)
- Collaboration with international scientific and clinical organizations (e.g. WASPaLM)
- Education and management support for developing countries
- Improved website publications and communications
- Promoting both quality and the added value of laboratory medicine
- Facilitating more professional congresses conferences and meetings
- Restructuring of the Executive Board (Federations representative)
- Financial transparency and stability
- Development of an efficient and much valued IFCC Office team
- Strengthening ‘The Family’ of IFCC

At the end of 2015 the EB debated on the future direction for laboratory medicine to update and ameliorate the strategic plan. We decided to perform a SWOT analysis that is a structured planning method used to evaluate the strengths, weaknesses, opportunities and threats involved in a project or in a business venture. A SWOT analysis can be carried out for a product, place, industry or person. It involves specifying the objective of activity and identifying the internal and external factors that are favorable and unfavorable to achieve that objective. For this activity we utilized an external professional company.
With this partner we recently organized a meeting with the participation of the EB, Division chairs, Federations representatives, Corporate representative and IFCC office. The experience was very interesting and at the end of the two-day working we learned a lot on how to evaluate our activity and we reached the goal to produce a list of priority actions for the next three periods (<6 months, 6-12 months, 9-24 months). Moreover, we defined a new vision of IFCC. With this activity we reviewed our strategic plan that will be presented in Madrid.

I would like to conclude saying that IFCC is a vibrant organization which enjoys growing international recognition and respect and is ideally placed to play a leadership role in helping to shape the future of laboratory medicine at both national and international levels.

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The aim of the IFCC General Conference, held mid-way between the triennial Council meetings, is to convene the IFCC Executive Board and all the IFCC functional units to network together and to meet the Presidents and Officers of the IFCC Regional Federations and Representatives of Full, Affiliate and Corporate Members at one time and location. Current activities and projects are discussed, future actions of the organization are decided and planned. This enables face to face discussions and helps to further develop the ‘IFCC family’ allowing the members of the various functional units and various IFCC members to hear about the activities carried out within IFCC, and to understand how their efforts fit in with the other components of the IFCC.

IFCC supports special projects to fulfil its role in promoting high scientific standards in the worldwide practice of Clinical Chemistry and Laboratory Medicine with the aim to advance knowledge and improve the quality of clinical laboratory science in health care and medicine.

IFCC relies heavily on volunteers to run the organisation and undertake its range of activities and programmes. In the recent years, the activities of IFCC have increased sharply with the formation of new scientific functional units in accordance with the vision and mission of IFCC as the world leading organization in clinical chemistry and laboratory medicine. The number of volunteers working actively in these activities has reached over 300. While appreciating and supporting these activities and voluntary work of the members, IFCC needs and seeks more financial sources and support for the sustainability of these activities. The aim of the IFCC Board is to set up a realistic budget, seeking to promote and sustain the current activities while making space for the funding of innovative projects. The General Conference will provide an opportunity to inform you about the financial situation of IFCC regarding the details of the operational revenues and financial income and operational costs and financial charges.

I wish you all a pleasant and fruitful meeting and hope that General Conference in Madrid will be a long memorable event for all of the participants.
IFCC’s Corporate Members contribute significantly to the overall IFCC activities in all three Divisions and in their Executive Committees. They actively collaborate in most of the scientific activities and sponsor conferences and travel programs as well as scientific awards.

The IVD industry is facing significant changes, reflecting challenges alongside with new opportunities. Some examples are:

- The IVD industry is very innovative but it is getting more challenging to make the medical value associated with new tests / products available to patients and healthcare providers at adequate reimbursement in reasonable time.
- Decision making is shifted from lab professionals to budget controllers. Price often ‘eats’ quality.
- Regulatory submissions are becoming more complex. Local regulatory requirements increase.
- The recognition of lab professionals being in charge of lab testing, quality assurance and result interpretation is sometimes challenged and the belief becomes prevalent that ‘everyone’ can test and interpret the data, including new tests or combinations of tests.
- More people get access to healthcare. Economic growth often goes along with better access to healthcare for a large proportion of the population. ‘Middle-class’ people are becoming more health-conscious.
- ‘Big Data’ companies are providing solutions that are partially complementary to IVD products and enhance their usefulness, and partially competitive.

Some ways how IFCC can help its Corporate Members in this situation:
- Increase awareness for the importance of lab testing.
- Together with clinical societies, support medical claims leading to reimbursement.
- Emphasize the importance of quality and use IFCC’s unique expertise in standardization.
- Align more with others (CLSI, FDA, clinical societies, etc.) to avoid inconsistency and duplication of guidelines and recommendations.

MedTech Europe (an organization comprising EDMA and Eucomed) has issued a new code regulating the interaction between the IVD industry and healthcare professionals (HCPs) on various levels. The new rules for industry sponsorship of conferences will impact IFCC and the current model of conducting conferences will need to change:
• For third-party organized conferences (main program): Companies may not directly support an HCP, neither as a delegate, nor as a speaker.
• For company-organized events in the framework of third-party organized conferences (e.g. satellite symposia): Companies may directly support speakers (i.e. their consultants) but not delegates.
• Educational grants are still possible. They can only be provided to legal entities but never individuals.
• Companies will be able to define the type of recipients which should be eligible for the grant but not individual recipients.
• Companies must have an internal & independent process based on objective criteria to assess the grant requests.

In January IFCC conducted an analysis of its strengths, weaknesses, of opportunities and threats (SWOT). The major topics from a corporate point of view were:
• How to re-define & enhance the value of IFCC for Corporate Members to increase corporate membership and avoid membership termination to guarantee the important financial contribution of the IVD industry?
• How to better (1) enable and (2) monitor the efficacy and effectiveness (= output) of committees, working groups and task forces?
• How to better link IFCC to clinical societies?

Corporate Members fully support IFCC’s vision to advance excellence in laboratory medicine for better healthcare worldwide.

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The Arab Federation of Clinical Biology (AFCB) was established in 1974 in Egypt. The AFCB is managed by its Executive Board (EB) that is elected periodically every three years. Each member society in the AFCB is represented by one delegate in the EB. The past AFCB president also is a member of the EB. AFCB is a federation of associations, syndicates and bodies representing specialists in the field of laboratory medicine and health, in scientific and educational institutions and in medical laboratories for diagnosis and research in both private and public sectors, within the Arab world.

The twelve countries that currently form the AFCB are: Algeria, Egypt, Jordan, Lebanon, Libya, Morocco, Palestine, Saudi Arabia, Sudan, Syria, Tunisia, and Yemen.

Among the aims of the Federation: tighten relationships between all those who work in the field of Clinical Laboratory all over the Arab world including:

1. sharing information, expertise and scientific achievements;
2. organising seminars and training in clinical biology and laboratory medicine;
3. publishing scientific journals and periodicals specializing in clinical and laboratory medicine;
4. organising training and educational sessions;
5. participating in the creation of national bodies and associations within the Arab countries that do not have such organizations in respect to their local legislation;
6. giving support and advice to national bodies and associations within the Arab countries;
7. providing consultation and expertise as requested to scientific and production institutions in the Arab world;
8. organise scientific congresses, participate at both regional and national congresses in the Arab world, provide the organizing countries with all the scientific support needed;
9. co-ordinate with the Council of Arab Ministers of Health on clinical laboratory scientific matters;
10. implement International Units;
11. provide support to IVD industry in the Arab world;
12. support Quality Management Programmes in Health Laboratories.


Our Vision:
To work on the development of the profession and the science of laboratory medicine in the Arabic world.

Our Mission is:
1. being the legitimate voice for the profession of laboratory medicine in the Arabic world.
2. being the lead in the Arab and international community with regard to the profession of laboratory medicine
3. serving members with the maximum potential.
4. maintaining high professional standards in the practice of medical laboratory sciences in the Arabic world.
Africa is facing many challenges with regards to health care delivery, especially in the area of medical laboratory services. Modest achievements were recorded as a result of two different initiatives which took place in the Eastern part of Africa. Such efforts can be applied to other regions of Africa and developing world, while the ones that started in the East Africa can be strengthened. I will also discuss the challenges of laboratory services, which cuts across most parts of Africa, the way forward and the support we in Africa are looking forward to, from the IFCC.

Facilitated by IFCC, Randox Laboratories sponsored an EQA program in Zambia called Randox International Quality Assurance Scheme (RIQAS). Health facility laboratories in the public and private hospitals enrolled in the program with the approval of the Zambian Ministry of Health (MoH). The EQA program was started in 2014. A total of twenty one (21) laboratories registered to participate in the EQA program out of over 270 laboratories in Zambia. Only six out the 21 laboratories performed reasonably well, when the project was reviewed after 12 months. We hope that Randox will partner with Health Ministry to make sustainability of this program a reality.

The second initiative is Lab Skills Africa, which is a health systems strengthening initiative, aimed at building the capacity and improving the standards and the quality of laboratory services in sub-Saharan Africa through skill training, knowledge transfer, leadership development and mentoring. Developed by the Royal College of Pathologist (RCPath) in partnership with College of Pathologist of East, Central and Southern Africa (COPECSA), the British Division of the International Academy of Pathology (BDIAP) and the East, Central and Southern Africa Health Community (ECSA-HC), the initiative has been piloted in 20 public sector laboratories in Kenya, Uganda, Tanzania, Zambia and Zimbabwe. In total, these laboratories serve a combined population of 110 million and perform more than 1.7 million tests annually.

Lab Skills Africa trained 100 pathologist, biomedical scientist and laboratory technologist in the areas of leadership, quality management, personal development, planning and technical bench skills. Throughout the process, the participating laboratories and their staff have been supported and mentored by highly skilled and experienced volunteers drawn from the UK, Africans in Diaspora such as those in North America and Australia.

Africa is in dire need of increase in the number of trained laboratory personnel most especially pathologist. This can be achieved by provision of conducive environment for training and services. We in Africa also lack infrastructural facilities, equipment and reagents. All these deficiencies have profound effect on the type and quality of health care delivery and laboratory services in Africa.
Way forward for Africa and some other developing countries were discussed with suggestions that these initiatives can be spread to other parts of Africa incorporating lessons learnt from the previous projects and expected roles of IFCC were also highlighted.

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Latin America has more than twenty million square kilometers, 13.5% of the land surface of the planet with a large geographic and biological diversity.

Latin America has the largest population of Spanish speakers, with 619,687,000 inhabitants account for 6% of the world population, distributed in mega cities with over 10 million inhabitants as the following cities: Mexico, Sao Paulo, Caracas, Buenos Aires and areas with poor population like the Amazon zone in Brazil or the Patagonia Argentina. This leads to significant differences cultural, which is reflected in the activity of professional laboratories.

There are so mega laboratories which process large numbers of samples for day and small laboratories with a single professional in small towns.

The Latin American Confederation of Clinical Biochemistry - COLABIOCLI - began to take shape in December 1968, during the First Latin American Congress of Clinical Biochemistry developed in the city of Mar del Plata - Argentina – this was the initiative of a professionals group belonging to the Federation Specialists Biological Analysis of the Province of Buenos Aires (today Biochemistry Federation of the Province of Buenos Aires - FABA-), five years later being officially established on November 28, 1973, during the II Congress held in the city of Porto Alegre – Brazil.

The overall objective of COLABIOCLI is the constant improvement of the profession in terms of ethics, science, technology and economy, to become the best way to individuals and society to:

- grouping of national associations dedicated to the development of Laboratory Sciences.
- organizing and promoting scientific and trade events, and programs of external quality assessment.
- implementing Accreditation Standards and establishing postgraduate programs in member countries.

COLABIOCLI groups

- Confederación Unificada Bioquímica de la República Argentina - CUBRA
- Sociedad Boliviana de Bioquímica Clínica - SBBC
- Sociedade Brasileira de Análises Clínicas - SBAC
- Sociedad Chilena de Química Clínica - SCHQC
- Colegio Nacional de Bacteriología Colombia - CNB
- Colegio de Microbiólogos y Químicos Clínicos de Costa Rica
• Sociedad Cubana de Patología Clínica
• Sociedad Ecuatoriana de Bioquímica Clínica - SEBIOCLI
• Colegio de Profesionales del Laboratorio Clínico de El Salvador
• Asociación Española de Farmaceúticos Analistas - AEFA
• Asociación de Químicos Biólogos de Guatemala - AQBG
• Colegio de Microbiólogos y Químicos Clínicos de Honduras
• Colegio Mexicano de Ciencias de Laboratorio Clínico, A.C. - CMCLC
• Asociación de Microbiólogos y Químicos Clínicos de Nicaragua - AMQCN
• Colegio Nacional de Laboratoristas Clínicos de Paraguay - CONALAC
• Asociación Bioquímicos de Paraguay - ABP
• Asociación Peruana de Profesionales del Laboratorio Clínico
• Colegio Dominicano de Bioanalistas - CODOBIO
• Asociación Bioquímica Uruguaya - ABU
• Colegio de Tecnólogos Médicos de Puerto Rico - CTMPR
• Federación de Colegios de Bioanalistas de Venezuela - FEDECOBIOVE

Note
The APFCB has 17 Ordinary members, 4 Affiliate members and 19 Corporate members as of 1 January 2016.

Summary of APFCB activities in 2015/2016

I. IFCC-Abbott Visiting Lecturer for 2015 and 2016

Prof Howard Morris delivered talks on vitamin D and bone disease in Hong Kong, Taiwan and Nanjing in 2015.

II. APFCB Travelling Lecturer for 2015 and 2016

In 2015, Associate Prof Graham Jones spoke on the topic of Chronic Kidney Disease (CKD) in Singapore, Vietnam, India, China and Mexico (WASPaLM World Congress). He delivered his lectures in Hong Kong in January 2016 and will deliver a plenary lecture at the 14th APFCB Congress in 2016.

