



IFCC GENERAL CONFERENCE
BUDAPEST NOVEMBER 9-11, 2018


IFCC General Conference 2018

Laboratory medicine: Preparing for the 2020's


10th – 11th November 2018
Hotel Novotel Budapest City, Hungary



Advancing excellence in laboratory medicine for better healthcare worldwide




Standardization in Molecular Diagnostics: Outcomes and Perspectives




Deborah 'Debs' Payne, PhD, DABMM, DABCC Co-Chair
On behalf of the IFCC Committee for Molecular Diagnostics
Mark Linder, PhD, DABCC Co-Chair
Parviz Ahmad-Nejad, PhD Future Chair
Prof. Graciela Russomando, MSc., PhD Full member

Clinical Trials and Development, Vice President, Senior Scientific Officer, American Pathology Partners, Denver, Colorado, USA
University of Louisville, Professor, Kentucky, USA
Institute for Med. Lab. Diagnostics, Helios Universitätsklinikum Wuppertal, Witten Herdecke Universität, Germany
Dept. Molecular Biology and Biotechnology, Head Director of Research, IICS-UNA Instituto de Investigaciones en Ciencias de la Salud Universidad Nacional de Asunción



Advancing excellence in laboratory medicine for better healthcare worldwide





Managing Transition

2

In early 2018, membership from the Task Force for Pharmacogenomics was merged into the Committee for Molecular Diagnostics.

Name	Position	Country	Term Time in Office
P. Ahmad-Nejad	Chair	DE	1st 2019 01 - 2020 12
M Linder	Member	US	1st 2019 01 - 2020 12
G. Russomando	Member	PY	1 year extension 2019 12
W. Steimer*	Member	DE	1st 2018 01 - 2020 12
Call for nomination for 1 member:			3 years' term 2019 01 - 2021 12
Call for nomination for 1 member:			2 years' term 2019 01 - 2020 12
M. Relling	Consultant	US	
H. Parkes	Consultant	UK	

Challenges and addressing changing leadership:

- A project management software (SmartSheet) trial was established to facilitate communication between Co-Chair and Future chair.
- Frequent email communications and Skype calls between Co-Chairs, Future Chair and Latin American Representative were used to assist transition



Advancing excellence in laboratory medicine for better healthcare worldwide