III. Courses and Congress Symposia and Workshops

a. APFCB-sponsored symposium at the WASPaLM World Congress in Cancun, November 2015.

b. At the 14th APFCB Congress there will be a joint WASPaLM-APFCB Accreditation workshop, an APFCB Pre-analytical workshop and a hypothetical entitled “The Value of Pathology” organised by C-ELM and Roche to raise awareness of the importance of pathology testing.

c. APFCB-Roche workshops/courses on Lean-Six Sigma for member societies, the first of which will be in Vietnam in 2016.


e. APFCB-sponsored symposium at the AACC 2016 Annual Meeting entitled “Addressing pre and post analytical issues in developing countries”.

f. APFCB-sponsored symposium at EFLM-UEMS conference in Poland, 2016.

IV. Interpretative comments programme

There were six cases in 2015. Another six cases are planned for 2016.

V. Young Scientist Competition at the 14th APFCB Congress in Taipei, November 2016

VI. Regional reference interval study

VII. Regional project on building a case record database of haematological malignancy

VIII. Urine steroid metabolomic studies by gas chromatography mass spectrometry to aid the diagnosis of disorders of sex development in Vietnamese children

IX. Annual Vietnam Chemical Pathology Course conducted under
APFCB auspices

X. Annual Vietnam Point of Care Testing Workshop

XI. Regional project for harmonisation of mass spectrometry-based steroid assays

XII. APFCB Chronic Kidney Disease

XIII. On-line live telecast on the APFCB website of the Vietnam CPC on 6th June 2015

XIV. APFCB e-News is published online on the APFCB website.

XV. The 14th APFCB Congress will be held in Taipei from 26 till 29 November 2016. The theme of the congress is “Laboratory Medicine in Cloud”. There will be symposia and workshops sponsored by the APFCB, IFCC, WASPaLM, EFLM, NACCCA, AACC and APFCB member societies.

XVI. Turning Science into Caring (TSIC) 2015
Abbott Laboratories has held TSIC meetings in the Asia-Pacific region in conjunction with the IFCC and APFCB with the aim of bringing laboratory and other healthcare professionals together to exchange information on trends in laboratory medicine. The 2015 TSIC was held in Bali, Indonesia from 2nd till 3rd December with the theme “Elevating the standard of patient care”.

XVII. Asia Pacific Federation for Clinical Biochemistry and Laboratory Medicine (APFCB)-Beckman Coulter (BC) Scientific Symposia
These scientific symposia were held in Ho Chi Minh City on 8 October 2015, Jakarta on 10 October 2015 and Bangkok on 14 October 2015.

XVIII. Travel scholarships to congresses
APFCB-AACB Travel scholarships
APFCB-Siemens Travel Scholarships
The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM), with its 41 National Society Members, represents almost 22,000 Specialist in Laboratory Medicine in Europe and almost half of the IFCC National Society Members. Representing IFCC in Europe, EFLM acts as a collector of proposals and/or concerns from EFLM members and, if necessary, brings these to the attention of the international community.

The main activities of EFLM relate to education, research, development of the profession, requirements for competence, quality and accreditation of laboratories, organization of scientific congresses and publications.

EFLM has five Committees:
- Communications (C-C)
- Education and Training (C-ET)
- Profession (C-P)
- Quality and Regulations (C-QR)
- Science (C-S)

In the last years, we have assisted to the evolution of the Federation from a group of highly motivated volunteers to a structured organisation, not to mention the establishment of EFLM as a legal entity. A Professional Legal Advisor in Belgium cooperates for the financial auditing of the EFLM budget and legal aspects related to EFLM activities. The release of the EFLM Procedure Manual has been of great help to the growth of EFLM, thanks to the standardization and monitoring of all internal processes.

The EFLM Executive Board has a biannual Strategic Plan, prepared after consultation of National Society Members in order to collect needs and proposals and to reflect their expectations. Furthermore, to improve the engagement with National Societies and to raise the profile of the Federation, every year EFLM promotes a program supporting the visit of one member of the Executive Board at National Society and Regional meetings.

EFLM strongly support the presence of young scientists in their Working Groups and an important part of the Federation’s budget is allocated for bursary programmes to permit young colleagues to attend EFLM congresses and educational courses.
EFLM has no corporate membership, but has active cooperation in place with IVD industries in setting up various specific projects supporting the development of the laboratory profession in Europe.

For the future, EFLM intends to set up even wider collaboration with sister Regional Federations in order to harmonize scientific, educational and professional efforts in a complementary fashion worldwide.

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The North American Federation for Clinical Chemistry and Laboratory Medicine (NAFCC) representing the American Association for Clinical Chemistry (AACC) and the Canadian Society of Clinical Chemists (CSCC) was formed in 2014 and was recognized as a Federation in 2015. The NAFCC was formed in response to proposed changes to the procedure for election to the IFCC Executive Board and to allow for representation and participation from North America in the IFCC. The NAFCC also serves to formalize greater communication and cooperation between the AACC and CSCC at the executive level. Dr. David Kinniburgh is the NAFCC Representative to the IFCC EB for 2015-2017.

The AACC and CSSC were active in a number of initiatives in 2015, some of which, while independent, are complimentary.

AACC:
- 2015 AACC Annual Meeting & Clinical Lab Expo in Atlanta, Georgia.
- Establishing of a Universal Sample Bank, with more than 700 healthy donors.
- Continued success and growth of the Lab Tests Online web site with increased usage and major reviews, updates and additions.
- Announcing a new Journal, The Journal of Applied Laboratory Medicine. An international, peer-reviewed publication that will showcase applied research on clinically relevant laboratory topics.
- Supporting the multinational effort to develop a model to define the value proposition for laboratory medicine in different national healthcare systems.
- AACC’s US advocacy program covers a wide range of topics important to laboratory medicine, including the harmonization of clinical laboratory test results, laboratory developed tests, pediatric testing, and participation in payment deliberations that shape the direction of healthcare. AACC strategically identifies and takes action on issues of global significance and actively works within the legislative and regulatory realms to influence public policies affecting clinical laboratories; most recently the Association urged government officials to grant laboratory professionals access to residual specimens to develop new assays and improve the quality of testing. AACC collaborates with industry and other laboratory partners to promote policies that advance science, best practices, and the adoption of newer technologies worldwide.
CSCC:
- 2015 CSCC Annual meeting with CAP in Montreal, Quebec.
- Supporting Appropriate Laboratory Utilization through presentations by CSCC members and working with partners such as the Canadian Association of Pathologists (CAP), the Canadian Agency for Drugs and Technology in Health (CADTH), and Choosing Wisely Canada.
- Participation on the Canadian Leadership Council on Laboratory Medicine (CLCLM) to advocate in the areas of education, workload and quality assurance.
- Working with other laboratory medicine organizations and industry partners to identify a strategy to promote the value of laboratory medicine and bring stakeholders together in a unified response.
- Supporting the EPOCC initiative (Educating People on Clinical Chemistry) in its efforts to promote the CSCC and its members.
- Supporting initiatives in Alberta and Ontario to achieve regulation under provincial Health Professions Act, whereby clinical biochemists would be legally recognized as members of the healthcare team and better able to regulate their profession and maintain the highest standards of quality and patient safety.
- The CSCC modified its bylaws to allow for stronger continuing education requirements within the Canadian Academy of Clinical Biochemistry in anticipation of more stringent government requirements.
- The CSCC signed an MOA with the Association for Clinical Biochemistry and Laboratory Medicine (ACB) to enhance the relationship and promote education exchanges between the two associations.

Note
A three year strategic plan (2015 – 2017) was produced by the EMD-EC on the 16th of January 2015 during the EMD-EC meeting in Milan and circulated to all Chairs of Committees, Working Groups and Special Projects for their comments and recommendations before being finalised and agreed at the EMD-EC meeting in Paris on 20th June 2015.

All Committees, Working Groups and Special Projects have largely achieved at the end of 2015 what they stated in their action plans for 2015 and should be congratulated for their considerable achievements. It is not possible to mention all the achievements in this short abstract but these are mentioned in the EMD Annual Report for 2015 that has been submitted to the IFCC EB as well as to all EMD Chairs of Committees, Working Groups and Special Projects with the hope that this will be shared will all their members.

EMD now has six committees, with the latest addition on 1 January 2016 of the Committee for Education in the Use of Biomarkers in Diabetes (C-EUBD). The number of working groups has also increased from two to four working groups with the addition of Cancer Genomics (WG-CG) and Harmonisation of Interpretive Comments EQA (WG-ICQA) in 2015. The number of special projects has increased from two to three with the addition of Mentoring Programme for Developing Countries (MENT) in 2015.

The IFCC-Visiting Lecturer Programme (IFCC-VLP) has been a flagship activity of IFCC and has over many years been generously supported by Abbott until the end of 2014. The IFCC and the EMD would like to thank Abbott for its generosity that has enabled the VLP to benefit many member societies. Sixteen VLPs were approved in 2015 and this programme was supported by IFCC in 2015.

In the EMD session at the General Conference we intend to feature DQCML because this special project could be of enormous benefit to members from developing/emerging countries and is still being underutilised by IFCC member societies. The recently established C-EUBD, WG-CG and MENT will also be featured. Unfortunately, due to time constraints we are unable to feature the recently established WG-ICQA. The mission of WG-ICQA is to seek harmonisation in the operation of EQA schemes for interpretive comments with a view to increasing the possibility of obtaining evidence to demonstrate benefit to patients.
The mentoring programme, initiated in 2013, is intended to make readily available the expertise of well-respected acknowledged laboratory experts in developed countries to potential laboratory leaders in developing countries. It is done on a one-to-one basis through the matching by the programme director of a Mentor from a developed country with an Associate (the IFCC name for a mentee) based on shared interests. To date the programme has about 15 Mentors and almost 30 Associates. In many cases, the Associates have indicated the benefits that they have received through the programme. I am most grateful to both the participating Mentors and Associates. While the programme was initially focused on sub-Saharan Africa, it has recently expanded to Latin America where Mentors and Associates can work with each other in their own language. The programme director has recently begun working with the Clinical Laboratory Standards Institute (CLSI), which runs several training programmes in Africa. There is potential to develop complementary relationships with other organizations. The programme director is interested in learning of other organizations with which IFCC could collaborate in a similar manner.

He is also interested in recruiting additional volunteers as both Mentors and Associates.

Additional information can be obtained from Donald Young at donaldyo@mail.med.upenn.edu and Silvia Colli Lanzi at colli-lanzi@ifcc.org.
The Developing Quality Competence Project was established in 2006 as a strategic action of the IFCC Executive Board to assist in the development of a route to laboratory accreditation for those countries with limited resources.

Under the direction of the Education and Management Division (EMD) of IFCC its aim has been to assist National members on all aspects of quality, but concentrating particularly on internal quality control, external quality assessment and support for those working towards laboratory accreditation and the adoption of a quality system in line with the international standard ISO 15189.

It does this largely through the provision of educational modules that can be transferable between countries and regions requesting assistance in these areas.

The success of the project is built on close working between the committees of EMD and the generous sponsorship of Abbott Diagnostics, via the VLP initiative and Siemens Healthcare, with whom work has been done in developing distance learning packages.
Testing the genes and genomes of patients and their cancers has quickly become standardized practice over the past ten years. Initially, genetic assessment of cancer was limited to single biomarkers to guide the use of therapies. The presence of biomarkers was used to inform therapeutic decisions and predict patient outcomes. In the case of breast cancer, the presence of HER2 amplification was used to determine HER2 targeted therapy (e.g., trastuzumab). Similarly, in breast cancer, multigene expression panels were used to predict patient outcomes (e.g., Oncotype DX, Genomic Health). In contrast, biomarkers have also been developed to determine when therapy will be ineffective (e.g., KRAS mutations are a contraindication to EGFR targeted therapy).

These initial approaches were targeted to specific genes for specific cancer types. Over the past five years, analytical approaches have expanded to include panels of genes ranging from dozens to thousands. Furthermore, large panels of genes are now applied to cancers regardless of histologic subtype or stage of disease. A significant amount of literature has now established that activating genetic mutations can be found in multiple cancer subtypes. In the United States, the use of gene panels to evaluate cancers has become routine not only in clinical trials, but also in daily clinical practice. The rise in clinical use of cancer genome sequencing has become particularly common in patients who have failed standard therapy; the clinical rationale is to find a mutation which may be associated with a therapeutic.

In parallel to the expanded use of genomic methods in evaluating cancer testing has been the emergence of clinical laboratory standards. In both the United States and the European Union there have been multiple suggested standards for both the analytical testing as well as the interpretation of results. In addition to standards of performance and interpretation, there are now reference materials (e.g., US NIST Genome in a bottle, NA12878). Most recently, the US FDA has suggested that new genomic tests may have a novel regulatory mechanism which would use databases instead of clinical trials for the establishment of clinical evidence.

The clinical laboratory practice of cancer genomics should embrace standardization and the use of reference materials. In the context of clinical trials and the management of patients, international standardization genomic testing is possible and necessary.
In 1968 Rahbar described an “abnormal” haemoglobin (Hb) in red cells of diabetics, thus sparking a major interest in this area of research. But this fraction had been identified over a decade earlier when in 1955 Kunkel and Wallenius described the occurrence of “minor components” in normal adult Hb which were named HbA1a, HbA1b, HbA1c, HbA1d, and HBA1e; all eluted before the main HbA0 fraction. In 1975 Bunn et al showed that open chain forms of sugars react with proteins to form a labile aldemine. This product may hydrolyse back to glucose and protein or undergo an Amadori rearrangement to form a 1-amino-1-deoxyfructose derivative. A number of factors will affect non-enzymic glycation: the concentration of the reactants; the access to reactive sites; the time of exposure of the reactants (red cell life span); pH and the microenvironment. In an individual these factors will be constant; the concentration of glucose being the only variable determining the level of HbA1c; but between individuals these factors may differ significantly.

Since the late 1970’s large numbers of HbA1c methods have been introduced into clinical practice, but there was a significant difference in the results produced by different laboratories. Lack of international standardisation resulted in several countries developing National Standardisation Programs. The IFCC WG-HbA1c was established to develop a reference measurement procedure (RMP) for HbA1c, to facilitate the uniform international calibration of HbA1c methods. Nowadays methods used worldwide in the Clinical Laboratory should be standardised to the IFCC RMP that anchors patient results through an unbroken traceability chain to a Primary Reference Material. Analytical quality will be assured by laboratories having a robust quality system to include frequent analysis of Internal Quality Control Material; it is also essential that laboratories participate in a National External Quality Assessment Scheme/Proficiency Testing to assess accuracy and assess the relationship to other laboratories.

There is a lack of understanding among professionals in what exactly is being measured, potential interfering factors and frequency of testing. It is apparent that there is a lack of understanding relating to method principles used, and what these methods are measuring; there is also poor understanding of how HbA1c measurement relates to glycaemic status in patients. It is not surprising therefore when the IFCC, in partnership with the World Health Organisation and the International Diabetes Federation, undertook a global questionnaire in an attempt to understand the different practices that have been adopted in different countries, one of the most
important requirements identified was the need for education. It is fascinating to consider the improvements in the measurement of HbA1c that have been implemented over the past 40 years; the science associated with the measurement of HbA1c has evolved into high quality analytical procedures, but the use HbA1c in clinical practice, either for monitoring or diagnosis, requires an understanding of the nature of its formation, biological variation and the methodology used.

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Distance Learning is a key objective of the International Federation of Clinical Chemistry (IFCC) in support of its regional and national members. The Education and Management Division (EMD) Committee on Distance Learning (C-DL) is developing the IFCC curriculum and educational content and the Communications and Publications Division (CPD) Committee on Internet and e-Learning (C-IeL) will publish this material in a usable format on the internet. Both groups have worked together to develop the concept of an IFCC eAcademy, the second phase of which is to be released at this meeting.

The IFCC eAcademy is a Learning Management System utilising a curriculum based approach to catalogue and access educational material on the IFCC website. It contains linked presentations, webinars and other educational materials managed through a content management system (Umbraco). Phase 1 of the IFCC e-academy was launched in June 2015, at the EuroMedLab Congress in Paris. Phase 2 of the project will incorporate the development of a registered user interface and database to allow users of the website to track the materials accessed and work through the curriculum content. Phase 3 of the project will include online quizzes which Individuals will be able to undertake to receive credit for local Continuous Professional Development (CPD) programs. Preliminary work, in terms of content, has concentrated on some of the topics highlighted by National Societies as those for which distance learning modules would be of benefit to them and to their members. This session will provide an update on the development of the e-academy, with a demonstration of its use and the content currently available, together with information on material currently being developed which will be available on the website in the near future. We are concentrating on two distinct formats of educational material. The first is using the software present.me, with which presentations using PowerPoint slides coupled with video and voiceover can be prepared from a desktop PC. This is primarily being used for the preparation of 20-30 minute modules, covering specific topics and we are grateful to IFCC officers and other experts who are giving their time to this initiative. The second is to record sessions at IFCC and National Society congresses and to make these available on the website. Scrutiny of the congress scientific programmes allows us to identify sessions of particular relevance in advance and to then liaise with the congress organisers to arrange recordings. We are
reliant on the support of National Societies and congress organisers to enable us to move forward with this. We are grateful for the generous sponsorship of Siemens for this initiative. In addition to these approaches, we are working with other organisations such as the AACB and EFLM to allow us to link from the e-academy to their distance learning modules.

This is an interactive session and comments on the structure and ease of use of the e-academy, together with suggestions for future topics for which there is the need for educational modules and the availability of external material are welcomed.

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The Communications and Publications Division of IFCC is one of three divisions within the IFCC organization reporting to the Executive Board and is responsible for all of the communication and publication activities of the IFCC. The CPD is composed of an Executive Committee, a Committee on Public Relations and Committee on Internet and e-Learning and Working Groups for each CPD program. Ad hoc task forces for specific projects can also be formed. The main aim of the CPD is to communicate the work of the IFCC to clinical scientists, physicians and health policy-makers world-wide, and to provide continuing education in printed and electronic forms. The CPD publishes the eJIFCC, IFCC News and educational tools including scientific monographs. The CPD coordinates translations of important documents into languages other than English. The CPD is responsible for the coordination of the Internet activities of the IFCC, primarily through the IFCC web site. This includes preparation and promotion of the IFCC website, establishment of links between relevant resources and the production and participation in Internet and online educational courses designed to promote the IFCC. In addition, the CPD publishes the eJournal of the Federation (eJIFCC) on the web, IFCC recommendations and documents in a formal collaboration with the journal Clinica Chimica Acta (CCA) and other international journals in the field. The CPD uses electronic communication to facilitate the availability of IFCC documents to all members at no cost. All IFCC publications are copyrighted by IFCC.

Major advancements have been made over the past few years in IFCC communication tools/media including: a) A new and intuitive website that is easy to navigate and provides access to key IFCC media and documents, as well as information on IFCC organization and structure; b) A new IFCC eNewsletter with significantly more content and improved format enhancing communication across the IFCC community and national societies; c) A newly formatted IFCC eJournal with major enhancements in scientific content and improved graphics/presentation, publishing a series of special issues with major global interest and impact. In addition to these recent enhancements, CPD in collaboration with EMD launched the “IFCC eAcademy” aimed at delivering eLearning and distance education programs to IFCC member societies and their membership. CPD has also worked closely with RIA (Rincón Iberoamericano) and WG-IANT (Ibero-American Nomenclature and Translations) to improve communication links with Latin American national
societies and COLABIOCLI, increasing their involvement in IFCC activities and publications. Finally, CPD will be launching two new initiatives in 2016 including an IFCC MOBILE APP on both iTunes and Google Play platforms (for iPhone and Android smartphones/tablets) to allow easy access to key IFCC media including the website, eNews, eJournal, and eAcademy. We have also developed a new ANNUAL IFCC CPD SURVEY to be circulated to all national societies and IFCC officers. The results of this survey will be analyzed and published in the IFCC eNews on an annual basis.

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Saturday 19 March
The International Federation of Clinical Chemistry and Laboratory Medicine being a worldwide, umbrella organisation provides a major forum enabling close collaboration and networking among over 85 National Societies, 6 Regional Federations across the globe. In association with other international organisations, IFCC plays a key role in setting global standards in laboratory medicine, and providing scientific and educational material to scientists and professionals around the world.

The Communications and Publication Division (CPD) of IFCC plays a major role in delivering on this mission statement, by promoting the field of laboratory medicine and the image of the IFCC organization and communicating the vital work of IFCC’s Divisions, Committees, Working Groups and Task Forces to clinical laboratory scientists, physicians and health care policy makers worldwide.

The Committee on Publication Relations (C-PR) strives to identify, evaluate and keep up to date the types of PR communication methods and of multimedia for disseminating the relevant information to IFCC members. IFCC has moved from printed to electronic media that offer variety, flexibility and speed. They however suffer from their short lifetime resulting in rapidly obsolete information. Moreover, the massive load of electronic information each individual receives, adulterates the truly important messages that hence go by unnoticed.

The C-PR aims at developing strategies to tackle this challenge and thus improve the worldwide visibility and use of the documents and resources provided through the work of different IFCC functional units.
Systematic evidence for the contribution of the clinical laboratory to the overall assessment, diagnosis, and management of patients is not readily available. Establishing this evidence is vital to all promotional activities by the IFCC and other organizations involved in laboratory medicine. There is a critical need for both a systematic review of the available evidence in the published literature as well as the initiation of new retrospective and prospective studies to more clearly establish this crucial evidence. The IFCC established a new taskforce to evaluate the published evidence on value and impact of laboratory medicine on clinical outcomes and healthcare delivery, and if necessary propose new studies to more clearly establish this evidence. This taskforce led by Dr. Mike Hallworth, the taskforce chair, completed its work in 2015 and prepared a manuscript summarizing their key findings and recommendations. A critical review of the evidence supporting the value of laboratory medicine in clinical care led to a series of important findings and conclusions. The work has now been published in Clinical Chemistry (Clin Chem 2015 Apr; 61(4):589-99). Dr. Hallworth also presented the findings of the taskforce at a special symposium organized by CPD at the EuroMedLab 2015 in Paris. The taskforce reviewed the evidence supporting the key role of laboratory medicine in clinical management and outcomes and attempted to identify the gaps requiring new studies, and discussed the data demonstrating the value of laboratory testing from a clinical and economical perspective. The following is an excerpt from the report published in Clinical Chemistry: “To maximize the value of laboratory medicine, work is required in 5 areas: (a) improved utilization of existing and new tests; (b) definition of new roles for laboratory professionals that are focused on optimizing patient outcomes by adding value at all points of the diagnostic brain-to-brain cycle; (c) development of standardized protocols for prospective patient-centered studies of biomarker clinical effectiveness or extraanalytical process effectiveness; (d) benchmarking of existing and new tests in specified situations with commonly accepted measures of effectiveness; (e) agreed definition and validation of effectiveness measures and use of checklists for articles submitted for publication. Progress in these areas is essential if we are to demonstrate and enhance the value of laboratory medicine and prevent valuable information being lost in meaningless data. This requires effective collaboration with clinicians, and a determination to accept patient outcome and patient experience as the primary measure of laboratory effectiveness.”

The main learning objectives for this presentation are: a) Describe the
available evidence on clinical utility of laboratory testing and identify the evidence gap in determining the value of laboratory medicine in clinical management and outcomes. B) Learn the clinical and economical data linking high quality laboratory testing with improved clinical decision making and patient management; c) Describe the promotional activities led by the IFCC to promote both the field of laboratory medicine and the IFCC organization.

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Having a well designed, user friendly and accessible website is essential to allow IFCC to meet its objective of co-ordinating the development of Clinical Chemistry and Laboratory Medicine on an international basis. The website is key to the Communications and Publications Division’s (CPD) aims of communicating the work of the IFCC to clinical scientists, physicians and health policy-makers world-wide, and providing continuing education in printed and electronic forms. Along with supporting the Educational Management Division (EMD) through the creation and promotion of web-based e-learning and educational activities; development and ongoing enhancement of the IFCC website is a core activity of the CPD Committee for Internet and e-Learning (C-IeL).

Organised to reflect the structure of IFCC, the website is comprised of over 760 pages maintained and managed by the IFCC office staff and C-IeL, supported by web development company InSoft Digital. An open resource, the IFCC website contains a wealth of IFCC information, news, media and publications. Visitors have ready access to a vast array of material including:

- Details of IFCC organization and structure including member societies (organizations and individuals), corporate members (companies and individuals), IFCC units (Divisions, Committees, Working Groups) and the membership, terms of reference and current projects/outcomes of these groups.
- Links to member societies, Regional Federations, corporate sponsors and other sites relevant to the development of Clinical Chemistry and Laboratory Medicine worldwide.
- An up-to-date event calendar detailing forthcoming congresses and meetings in the fields of Clinical Chemistry and Laboratory Medicine that includes the ability to download selected events directly to major e-calendar programs.
- A growing collection of continuing education material such as webinars produced on behalf of IFCC for the eAcademy.
- An up to date database of IFCC publications dating back to 1973.
- The IFCC publications eNews and eJIFCC; available as current and archived editions.
- An expert database to facilitate contact with experts in particular fields of laboratory medicine.

The IFCC website (www.ifcc.org) is a portal to international resources for
laboratory medicine. As content largely represents the work of IFCC Committees, Working Groups, National Societies and Corporate Members, liaison with the broad range of activities of IFCC is essential. Members of all groups within IFCC are encouraged to take an active role in ensuring their efforts are published and kept current on the site by providing updated information to the IFCC office.

*Note*
As the paperless society evolves, digital publishing of academic textbooks has moved rapidly forward with the development of software and hardware and the increasing adoption of tablets and mobile devices in universities and high schools. Many publishers are becoming increasingly aware of the benefits: content can be updated rapidly and easily; content can be interactive and can also be embedded in the internet; usage can be monitored and assessed. Students can be tested within the interactive content. Furthermore, all of these features can be accessed at a relatively low price making books more available across the world via the internet, especially in developing countries. There are a number of different formats available because of the direction different companies have taken and it can be problematic for an author to choose the appropriate format. In view of this, the International Digital Publishing Forum (IDPF) developed uniform standards for electronic publishing and this is embedded in the so-called ePub3 format. EPUB 3 is the latest version of EPUB. EPUB 3 is based on the latest HTML5 standard, which means EPUB publications can now contain video, audio, and interactivity – just like websites in modern browsers. An EPUB publication’s content is by default reflowable and most reading systems dynamically paginate that content. Adapting content display to the screens rather than forcing the reader to pan and zoom around pre-formatted content (and, more generally, making content accessible to different modes of consumption) is one of the key characteristics that distinguishes EPUB from PDF, a portable document format designed to represent print-replica content. PDF is limited to mimicking paper and thus too restrictive for digital readers in an increasingly multi-screen world. It is also an isolated technology silo not aligned with HTML5 and the modern web platform. Publishers can create a single EPUB file and deliver it to all distribution channels that accept the EPUB format. For eBooks, EPUB has become the most prevalent format used by publishers for content creation and distribution around the world and hundreds of different reading systems support this format. Interoperability, for content publishers, can be considered the most fundamental benefit of EPUB and it has, from its inception, facilitated this “supply chain” function. However, not all distribution channels that accept EPUB deliver actual EPUB files to consumers, and not all EPUB files can be read on different devices and software programs. Some publishers such as Amazon convert EPUB to their own proprietary format (Amazon Kindle). Others such as Apple use a different type of EPUB format (loosely based on EPUB3) and proprietary technology such that it can only be read on the vendors own software and devices, in this case Apple. However, at this point in time, Apple iBooks offers...
the most advanced and powerful features in an electronic publication and is therefore
the chosen platform for many authors. I will provide a live demonstration of several
clinical chemistry books using this platform to illustrate the features of the technology
available including video, audio, interactivity and 3-dimensional images.
Cardiovascular Disease (CVD) remains the leading cause of death and disability worldwide, with increased hospital discharge rates, possessing a serious public health issue and an economic burden. Recent demographic transitions, including ageing of the population, low fertility, urbanization and shift towards unhealthy behaviours have resulted in tremendous increase in the prevalence of several cardiometabolic disorders (i.e., hypertension, obesity, diabetes). According to WHO, and other international Organisations’ reports, a substantial number of cardiac episodes could have been prevented through lifestyle modifications (i.e., diet, physical activity, smoking cessation). Regarding secondary prevention, it is well documented that effective cardiovascular rehabilitation requires a multidisciplinary approach, including medical treatment, as well as proper lifestyle changes. Diet has been recognised as one of the most important modifiable and preventable factors, being undoubtedly beneficial in primary prevention, as well as among cardiac patients. However, studies among CVD patients are scarce, and with inconclusive results. The most studied dietary pattern is the Mediterranean-type diet, with several observational studies and clinical trials demonstrating its protective role against first, as well as recurrent cardiac events, whereas evidence regarding other well known models, including Western-type, Vegetarian, Asian-type and Dietary Approaches to Stop Hypertension (DASH) diet, are rather limited. Despite the important findings from numerous of studies, there is no doubt that the Mediterranean diet is being progressively lost, especially in the younger generations. Therefore, immediate actions are needed by public policy makers in order to preserve the wisdom of our ancestors.
Traditionally, there has always been a strong co-operation between IFCC’s Corporate Members and all other stakeholders within IFCC. The benefit is a mutual one: The Corporate Members make a substantial financial contribution to IFCC in terms of annual fees, by exhibiting at IFCC conferences, by enabling scientific lectures and travel of speakers and delegates - in particular from countries where resources are limited -, by sponsoring awards, and by contributing to the scientific and educational projects within IFCC. These are only the major fields of collaboration. In turn, IFCC provides its Corporate Members with scientific expertise, in particular with regard to standardization but also in the form of recommendations and guidelines, allows networking with experts on an international level, and organizes conferences that enable the Corporate Members to meet customers and potential customers. Both industry and academia within IFCC share the common vision to advance excellence in laboratory medicine for better healthcare worldwide.

Yet, over the history of this fruitful co-operation the environment in which the Corporate Members operate has changed significantly in many aspects and the pace is getting faster year by year. This requires thinking about how IFCC should collaborate with its Corporate Members in the future. For this reason, we have decided - for the first time - to organize this session by the Corporate Members. Next, Dr. Graham Beastall, IFCC past-president, will explain his ideas about how partnership between IFCC and Corporate Members can be strengthened.

Some of the industry’s challenges that have been touched briefly in the Corporate Members’ report yesterday will be discussed in more detail in the keynote lecture by Mr Patrick Bugeon, Senior Vice President International Government Affairs at Bio-Rad. He will as well explain where he sees where and how IFCC could support its Corporate Members.

Thereafter, we will have a discussion, and I would like to invite and encourage all of you to contribute with ideas how Corporate Members’ needs can be addressed now and in the years to come.
Corporate Membership of IFCC is open to any organisation that manufactures products or offers services in the field of clinical laboratory science. Whilst the majority of Corporate Members come from the in-vitro diagnostics industry IFCC also values Corporate Members from private laboratory networks and from the publishing sector. Looking to the future IFCC would welcome Corporate Members from the pharmaceutical sector, with expertise in companion diagnostics, and from the laboratory informatics sector.

The relationship between IFCC and its Corporate Members is stable but perhaps it is not optimal. The IFCC SWOT analysis (January 2016) and the General Conference (March 2016) provide an opportunity to strengthen the partnership and set new parameters and targets to optimise the working relationship.

The current benefits of the partnership between IFCC and its Corporate Members include:

- Corporate Member representation on the IFCC Executive Board and each of the three IFCC Division Executive Committees
- Corporate Member involvement in several IFCC scientific and educational projects
- Two-way access to all IFCC communication channels
- Discounted fees for participation in IFCC congresses

From an IFCC perspective the partnership with its Corporate Members is regarded as suboptimal because:

- There is limited engagement with IFCC in the areas currently available
- Communication is generally poor, perhaps reflecting the internal communication challenges of complex international companies
- Some companies believe that the partnership is one-sided with IFCC being seen as only interested in financial contributions from fees, sponsorship and exhibitions

Looking to the future there are many ways in which the partnership between IFCC and its Corporate Members may be strengthened. These need to be discussed by Corporate Members and incorporated into a joint action plan. Discussion topics for strengthening the partnership between IFCC and its Corporate Members may include:

- Opening up IFCC Membership to more national societies and wider fields
of Laboratory Medicine
• Creating sub-groups of Corporate Members to allow for more focussed collaboration with IFCC
• Creating a joint discussion forum to identify and progress topics and projects that relate to the future of Laboratory Medicine
• Joint promotion of the value of Laboratory Medicine and its contribution to improving healthcare
• Greater collaboration with international clinical organisations
• Collaboration in general scientific issues such as understanding traceability; nomenclature; reference intervals etc.
• Identifying ways to achieve greater involvement of Corporate Members in IFCC activities
• Agreeing how the newly launched IFCC Foundation for Emerging Nations and the impending MedTech Code of Ethical Business Practice will influence the ways in which Corporate Members can provide educational support to developing countries.

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The IVD industry is today confronted with rapid changes occurring in their environment at all levels: first, high revenues countries are trying to contain their healthcare expenses, in spite of growing needs related to an ageing population; emerging countries still have a faster growing rate to satisfy the needs of the population, in a context which is too often price driven. As a consequence laboratories are concentrating, to form in some cases multinational operators, with global needs, requiring higher throughput, automation, and information systems. At the same time, the level of regulatory requirements is slowing down the market access for innovation, increasing the development costs in a market where prices are not regulated and therefore constantly under negative pressure. The lack of mutual recognition for countries which have their own regulatory system make it even more difficult and costly for the industry to introduce their products worldwide.

The laws put in place by more and more countries regarding the transparency of the relationship between healthcare professionals and suppliers have certainly a lot of positive income, although compliance required more workload and expenses to document all collaborations, including research conventions and post-graduate trainings. This may slow down significantly collaborations between the industry and healthcare professionals.

Nevertheless, the progress made in science to better understand the diseases mechanisms, the need to counter growing resistances to antibiotics, the emergence of new diseases calls for more innovation. The labs restructuration also drives the development of innovative solutions in automation, including robotics, software and information systems to transfer and store safely patient data. In this context, new technologies are also opening new opportunities for faster, safer diagnosis, allowing doctors to make better and faster decisions to treat and heal their patients. In the same spirit, companion diagnostics are going to develop personalized medicine, allowing expensive treatments to be used more wisely and with a better rate of recovery.

The growing share of chronic diseases in public healthcare expenses called for better tools for monitoring the patient status in order to adapt the treatment, and allowed he development of decentralized tests, used either as Point of care or for self-testing, like for glycaemia.

Last but not least, the recent progress of science and technology allows now to think about disruptive approaches to diagnostic, where the way to consolidate and forward the information will be as important as the quality of
the result itself, especially for patients remote monitoring. New solutions will also be provided by new entrants in the healthcare field, like connected devices (IOT). The industry will have to combine all these challenges with the opportunities provided by accelerated science and technology discoveries to expand its role in healthcare management, helping everyone to have a better life.

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The Scientific Division (SD) aims to promote the advancement of clinical laboratory science and its application, with a particular emphasis on the standardisation of laboratory measurement procedures. While there have been significant improvements in recent years in analytical techniques, considerable differences remain between laboratories and methods terms of clinical results on similar samples. With increasing use of national and international clinical guidelines which recommend specific decision limits, variation in laboratory results can have a significant impact on patient care and outcomes.

SD activities are run under the auspices of a number of Committees (Cs) and Working Groups (WGs). Cs are theme orientated and have a number of goals and objectives related to a group of measurands. For example, the Committee on the Standardisation of Thyroid Function Tests is currently working on both free T4 and TSH as target measurands. WGs typically address a single topic and work over a limited period to achieve agreed objectives. New projects are adopted based on suggestions from interested scientists or bodies, after review by members of SD.

Currently SD has 6 Cs and 14 WGs, the success of which is dependent on the commitment of volunteers drawn from across the global scientific community. Over a number of years SD has been responsible for significant improvements in many common laboratory tests, working closely with key partners to ensure the adoption of standardised testing where appropriate and to improve patient care, and current projects should ensure further advances in key areas of need.
A high percentage of all clinical decisions are influenced by data from laboratory medicine. This places laboratory medicine at the centre of healthcare with a responsibility to deliver high quality services that maximise clinical effectiveness. At the same time globalisation and electronic communication enable data and practice to be compared, transferred and adopted with ease. External quality assessment schemes reveal that for many key biomarkers there is considerable method to method variability. There is evidence that this variability can lead to misinterpretation of data leading to a negative impact on patient care. Therefore, method standardisation and harmonisation is necessary to:

- Assure patient safety
- Improve the effectiveness of clinical guidelines
- Reduce public / patient confusion
- Enhance clinical governance in laboratory medicine
- Facilitate the transfer of data between centres

To date a relatively small number of clinically important biomarker assays have been standardised on a global basis. Two such biomarkers are serum cholesterol and HbA1c and in both cases the clinical benefit of standardisation is becoming apparent. Projects have commenced to try to standardise several other important biomarkers and parathyroid hormone and HbA2 can be used as examples to demonstrate why reducing between method variability is desirable.

The challenge facing laboratory medicine specialists is that there are hundreds of clinically important biomarkers and the number is growing, especially in the areas of infectious disease and molecular diagnostics. A co-ordinated global effort on method standardisation is required if the clinical effectiveness of laboratory medicine testing is to be increased.
Results between different clinical laboratory measurement procedures should be comparable, within clinically meaningful limits, to enable optimal use of clinical guidelines for medical decisions. The ISO standard 17511:2003 “In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials” describes a hierarchy of calibration traceability schemes to accomplish standardization of results. The most desirable and best developed approaches for calibration traceability utilize primary (pure substance) reference materials to prepare calibrators for high level reference measurement procedures. The ISO standard for traceability provides for the situation when there is no reference measurement procedure and traceability is to a secondary (matrix) reference material. However, inadequate attention to the commutability of secondary reference materials has led to the situation when clinical laboratory procedures are traceable to a reference material, yet results for patient samples are not equivalent when measured with different routine laboratory procedures. For many analytes, secondary reference materials are not available, and alternative approaches based on traceability to a harmonization protocol are used to achieve harmonization. An International Consortium for Harmonization of Clinical Laboratory Results has been formed to provide a global infrastructure to enable a systematic approach for identification and prioritization of analytes to be harmonized, an information portal to foster collaboration among organizations contributing to standardization and harmonization, and a technical focus on analytes that do not have reference measurement procedures. Revision of ISO 17511 is in progress and is expected to include a standardization category for calibration traceability to a harmonization protocol. A new ISO standard for requirements for a harmonization protocol is in development and will enable JCTLM to list harmonization protocols for calibration traceability.
Session 5

Standardization - the example of thyroid function tests

Linda M Thienpont, C-STFT Chair

**Background:** Laboratory testing of serum thyroid hormones is essential for the diagnosis and management of thyroid diseases. The testing should meet modern clinical and public health needs, such as interchangeability of results. To accomplish this in the domain of free T4 and TSH testing, the IFCC established the Committee for Standardization of Thyroid Function Tests (C-STFT). Its mission statement was to document the standardization status of free T4 and TSH immunoassays (IAs), and if needed, to develop, apply and implement an approach to improve.

**Methods:** The C-STFT invited IVD manufacturers for participation in its activities. These started with performing a first method comparison study with a panel of native samples. When this study documented the need for standardization of free T4 and TSH IAs, the C-STFT developed reference measurement systems (RMSs) to establish metrological traceability. For free T4, this was done by defining the measurand and units for expression of results (pmol/L), followed by developing a conventional reference measurement procedure (cRMP) based on equilibrium dialysis and isotope dilution-mass spectrometry (ED ID-MS). For TSH, it was considered unlikely to accomplish SI-traceability in short to mid-term. Therefore, the C-STFT developed an alternative approach leading to harmonization rather than standardization. It preserves the traceability of IAs to the WHO international unit (IU) system and makes use of a surrogate RMP based on a statistical factor analysis (FA) model applying a robust alternating regressions method to calculate the all-procedure trimmed mean (APTM) from a multimethod comparison study with clinical samples. The C-STFT documented the feasibility of free T4 standardization and TSH harmonization in several method comparison studies, each using native samples covering a clinically relevant measurement range. In addition, the Committee developed a “step-up approach” to allow new IVD manufacturers to join the activities, and to ensure sustainability of the standardization/harmonization basis. Recently, the C-STFT tackled the technical process of standardization/harmonization – the so-called Phase IV recalibration studies. This process again was based on free T4 and TSH method comparison studies with panels of clinical samples, followed by measurement of respective reference interval (RI) panels of 120 samples each. Twelve IVD manufacturers participated.

**Results:** The Phase IV method comparison studies were successful. For free T4, the data were used for recalibration of the IAs against the ED ID-MS cRMP targets, for TSH against the statistical APTM. If already available by the general conference, the data for the RI panels measured with the recalibrated
assays will be documented and discussed.

**Conclusion:** The C-STFT is technically ready with the standardization/harmonization of free T4 and TSH IAs. The measurement data of the RI panels will be explored to serve as proof-of-concept for standardization/harmonization and to demonstrate that the different assays can use common RIs or decision limits. This achievement made the C-STFT ready to enter the phase of implementation. This requires careful preparation of all involved stakeholders (regulatory authorities, laboratories, clinicians and patients) for the impact standardization/harmonization will have. Another challenge is to assess the sustainability of the standardization/harmonization basis. Activities planned in this respect will be explained.

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**Note**

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IFCC Scientific Division: being aware of advances in scientific knowledge and of their practical implementation for clinical use in laboratory medicine

Philippe Gillery, SD Vice-Chair

A key mission of IFCC and especially of its Scientific Division is to be aware of advances in scientific knowledge and of their practical implementation for clinical use in laboratory medicine. In this regard, a special attention must be paid to the development of new concepts. In introduction to this session, the keynote lecture given by Larry Kricka will be devoted to emerging and disruptive technologies which could constitute promising technological developments in the future. Then, two examples of outstanding advances made in the field of standardization or harmonization of specific assays by IFCC-SD working groups will be given. The first one, presented by Kaj Blennow, WG-CSF (Working Group on Cerebrospinal Fluid Proteins) Chair, will be related to measurement and clinical utility of CSF proteins. The importance of establishing reference materials and methods for CSF markers such as Aβ1-42 for Alzheimer’s disease will be discussed. The second example will be related to the development of strategies for harmonizing auto-immune tests. Challenges related to the causes of variability of antibody measurements, the identification of auto-antibodies suitable for harmonization and the production of reference materials will be discussed, and illustrated with successful examples related for example to measurement of anti-myeloperoxidase auto-antibodies in vasculitis. This presentation will be done by Joanna Sheldon, WG-HAT (Working Group on Harmonization of Autoantibody Tests) Chair.
We live in an age when many technologies have disrupted both our everyday lives and commerce (e.g., tablets, cell phones, Wi-Fi, the Cloud, Skype, Amazon, Expedia, Google). In laboratory medicine, there are several emerging or disruptive technologies that could unexpectedly displace an established technology. The level of automation in the laboratory could increase with the introduction of the type of humanoid robots already deployed in some laboratories. At the test level, array-based analytical methods may become more widespread and dominant (e.g., single molecule detection, DNA sequencing). New technologies are creating unprecedented possibilities for self-testing and monitoring (e.g., contact lens, tattoo-based systems, disposable stick-on sensors). Particularly important is the explosion of tests based on USB stick-based analyzers and medical apps for phones and tablets.

A disruptive trend in point-of-care testing has been the use of disposable electronics to minimize steps performed by the operator and to provide more information and an improved user-interface. There have also been major changes in access to tests and testing. The consumer can now choose from numerous locations that provide direct testing (e.g., pharmacies, Retail Health Clinics), and has many routes to obtain diagnostic medical tests (e.g., Direct to Consumer Testing via the internet, collection kits for drugs of abuse, infectious disease, and pharmacogenomic tests available from a pharmacy).

Major disruption may also come from the expansion of home tele-health systems, and P4 Medicine (Personalized, Predictive, Preventive, Participatory). In the latter context, the various on-going population-scale genomic projects may accelerate our understanding of genomics and spawn more genomic tests. Finally, the Qualcomm Tricorder XPrize provides a view of several emerging technologies that may ultimately turn out to be disruptive.
Collection of cerebrospinal fluid (CSF) by lumbar puncture is a routine procedure in clinical medicine. The Alzheimer’s disease (AD) CSF biomarkers total tau (T-tau), phospho-tau (P-tau) and β-amyloid (Aβ42 or Aβ42/40 ratio) reflect central pathophysiological mechanisms of the disease, including neurodegeneration (T-tau), tau pathology (P-tau) and β-amyloid deposition (Aβ42). These CSF biomarkers have repeatedly been shown to have high diagnostic accuracy to identify AD already in the prodromal (MCI) stage of the disease. Low CSF levels of Aβ42 have very high (~95%) concordance for with amyloid PET measurements of brain amyloidosis. Thus, these AD CSF biomarkers are important tools for early diagnosis, and are central in the novel diagnostic criteria for the disease.

However, standardization efforts are ongoing due to the high between-lab and between-batch variability for current ELISA methods. The IFCC-WG for CSF proteins aims to develop Certified Reference Materials (CRM) for distribution to assay vendors and laboratories to harmonize assay readouts. Mass spectrometry-based have been developed for CSF Aβ42, and have been approved as Reference Measurement Procedures (RMP) by the Joint Committee for Traceability in Laboratory Medicine (JCTLM). Biotech companies are developing high-quality fully automated assays with minimal analytical variability. Data from the Alzheimer’s Association quality control (QC) program show that between-lab variability drops to 3-4% for fully automated methods (from around 20% for the ELISAs). Taken together, these efforts will allow uniform cut-off levels and enable the large-scale introduction of CSF biomarkers in diagnostic routine.

New developments include biomarkers to monitor synaptic dysfunction. Recent studies show a marked increase in CSF levels of the dendritic protein neurogranin in AD, with higher neurogranin levels predicting a more rapid cognitive decline and with progression to AD dementia. A first study also suggests that the increase in CSF neurogranin is specific for AD. Thus, synaptic biomarkers may be valuable to select early AD cases for inclusion in trials, to monitor drug effects on synaptic function and integrity, and to study disease pathogenesis in longitudinal studies directly in patients and elderly individuals.
Standardisation of autoantibodies is not straightforward. Antibodies or immunoglobulins have a high degree of molecular heterogeneity, IgG and IgA have more than one subclass and the affinity and avidity of antigen-antibody binding can vary both between and within individuals. An immune stimulus generate a monoclonal, oligoclonal or polyclonal response which may vary between individuals or within an individual over their disease course. There are multiple methods available for autoantibody detection which will vary in their abilities to detect different types of immunoglobulins. Finally, the antigen to which we are trying to measure antibodies is usually a protein with its own molecular heterogeneity which may also be influenced by the source of the antigens and the preparation process. Considering these complexities, it is unsurprising that there is marked variation in autoantibody concentrations measured with different methods (up to 1000x differences). It is also unsurprising that in approximately 30 year since quantitative autoantibody testing became available there have been no certified, commutable, traceable reference materials available.

The IFCC Harmonisation of Autoantibody Testing Working Group (WG-HAT) was formed in 2010 with the primary aim of producing certified materials for autoantibodies. We also wanted to gain a better understanding of the problems around autoantibody measurement and develop protocols for long term sustainability of standards in autoimmune serology. The group included members from the IFCC, the Institute of Reference Materials and Measurements (IRMM), members from the autoantibody and rheumatology community and colleagues from the diagnostics community.

Our initial focus was on 5 autoantibodies where the concentration of the autoantibody had a clear role in the diagnosis and management of patients. We sourced raw material from patients with the relevant disease and the IRMM, have produced the first certified reference material for an autoantibody; IgG anti myeloperoxidase ERM Da 476. This is one of the anti neutrophil cytoplasmic antibodies (ANCA) which associated with vasculitic diseases and with rapidly progressing renal impairment. Reference materials for IgG anti proteinase 3 (another neutrophil enzyme associated with ANCA vasculitis), and IgG anti β-2 glycoprotein 1(associated with hypercoagulable conditions) are in the final stages of evaluation and value assignment.

Historically, values for “standards” in autoimmune serology have been quoted in units or international units although both are arbitrary. The materials for IgG anti proteinase 3 and myeloperoxidase have been value assigned in mg/L,
traceable to ERM Da 470k/IFCC, the certified reference materials for IgG.

The initial evaluation of patient samples with respect to ERM Da 476 showed that there was a significant reduction in the spread of the numerical results over 9 different methods. However, there was only 30% concordance between positivity and negativity of results when interpreted with respect to each methods reference ranges. It is vital that we have a better understanding of these differences therefore a large independent study is in progress of both IgG anti myeloperoxidase and IgG anti proteinase 3 and a group of well characterised samples from patients with ANCA vasculitis and a selection of different methods.

We have taken a significant step forward in standardisation of autoantibody testing but reducing the variability in the results given is only one aspect and the complexity of the analytes means that many challenges!

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**Session 6 - Simultaneous interactive workshop**

**Rationale use of contemporary and high-sensitivity cardiac troponin assays**

**J. Ordoñez-Llanos**, TF-CB Chair

**Antecedents.** The IFCC Task Force on Clinical Applications of Cardiac Biomarkers (TF-CB) was created in the year 2011 following an initiative of the IFCC President. The TF-CB was committed to develop educational initiatives in the evolving field of cardiac biomarkers. The promoters of the TF-CB invited to several clinical and laboratory specialists with reputed expertise in cardiac biomarkers to join the group. Currently, TF-CB is formed by half clinicians (ED physicians, cardiologists) and half clinical chemists. There are also corporate members representatives of the companies implicated in the cardiac biomarkers development; their support and advice is fundamental for the TF-CB work.

**Achievements.** The first steps of the TF-CB coincided in time with the introduction of high sensitivity cardiac troponin (hs-cTn) assays in clinical practice. Accordingly, the TF-CB aimed to provide clinicians and clinical chemists with educational materials highlighting the main characteristics of the hs-cTn methods and their performance when used for managing acute or chronic cardiac diseases. The mixed composition of the TF-CB permitted to produce recommendations addressing both clinical and laboratory issues. The recommendations were published in two separate documents (Apple FS et al. Clin Chem 2012; 58:54-6; Clin Biochem 2015; 48:201-3). The content of the documents was summarized in pocket-size and sheet-size formats for being distributed among all the IFCC Societies and during the IFCC meetings. The documents are also available in the IFCC web site ([http://www.ifcc.org/executive-board-and-council/eb-task-forces/task-force-on-clinical-applications-of-cardiac-bio-markers-tf-cb/cardiacbiomarkersresources/](http://www.ifcc.org/executive-board-and-council/eb-task-forces/task-force-on-clinical-applications-of-cardiac-bio-markers-tf-cb/cardiacbiomarkersresources/)).

**Current activities.** The TF-CB is currently developing two new educational activities. First, the redaction of a new educational material related to the usefulness of all existing cTn assays, including the so-called “contemporary” methods and the methods implemented in point-of-care or near-to-patient instruments. Second, the TF-CB will discuss in the IFCC GC in Madrid, the appropriateness of developing a document, useful for diagnostic companies and laboratory professionals, which include the characteristics that a population should fulfill to be used in the calculation of a cTn 99th reference percentile. Up to date, this is a very confusing topic that could deeply affect the clinical utility of cTn assays.

The past and current TF-CB activities will be presented to the delegates attending the interactive workshops of the IFCC Functional Units, next March, in Madrid.
Adverse drug reactions are responsible for 5-7% of hospitalizations each year. Effectiveness of drugs is reported to be only 25-60%. Interindividual variation in drug metabolism is a key factor underlying part of these unwanted effects. Genetics causes an important part of this variation: DNA variants in metabolizing enzymes make that not each individual has the same metabolizing capacity in the liver. Since it is genetic, it can be determined upfront of therapy from DNA isolated from blood or saliva. This enables us to leave the approach in treating all patients with an average dose, to prescribing drugs based on DNA information. This will result in less Adverse Drug Reactions and an increase in drug efficacy. There is a huge demand from patients, physicians, pharmacists, insurers and regulators for this approach. In January 2015, Obama launched in this aspect the Precision Medicine Initiative, with huge funding of billions of dollars. Laboratory medicine can, and should play an essential role in making Personalized Medicine become a reality.

With over 5,000 articles per year being published on potential genomic markers to guide drug therapy, choosing the most promising markers for routine use is a challenge. Genetic polymorphisms in the Cytochrome P450 system, which is involved in the metabolism of 80% of all drugs, seem an important contributor. For instance, 5-10% of the population are deficient in the important CYP2D6 enzyme, that is involved in the metabolism of 25% of all drugs. Such a deficiency can nowadays been analyzed quickly at reasonably low costs, and will allow adjusting therapy for antidepressants, antipsychotics, pain medication, betablockers and the anticancer drug tamoxifen. Each cytochrome has in this ay its own spectrum of drugs and associated risks.

For a successful implementation, essential factors are education, access to testing, existence proficiency testing schemes, harmonization of testing and of reporting, uniform interpretations and actionable results, development of decision support tools, information on limitations and advantages of testing. Many of these factors are currently available. In the Netherlands, routine testing for pharmacogenetic markers is being done for over 10 years. This DNA information can be used in any pharmacy in The Netherlands to obtain personalized dosing for more than 80 drugs. This successful approach is the basis for the European Pharmacogenetics Implementation Consortium (www.eu-pic.net) in which the experiences in The Netherlands are combined with
those of 18 European countries by means of a laboratory network, organized through the IFCC TF-PG, in collaboration with ESPT. This workshop will demonstrate the current state of the art of personalizing drug treatment in clinical practice, and address the challenges and some solutions, based on experiences from the last years. And the question to you: do YOU already have your DNA passport for drug Therapy?!?

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The use of critical values for reporting clinical results requiring action to the requesting physician is a standard practice in many clinical laboratories. The choice of values for critical notification is made largely based on potential clinical impact and in discussion with the local users of the clinical laboratory. The rapidly changing physiology, less robust homeostasis and lesser reserves in premature and term neonates, infants and children have led to the use of different critical value levels in these pediatric populations.

We conducted a survey of pediatric critical values used in laboratories across the IFCC global community. More than 200 replies were received from fifty-four countries. Diversity of respondents included private/commercial laboratories, university hospital laboratories, and both primary and secondary care laboratories. In this workshop we will share the results of this survey, including: the choice of analytes for which critical values are defined; range of critical values used for the chosen analytes; implementation issues; and reporting practices.

We will discuss results in relation to current world literature and next steps for defining best practices for global pediatric populations.
Research is an academic activity and it means “a careful investigation or inquiry especially through search for new facts in any branch of knowledge.” Thus, it is an original contribution to the existing stock of knowledge making for its advancement. The purpose of research is to discover answers to questions through the application of scientific procedures to find out the truth which is hidden and which has not been discovered as yet. The reasons that motivate people to undertake research can be numerous because it is related to fundamental importance. Few related areas: 1) to get a research degree along with its consequential benefits, 2) concern over practical Problems, 3) to do some creative work, 4) respectability, 5) service to society, 6) directives & requirements and 7) employment. Research nearly provides the basis for nearly all government policies in our economic system. There are several different pathways to enter the clinical research profession as per the region. Largely at many places prospective research scientists must possess a bachelor’s degree in the biological sciences or a related field. Some institutions offer a degree specifically designed to prepare students to work in clinical research. This type of degree program includes courses in biochemistry, pharmacology, effective research techniques, scientific writing and data management. Most clinical research scientist positions require either an advanced degree in the biological sciences or a medical degree. Some universities also offer master’s degree programs in clinical research and learning about research procedures, scholarly publication practices, biostatistics, professional ethics and clinical trial practices. Many clinical research scientists choose to complete a dual degree program with majors in medicine and science which offers learning about medical practices and advanced research methodology. Clinical research scientists may work at universities, hospitals, pharmaceutical companies or for the government setup with the goal of understanding the causes of diseases, develop vaccines or medicines for treatment, clinical trial drugs and therapies. As the healthcare is rapidly growing both in knowledge and technology, so it is essential for young scientists and budding researchers to update the knowledge through different means of continuous education such as conferences, webinars, online courses etc. It will be advantageous and help them to attain high-level professional & managerial positions within their respective medical facilities.
Goal of this interactive workshop (IW) is to enhance the participants’ understanding of strategies for dealing with several important aspects of QC before running patient tests and the key steps to establish an effective QMS, so that they can more effectively address the problems in implementing continuous quality improvement efforts in the clinical laboratory. The IW will represent a “bottom up” approach such that actual and “real” laboratory issues concerning IQC and EQA questions including any regulatory requirements should be addressed by IW participants.

Strategy to achieve this goal is to conduct the IW three times. Each IW will last for 45 minutes and consist of 4 phases:

- (A) 5-minute initial “impulse lecture” by the IW moderators to present the agenda, aims and instructions for activity.
- (B) 5-minute - spontaneous group forming with 5 - 8 participants per group (Number of the groups depends on the availability of participants). Then, a questionnaire is handed out of groups.
- (C) 15-minute group discussion: “exploring” - experimenting with the ideas and finding most burning top three issues and listing those issues on flip charts.
- (D) 20-minute concluding activity: “closing” – evaluating, deciding, and listing actions.

Towards the end of (D), group leaders are asked to present their outcomes – 3-minutes for each group. The outcomes will be collated by the moderators and presented as an “IW Summary”.

Finally, moderators will ask participants for comments on what aspects of the workshop were most useful and how future workshops might be improved. The summary will be documented in a useful form to capture the findings for future IFCC events. As for logistics, Flip charts for recording participants’ ideas, Marker pens and Group name placeholders will be provided.
Laboratory Medicine specialists and their partners in the diagnostics industry have been successful in enabling the ready availability of high quality, low cost laboratory diagnostics. Whilst these developments are commendable it is now easy for unthinking physicians to order a large battery of tests in the hope that they may point to a diagnosis. This ‘scattergun’ approach to the use of the clinical laboratory has a number of consequences, including:

- A high percentage of ‘unnecessary’ results
- The perception that Laboratory Medicine is a ‘factory’ rather than a clinical specialty
- Rising costs for the clinical laboratory
- Challenges in introducing new, specialist investigations that have a high unit cost

Today Laboratory Medicine specialists recognise the need for a more discriminatory and evidence-based approach. A number of related areas are being developed, including:

- Workload management (called laboratory utilisation in some countries)
- Education of physicians on the appropriate use of the clinical laboratory
- Initiatives to illustrate the clinical effectiveness of laboratory investigations as part of demonstrating the value of Laboratory Medicine.

IFCC has committed to two related projects in the area of clinical effectiveness.

Increasing Clinical Effectiveness (ICE) is a programme organised by the Clinical Laboratory Management Association (CLMA), which is being supported by IFCC and other partners. It has been launched to encourage Laboratory Medicine specialists to collaborate with clinical colleagues to demonstrate that optimal use of the laboratory can have a measurable positive impact on patient outcomes. Each year ICE invites Laboratory Medicine specialists to submit an abstract that describes testing-related interventions and the quantifiable positive impact for patients that they produced. The winners of the 2015 submissions will present their work at CLMA’s Knowledge Lab 2016 whilst the winners of the 2016 submissions will participate in a symposium at IFCC EuroMedLab Athens 2017. Examples of winning abstracts will be illustrated in the ICE workshop.

The second IFCC project is still at the formative stage and workshop participants are invited to help develop the detail of the project. In outline the project will:
• Recruit a team of interested laboratory specialists
• Invite each specialist to write one or more short articles in a standard format. Each article will demonstrate how a specific clinical outcome is influenced by Laboratory Medicine results
• Publish the results in a single journal enabling a library of examples to be compiled to illustrate how the correct use of the laboratory can increase clinical effectiveness.

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Sunday 20 March
Rising costs and demands for improvement in the quality of healthcare are requiring increased services with reduced budgets and driving discussions on value in healthcare. The dominant model of funding for laboratory medicine is fee for service, which has focussed payers on costs and laboratory management on cost minimisation. The past period has seen an era where quality of laboratory testing has been under pressure with large scale automation and consolidation of laboratories being emphasised to achieve economies of scale to reduce costs. Opportunities for future stepwise reductions in clinical laboratory costs are likely to have diminished. The focus is now on delivering improved testing in a cost neutral or at least cost effective manner. This brings laboratory medicine into line with other health services that focus on value for money for payers and maximising health outcomes for patients. The IFCC advocates that laboratory medicine needs to ‘add-value’ to laboratory testing by improving patient outcomes on top of quality performance. This therefore raises the question as to how can this added value be demonstrated? One approach is to adopt the commercial concept of a Value Proposition which, when described for a particular test, will explicitly state a number of core attributes. These attributes include the suitability of patients for its use, the role the test result will play within the patient care pathway and the benefits and costs to all the relevant stakeholders. Application of the Value Proposition concept will extend existing principles of evidence-based medicine. It will importantly provide opportunities for the laboratory profession to provide leadership for both the adoption of new tests as well as modification of existing test usage rather than operating in the isolated and increasingly constrained laboratory medicine silo that typically describes current operations.
The cornerstone of bioethics and of medical practice in general is the Latin phrase ‘primum non nocere’, which means ‘first, do no harm’. Unfortunately, the reality in the healthcare sector is that this is not always the case. Despite significant improvements in patient safety, data from large-scale, retrospective, chart-review studies of adverse events reveal a high percentage of diagnostic errors and ‘zero defects’ remains a distant goal.

Clinical laboratories are particularly important in patient safety, because most of the decisions made by physicians are based on laboratory results. Although laboratory data are more objective than clinical symptoms, interpretation of test results by physicians shows wide variation. Misinterpretation of test results (post-analytical error) is a major source of laboratory errors. In this context, objective interpretation of laboratory data is as important as accurate test results.

We use test results for patients’ diagnoses, monitoring, screening and case findings. However, test results are not strict data and can vary over time due to three factors: pre-analytical influences, analytical variations, and inherent biological variation (BV). Using standard laboratory procedures, pre-analytical influences can be reduced significantly and analytical variations have been reduced to acceptable levels by using high-quality instruments. However, BV cannot be decreased or eliminated by using standard laboratory procedures or high-quality instruments. Consequently, physicians should be familiar with BV, particularly in diagnosing and monitoring patients.

For diagnosis, physicians use reference intervals to compare patients’ results. Due to inherent variation in test results, there are grey areas around the upper and lower limits of the reference interval. If a test result falls within these upper or lower reference limits, the patient may be misdiagnosed. In such cases, the test should be repeated and then a clinical decision should be made accordingly. Thus, to decrease diagnostic errors, physicians should be aware of variations in test results particularly around the lower and upper reference limits.

Objective interpretation of patients’ serial results facilitates patient treatment. Therefore, physicians should be familiar with reference change values (RCVs), otherwise some non-significant differences may be considered significant resulting in incorrect treatment of patients. To obtain a RCV, the equation given below can be used.

$$\text{RCV} = 2^{1/2} \times Z \times (CV_A^2 + CV_I^2)^{1/2}$$

Two points should be noted before using this equation. The first is that within-
subject BV (CVI) is higher in patients than in healthy subjects; the second is that the value of Z should be modified by using a larger Z value if the equation is applied to a comparison of more than two results (1).

In conclusion, to overcome errors related to misinterpretation, understanding of BV by physicians is essential. In this context, laboratory reports should be modified and new symbols added to alert physicians to significant changes.

References
1. Lund F, Petersen PH, Fraser CG, Sölétormos G. Calculation of limits for significant unidirectional changes in two or more serial results of a biomarker based on a computer simulation model. Ann Clin Biochem. 2015;52:237-44.
The main responsibility of a medical/clinical laboratory is to provide accurate and precise laboratory test results to users in time. Total testing process of a laboratory is under influences of many factors. Every factor should be taken into consideration in the managerial activities. This requires both business management and total quality management knowledge.

The laboratory examination techniques and/or methods performed in healthcare services are applied in routine practices after a long journey. This journey starts from the creation of a biomarker, continues with the production of related in vitro diagnostic medical device (IVD) or devices, validation for acceptance for marketing, and ends with the verification by users for presenting into healthcare services.

The laboratory professionals as the users of IVDs should be aware of the processes in an IVD life cycle both before and during routine practice, and also have knowledge about responsibilities in the steps of the life cycle. Then, they can take part in the creation of a new IVD and/or innovations which add value to the healthcare. They should be partners of the IVD management teams composed of all stakeholders including manufacturers, regulation authorities, and in hospital auditing committees. This requires both analytical and medical knowledge including management knowledge.

Since approximately 70% of individuals admitted to a hospital have laboratory tests, every laboratory can be considered as a data generation center of a hospital, and national health information system. Laboratory professionals should have knowledge and competencies in order to contribute to the development of exchange and display laboratory data in the electronic information system, and also utilization of laboratory data for effective and efficient health care services. This requires information technology, laboratory statistics, and evidence-based practices knowledge.

In most countries, the syllabi about knowledge, skills, attitudes and competencies, which laboratory professionals should have, are established in order to accomplish the requirements mentioned above. Also, the names of professions have been defined (Please see the electronic Journal of the IFCC, and EFLM EC4 activities). If there is a system that is structured under the legislations established together with the professional and scientific organizations in a country, and that is applied with the consensus without conflicts between specialists and medical scientists with doctoral degrees, the main challenge seems to develop effective education and training programs for the different backgrounds of trainees. The programs also should be prepared taking into consideration of exponentially growing information and
Main objectives of an LM education should be to gain the skills and competencies required in the “real world” work, and life-long learning skills to the graduates. In this context, I will try to present a competency-based education framework for designing and implementing education that focuses on the desired performance characteristics of professionals in laboratory medicine according to the “The Framework for qualifications of the European Higher Education Area”; “Proposal a Common Training Framework for Specialists in LM across the EU” and “The Chemical Pathology Milestone Project” by the Accreditation Council for Graduate Medical Education and the American Board of Pathology”.

Note
“Information Society” refers to the increasing capacity to produce more information and spread it even more rapidly. “Knowledge Society” refers to the critical and selective apprehension of information interpreted by people who know how to make the most of it. “Knowledge economy” is the use of knowledge to generate tangible and intangible values.

Technology, and in particular knowledge technology, help to transform a part of human knowledge to machines. This knowledge can be used by decision support systems in various fields and generate economic values.

The growth of clinical biochemistry information hinders the adequate, rational use and interpretation of the laboratory tests by health professional. Managing biochemistry information productively is not an easy task for professionals, who have to analyze it methodically and systematically. The most difficult challenge is to learn how to operate and interpret information in informatics contexts, with standardized terminology and semantic interoperability. Information and communication technologies (ICTs) comprises: data, information, knowledge, specific processes and collaboration among professionals, who have scarce resources and time.

Knowledge management is a process that implies a major use of information and communication technologies, to participate in the use and interpretation of biochemistry information with healthcare teams, in order to achieve better effectiveness in healthcare.

A consulting site is being created by a multidisciplinary group who develops a “Biochemistry Knowledge Management System” hosted in infobioquimica.org. (more than 1 million visits since its creation).

During the workshop we will present the Knowledge Management project that is under development using ICTs. It is constituted by 5 independent elements and sub-programmes.

1. Knowledge capture: Medical and biochemical elicitation system. Search by pathology and/or by laboratory test.
2. Knowledge search: Expert system “SABIO”, Biochemical Knowledge Assistance (ABC) and digital book “Biochemistry Information Interpretation”
3. Interconnectivity: Infobuttons in Electronic Clinical Records (ECR), Laboratory Information System (LIS) and apps for mobile devices.
5. Knowledge collective construction.

The workshop will bring into discussion 3 programmes:

- SABIO is a decision support system, it comprises: knowledge elicitation, collection of data, biochemistry and medical knowledge and a search engine. Currently in pilot testing with celiac disease.
- Online radio “El Microscopio” and Social networks. They have been developed for Knowledge socialization, to share expert knowledge and information.
- Lab-Surfing.com is a socialization tool that connects scientists from all around the world under the motto: Connection & Good Vibes. It improves communication among scientists and facilitates exchange programmes.

Knowledge management and improving interactive communications systems will be essential to comprehend greater amounts of complex information daily produced in clinical laboratories, at a great speed, leading to an outstanding performance in the use of biochemistry information. Furthermore, knowledge management will help us to improve practical effectiveness in the clinical laboratory to accomplish better patient outcomes. Therefore, it reflects the great interest and increasing need of communication and information technologies in the field of clinical biochemistry. We have called this new concept of clinical laboratories: Biochemistry 2.0.
The POCT task force was commissioned in 2012 to bring together health professionals interested in the safe quality use of POCT. This includes health professionals starting out on their PoCT journey as well as those running PoCT but wanting to ensure they have an appropriate quality framework implemented. Our Terms of Reference are:

1. To promote quality in the use, performance, interpretation and reporting of POCT across the full spectrum of clinical chemistry and laboratory medicine
2. To create a forum for high level discussion on a wide range of POCT related topics
3. To provide international leadership for developing the clinical practice of POCT in Laboratory Medicine.

Four key factors we have focused on are:

I. Implementing an appropriate PoCT quality framework
II. Education and training of PoCT operators
III. How much quality testing should be performed for PoCT tests
IV. Integrating PoCT into clinical practice

We have run two international PoCT satellite meetings (Istanbul and Mexico) sponsored by industry partners which have covered a range of technical and clinical topics presented by expert clinicians and scientists using PoCT. The task force has been greatly appreciative of industry support it has been given to date. Presentations from these meetings are stored on the IFCC website. In addition to the satellite meetings the task force has produced a document on “Thinking of introducing POCT Things to Consider” to assist people who are setting up a new PoCT service or who are new to PoCT and require further information. Over the last three years task force members have contributed to PoCT by giving presentations, co-authoring PoCT papers and meeting with other IFCC groups and organisations to improve PoCT knowledge base. The group has responded to requests from countries requesting PoCT support by planning PoCT satellite meetings – one held just recently in Mexico in response to a Mexican Clinician requesting assistance and another satellite planned for Worldlab 2017 Durban. The meeting planned in Durban will focus on the needs of the region in particular infectious diseases, which will also be relevant to other IFCC countries.

One work group was set up under the task force in 2013 on “How should Glucose Meters be evaluated in Critical Care”. This work large group representing many countries has been working very hard and should release
a document with their findings later this year. Over the next two years the task force is planning to deliver comprehensive education on blood gases, establish some recommendations on how PoCT troponin should be used, continue education on PoCT quality requirement, set up a POCT adverse events database and produce a special issue on POCT in a scientific journal based on the satellite meeting in Durban.

What the task force would like to know is what you as an IFCC member would like the TF to focus on. What topics would benefit you the most? It is important that as a TF we are focused on the needs of our community and we encourage you to use this workshop to inform us. If you don’t get the opportunity to or feel more comfortable emailing your ideas please send them to chair rosy.tirimacco@health.sa.gov.au.

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The TF-PT is “a multidisciplinary effort in the analysis and the exploration of the Proficiency Testing issues. This could lead to the establishment of specialized schemes under the hospices and recommendations of the IFCC and could greatly enhance and help to the prevalence of the methods derived from the work of the federation and to the harmonization of laboratory results.” The main project of the TF-PT is the creation of an online database - web application accessible via web browsers but also via specific applications for the major mobile platforms with much more functionalities and ease of use. The roots of this database will be the analytes (tests, measurands) that will be filed with all possible synonyms (one of them will be the “official” as proposed from the Nomenclature, Properties and Units (C-NPU) committee of the IFCC-SD) as also as the methods (assays, instruments, reagents etc) also with all possible synonyms. Another part of the DB, maintained with the cooperation of the IFCC committee for Analytical Quality (C-AQ) and of EQALM, will be the PT providers section containing all their contact information, their programs with the analytes, frequencies, type of statistics, commutability of control materials, their accreditation or certification status etc. All register users can add any term in the database, although the application will propose similar ones if there are already filed, searching all the possible synonyms, and if there is already filed they can “vote” expressing their desire for the introduction of a PT for this analyte.

During 2014 the TF-PT had his kick-off meeting at the WorldLab 2014 in Istanbul, afterward the members of the TF had private meetings at the annual meeting of AACC (July 2014 in Chicago) and the chair of the TF had a meeting with the board of EQALM in Toulouse at the end of October 2014 (during the EQALM board meeting), in order to request a close cooperation and the participation of EQALM to the TF-PT. A decision had been taken there to meet again during the next EQALM meeting in Bergen, in order to discuss our request of cooperation and to present the progress made from the TF-PT on his various projects. At this meeting, early October 2015, TF-PT and EQALM agreed to co-organize a symposium on EQA issues at the next EuroMedLab Athens 2017.

Moreover, at the EuroMedLab 2015 congress in Paris the members of the TF-PT had their second annual meeting. The result of this meeting was the production of two draft documents: one entitled “Exploration and Clarification of Specifications for the TF-PT Project” containing analytically the terminology...
of the project, and one entitled “Webpage IFCC Market Place Forum Supply and Demand EQA”, describing the basic workflow diagram of the proposed application-database with various examples in a table form.

In conclusion, the database in development from the TF-PT will interactively link our colleagues - final users of the tests, with PT providers, IVD manufacturers, accreditation bodies etc and will facilitate the search for a PT scheme for “rare” esoteric or new analytes, or the introduction of a new one if needed. Automated algorithms with well-defined thresholds will send request to appropriate PT providers, if an analyte has exceeded the limit of the required votes. IVD manufacturers want also to establish such PT schemes prior to the introduction of new assays as requested for the personalized medicine and the companion diagnostic assays. Moreover, the database can be used for the tasks of harmonization project of the AACC.

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Open meeting with all IFCC National Representatives and Representatives from Iberoamerican countries

Integrating IFCC activities, sharing experiences and pooling expertise. Open meeting with IFCC National Representatives

Rosa Sierra-Amor, IFCC EB Member

National Representatives of Full and affiliate member societies participate at IFCC activities in different ways. This interactive discussion meeting is looking forward to discuss actual and future actions on behalf of the membership developing implications, member motivation and international participation. IFCC is seeking for the best way to promote the profession and to develop tides with lab med and clinical National societies to improve laboratory medicine worldwide. As established in IFCC Status and Rules, National Representatives receive copies of all documents and publications distributed by the IFCC. They are responsible for providing their Societies formal responses and comments on these documents to the Executive Board or the specifically designated Division or Committee (or IFCC functional unit). Full Member representatives are the official conduit from the Member Societies for bringing relevant matters regarding the profession of clinical chemistry and laboratory medicine to the attention of the IFCC. They are eligible to hold an international or regional congress of clinical chemistry and laboratory medicine, and may seek support from the IFCC for international, regional, national or local meetings. The IFCC may grant either its auspices or sponsorship where appropriate (see Congress guidelines). They have entitled to have representation in Divisions, Committees and Working Groups as well as to nominate members of Division Executive Committees, Committees and Working Groups. The appointments for the Division Executive Committee membership and the Committee’s Chairs lie with the IFCC Executive Board on the recommendation of the appropriate Division Chair. Members of Committees and Working Groups are appointed by the respective Division Executive Committee. Each Full Member is entitled to appoint a corresponding member to every Committee and Working Group. As for other rights, Full Members are entitled to apply to host an IFCC Visiting Lecturer, through the Visiting Lecture Programme and to describe themselves as such in their publications and other promotional material. A working group on a specific topic for a Full Member or several such Members may be recognized formally as an IFCC Working Group. Full Members may submit a project proposal. Therefore, there are several activities for the National Representatives to host their position in IFCC activities. Furthermore, and since several years ago, surveys have been sent to National Representatives in order to improve the communication, to learn about IFCC activities and planning, to develop projects in conjunction with industry and with their support. Facilitating the knowledge and Sapienza in laboratory medicine,
which is the target and final objective of IFCC (1). For a more efficient policy theme, the interactive workshop will carry out networking activities intended to support, inform and analyze the dissemination and use of knowledge in a more strategic manner on the basis of an enlarged partnership. The ambition is to strengthen IFCC community actions by means of audacious reflections and a series of practical proposals that augurs well for a sustainable IFCC future and to remain competitive on the Regional and International level. During the interactive discussion meeting, we are planning to look into the above description of a National Representative activities, to facilitate and to improve the participation and cooperation in order to have a better representation and feedback from all IFCC Full Member societies. A summary of actions taken at this meeting will help us to work in parallel along the regions and within the regions of IFCC.

Reference: (1) IFCC Statutes and Rules 2013 www.ifcc.org

Note
The Spanish Society for Clinical Biochemistry and Molecular Biology (SEQC) was founded and admitted into the IFCC 40 years ago. The aims of the Society were bringing together the professionals from the Clinical Laboratory, promoting the professional development, research and education in this field oriented towards the benefit of patients and physicians activity and to the general population. It has nearly 2284 members who are university graduates coming indistinctly from schools of medicine, pharmacy or science (chemical or biological). Many of them are specialized in Clinical Biochemistry or Clinical Analysis. The General Assembly of members is the High Authority government. It meets once a year, usually coinciding with the National Congress of the Society. The Assembly elects the officers of the Board: President, Vice President, Secretary, Treasurer and five members-at-large, who manage and represent the Society. SEQC has its official headquarters in Barcelona. A few years ago it was established the “Jose Luis Castaño Foundation for Clinical Laboratory development” named in memory of a former SEQC President in order to promote and manage educational and research activities in the field of Clinical Laboratory. Since its foundation SEQC has been committed as a consultant to Spanish Government, as an active member of the Spanish Federation of Scientific Societies, as well as a number of collaborations with the Association of the in vitro Diagnostic Industry of (FENIN). SEQC had a main role in the establishment of the European Federation of Societies of Clinical Chemistry (EFLM) and the Confederation of European Community of Clinical Chemistry (EC4). SEQC is also an active member of the International Federation where many members currently serving in Committees and Working Groups. At National level SEQC has agreements with other scientific societies in the field (AEFA and AEBM) on national congresses and the publication of the scientific journal, “Laboratorio Clínico”.

The scientific, educational and technical tasks are driven by several committees: scientific, education, external programs of quality, communication, and congress. The Scientific Committee has twenty seven Committees and Working Groups and produce a number of publications (articles, monographs, recommendations) and events (workshops, symposia, etc.). The Education Committee organizes a continuing education program as well as a number of
courses or educational activities, many of them on line. The Committee for external Quality Assurance Programs organizes of up to fifteen external quality assurance programs including a pre-analytical one. The Communication Committee manages the Society website, the publications (journals, monographs and books), the Spanish version of “Lab-Test On Line” project, and other aspects related to the public image of the Society. The Congress Committee participates with the AEFA and AEBM in the organization of the annual National Congress of Clinical Laboratory. Recently was established a Committee for trainees and young scientists. For more information please visit http://www.seqc.es/es/Home/.

This is the second time that SEQC collaborates in the organization of IFCC General Assembly and therefore hosts Latin American National Societies members of the IFCC. It is a unique opportunity to come into direct contact with a considerable number of Societies that represent most of our Latin American colleagues and to take advantage to establish or consolidate links in a specific area of cooperation for mutual interest between SEQC and Latin American Societies. There is no doubt that sharing the same language and having affordable communication technology are strength points that can help solve old problems such as geographical distances. Links are important to provide tools in order to overcome today challenges such as globalization and maintenance of cultural identity, also in science. SEQC is convinced that this is a great opportunity to share and exchange experiences and scientific talent among all Spanish-speaking societies for the benefit of all professionals represented. The IFCC should be the ideal framework to impulse, protect and promote an active cooperation.

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Roles and Responsibilities

The Committee on Congresses and Conferences (C-CC) was established in December 2007 as the continuation of the former Congress and Conference Division (CCD) which was founded in 1996, but with an expanded charter and responsibilities. The C-CC has the major administrative and managerial responsibility within the IFCC for all meetings coordinated by the IFCC. The C-CC supports and promotes laboratory medicine science through congresses, conferences, specialised meetings, and other professional meetings.

The C-CC formulates and updates as required the guidelines, procedures and practices for IFCC-designated meetings; it also monitors compliance throughout the planning and organizational stages. The main congresses organised by the IFCC and the regional Federations are the ICCCLM-WorldLab and EuroMedLab Congresses and the APFCB, AFCB, AFCC and COLABIOCLI Congresses. IFCC Specialised Conferences are organised with cooperation of many companies such as the IFCC-Roche Diagnostics Bergmeyer Conferences and the IFCC-Abbott “Turning Science into Caring” Symposia. C-CC provides IFCC Auspices to high quality meetings which are mutually beneficial for the IFCC and the IFCC member societies to promote congresses to their members and to strengthen the global image of the IFCC. The number of meetings that have been granted IFCC auspices has grown from 26 in 2012 to 45 meetings in 2015.

The Hybrid Model for Congresses and Conferences – A Future Model for the IFCC?

The congress and conference events organised by societies as we know them today are experiencing a fundamental change which started around the time of the beginning of the new millennium. This change is caused by several factors. The first of the two most influential factors is the ever expanding use of information and communications technology (ICT) and social networks by the younger generations of laboratory professionals and physicians. The second is the pending revised industry regulations that become effective as of January 2017. Other influential factors include the gradual decline in the funding available for travel by individuals and the ever changing stability of the global economy, security and the environment. All of these factors may over time negatively impact the academic, commercial and financial well being of the historic model of congresses and conferences.
In order to assess these concerns, the C-CC will initiate investigation of the emerging “hybrid congress/conference model” as a potential future model for IFCC congresses and conferences.

The hybrid conference enables participation that is either physical (on-site) or virtual (through ICT and social networks) and therefore provides for opportunities to address many of the challenges described above. The hybrid model also provides opportunities for increased in interaction and revenue through increased participation and advertising.

As an example, the results of the hybrid conferences of the European Society of Cardiology from 2013 to 2105 provide evidence for the potential success of a hybrid model.

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Both governments and industry companies have tightened its regulations and ethics. In 2013, U.S. Government started The Physician Payments Sunshine Act - or, simply, the Sunshine Act. The Sunshine Act is designed to help decrease the possibility of conflicts of interest between doctors and pharmaceutical companies. It governs all related activities including industry’s support for congress- honorarium for speakers, payments for travels meals etc. In turn, the industry companies increased their regulations and ethics codes in this regard. On another hand, medical field and its professional organizations such as IFCC needs supports from industry, in order to function more effectively, particularly on association congresses. Without industry’s supports, it won’t be possible to organize any association congresses.

In my talk, I will highlight the evolution of the IVD industry’s ongoing support for congresses according the business ethics codes.
Dear Friends,

It is our great honour and pleasure to invite you to participate in the 14th Asia–Pacific Federation for Clinical Biochemistry and Laboratory Medicine Congress in Taiwan in 2016. It is the first time such a great event to be hosted by the Chinese Association for Clinical Biochemistry (CACB) in Taiwan.

The organizing committee will arrange scientific and social activities to enrich our knowledge, skills and networks. We also hope that you will enjoy Taiwan, which is well known as Formosa, the beautiful island, an interesting place with a wide array of tourism and ecological resources, a diversity of traditional folk customs, a rich culture, modern arts, fantastic food, and modern technology.

We have more than 200 mountains that soar above 3,000 meters in height, and our unique geology and topography have created countless arresting landscapes and alluring coastal scenes. We also have an unparalleled ecological diversity and a huge number of plant and animal species concentrated in a relatively small place. We have some of the friendliest people in the world, 24-hour bookstores and convenient stores, and bustling night markets. Taiwan is also a gourmet’s paradise, with the finest of Chinese cuisine, the booming development of foreign restaurants, and unique dining opportunities in establishments serving local Taiwanese snacks, Hakka dishes, aborigine banquets, and night-market foods, as well as exquisite international dining in five-star hotels. Whatever your preference and budget, Taiwan will easily satisfy your taste buds. We also have the advantage of convenient transportation and an excellent travel environment that you will want to enjoy again, and again.

On behalf of the organizer of the APFCB Congress 2016, I welcome you to visit our beautiful island.
Dear Colleagues and Friends,

On behalf of the Greek Society of Clinical Chemistry - Clinical Biochemistry (GSCC-CB) and the Congress Organizing Committee, I would like to invite you to the 22nd IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine “EuroMedLab Athens 2017” which will take place in Athens, Greece, on June 11th-15th, 2017 at Megaron - the Athens Congress Center. This congress will be co-organized along with the 25th Balkan Clinical Laboratory Federation (BCLF) meeting and the 15th National Congress of GSCC-CB, helping a fruitful exchange of opinions and visions between the Greek, the European and the International colleagues.

The scientific program, containing an interesting combination of presentations, symposia, discussions, sessions, workshops and open to the general public debates, describing the state of the art and the recent innovations in Laboratory Medicine in the 21st century, will be carefully finalized in collaboration with the European Societies through the active cooperation of the International Scientific Advisory Board. During EuroMedLab Athens 2017 we will be organizing a large, interesting and detailed exhibition of IVD industry products as also many Industry Sponsored Workshops. In Athens several thousand square meters will be allocated in order that the latest innovations in the field of the clinical chemistry, molecular diagnostics, cell counting, immunochemistry, and several other will be exhibited.

Athens, a city famous all over the world for its history and culture, has many places of interest within a relatively small area surrounding the city center (Syntagma Square) and in walking distance from the congress venue. The downtown Congress Center is also conveniently situated nearby to the districts of Plaka and Monastiraki (old town) as well as Kolonaki (shopping and museums area and night life district). Acropolis, the New Museum and charming historic quarters with restored 19th century neoclassical homes, picturesque pedestrian streets, shops and restaurants, and ancient monuments from classic and Roman era will offer you unforgivable memories to take home.

I am looking forward to welcoming you in Athens in July 2017.
Dear Friends,

It is a privilege to welcome you to the XXIII Latin American Congress of Clinical Biochemistry, organized by the Uruguayan Association, to be held in Punta del Este, from 17 to 20 September 2017.

This meeting will allow us to discuss scientific and technological advances in the clinical laboratory area, to meet with internationally renowned specialists, to exchange experiences and opportunities for collaboration, and especially reconnect with colleagues and friends.

The program of activities includes: lectures, symposia, courses, free presentations, covering: biochemistry, neonatal screening, microbiology, hematology, immunology, parasitology, new applications of flow cytometry, HPLC and molecular biology, pharmacogenetics and bioethics, quality management and management and accreditation of courses in the Latin American context.

We invite you to be part of this experience of scientific and cultural enrichment in Uruguay.

We wish you all will follow up our invitation and we look forward to meeting you in Punta del Este!
Session 7

23rd IFCC WorldLab Durban 2017
57th Meeting of the South African Association for Clinical Biochemistry
5th Congress of the African Federation of Clinical Chemistry
Multi-omics and laboratory medicine

Rajiv Erasmus, Congress President and Chairman of the Organizing Committee, WorldLab 2017, Durban

On behalf of the Congress Organising Committee and the South African Association for Clinical Biochemistry (SAACB), it gives me great pleasure to invite colleagues to the Congress of Clinical Chemistry and Laboratory Medicine (WorldLab). This meeting is also being organized in co-operation with the African Federation of Clinical Chemistry (AFCC). It is the first time that such a meeting is being held in Africa and reflects the growing importance of this continent. WorldLab 2017 promises to be one of the best with a unique blend of innovative science, evidence based laboratory medicine and an emphasis on personalized medicine. This reflects the changing directions of science and medicine with greater attention being paid to prevention and risk stratification. Because of the expanding role of laboratory medicine, we plan to combine this meeting with other clinical specialities which will underscore the overarching influence of laboratory medicine in health care. The scientific and social programmes will provide opportunities to forge new collaborations and to connect with leaders of the diagnostic industry at the IVD product show linked to the three-day conference/workshop program. We are confident that this meeting will attract delegates from all the member IFCC societies and that each regional federation will play an important role in making this meeting one of the best in recent times. Africa is traditionally associated with its magnificent wildlife and unique cultural diversity. South Africa provides an opportunity to discover both of them. Durban, a melting pot for African and Indian cultures, is a coastal city with a tropical climate and pristine beaches and surfing. Namibia, Zambia, Zimbabwe, Mozambique and Botswana are close by and can easily be assessed by air via Johannesburg. Durban is the site for various clinical trials and some of the major breakthroughs in the management of patients with HIV have been made here. The kingdom of KwaZulu-Natal, South Africa beckons and extends a warm welcome to all of you. It’s a unique cultural destination littered with historical sites of past battles fought between the Zulus and the British forces. Hiking in the majestic Drakensburg Mountains, barely an hour away, is an activity not to be missed. The famous Table Mountain in Cape Town and the world renowned Kruger National Park are easily accessible. The Organizing Committee of WorldLab, the South African Association for Clinical Biochemistry and African Federation of Clinical Chemistry look forward to welcoming you to Durban in the Royal Kingdom of KwaZulu-Natal, South Africa in 2017.
Barcelona will proudly host the EuroMedLab 2019, the 23rd IFCC-EFLM European Congress of Laboratory Medicine, from May 19th to May 23rd 2019.

The Congress Venue, the Barcelona’s International Convention Centre (CCIB), is formed by two buildings of great architectural value: the Convention Centre designed by the architect José Luís Mateo and the Forum Building by the architects Herzog & De Mouron. It has a total surface area of 100,000 m² distributed between 45 meeting rooms and a large 11,000 m² exhibition hall with a total capacity up to 15,000 people. It is placed at the end of the Diagonal Street, the principal artery of Barcelona and it is well communicated by the public transport network.

Barcelona is a Mediterranean city very well known for its architectural spots (roman, medieval gothic, art-deco...), art museums (Picasso, Miró...), cultural events (Opera, Ballet, Theatres...) and gastronomy (cuisine style based on creativity and Mediterranean cuisine). Moreover, it is the only large city in Europe that boasts 5 kilometers of beaches in the city itself. Barcelona is also a well-connected city with an excellent network of flights with its International airport located only 15 minutes from the city center by bus or metro.

On behalf of the Spanish Society of Clinical Biochemistry and Molecular Pathology (SEQC), Society founded 40 years ago it is a great pleasure to invite you to participate to this special event and to enjoy our lively city.
We look forward to the pleasure and privilege of inviting you to the 24th International Congress of Clinical Chemistry and Laboratory Medicine (IFCC WorldLab Seoul 2020), slated for May 24-28, 2020 in Seoul, Korea.

This most highly acclaimed meeting of Clinical Chemistry and Laboratory Medicine is expected to gather an estimated 5,000 participants from over 100 countries.

We are proud to highlight that clinical chemistry related communities in Korea have been growing rapidly both in quantity and quality, with the Korean Society of Clinical Chemistry (KSCC) playing a pivotal role in research, training, education, and clinical practices as a hub of medical science in Korea since its establishment in 1983.

As such, the KSCC will do its utmost to produce invaluable and intriguing programs focusing on the latest developments and research, as well as providing a vision of the future of clinical chemistry and laboratory medicine in the world. Our well-organized infrastructure and rich experience in organizing national and international conferences, such as the 12th Asian-Pacific Congress of Clinical Biochemistry, are sure to make for a successful IFCC WorldLab Seoul 2020.

We truly believe that the Congress will be a highly rewarding international festival for everyone and will bring enhancement of the academic level and industrial development, which will contribute to improve the quality of life for all. Therefore, we encourage you to support the KSCC so you can have the chance to explore the beautiful city of Seoul and experience the exciting Korean culture.

We look forward to meeting you at the IFCC WorldLab Seoul 2020, Korea.
Laboratory medicine, just as other areas of medicine, is obliged to adhere to high ethical standards. Many countries and professional societies have developed policies and guidance materials on ethical issues related to laboratory medicine. Despite the importance of ethics in laboratory medicine, there is variability in education that is focused on ethics in the laboratory. A recent report by the IFCC Task Force on Ethics (TF-E) indicates that formal teaching of ethics is absent from many clinical chemistry and laboratory medicine training programs and that there is a perceived need for online training tools.

The AACC’s Clinical Chemistry Trainee Council (CCTC) is a website that was created for laboratory medicine residents and fellows (and their mentors) which provides free educational materials and interactive tools. One feature, unique to the CCTC, is “Pearls of Laboratory Medicine”. These are short, peer-reviewed presentations about particular areas of laboratory medicine.

In collaboration with the CCTC, The IFCC TF-E has created three “Pearls of Laboratory Medicine” on the topic of ethics. These include: “Ethics in laboratory medicine” a basic tutorial; “Ethics in publishing”; and “Ethics training”. This presentation will discuss the CCTC “Pearls of laboratory medicine” as an innovative teaching tool and will present the three 15 minute pearls on ethics created by the IFCC TF-E.
Closing remarks

Outcome of Madrid General Conference and new perspectives for IFCC

Maurizio Ferrari, IFCC President

Monday 21 March
Free afternoon:  
City tour sponsored by Sociedad Española de Bioquímica Clínica y Patología Molecular (SEQC)
MONDAY 21 March 2016

BRISTOL + OXFORD ROOM (ground floor)

1. Biological variation and patient safety. How should clinicians interpret laboratory results? A. Coskun

2. Worldwide standardized education and training in clinical chemistry and laboratory medicine D. Aslan

Radio “El Microscopio”

Biochemistry 2.0

Biochemistry Knowledge Management - Knowledge economy. Improving the use and interpretation (value) of Biochemistry Information.

H. Fares-Taie, S. Fares-Taie

TF-POCT POCT: Tackling the Current Issues and Planning for Future Ones A. Khan

TF-PT Meeting the clients with the producers on Precision Testing of rare analytes A. Haliassos

Iberoamerican countries participation at IFCC activities, and sharing experiences: interactive discussion

19.30-20.00 Aperitif and Concert

20.00-22.00 Gala Dinner

08.00-09.00 Continuation of the EB/Divs (Cs+WGs) closed meetings

The emergent hybrid Lab Med Conferences: future vision of IFCC congresses and meetings T. Zima

10.20 Discussion

10.30-10.40 Coffee break

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Silvia Cardinale
Silvia Colli Lanzi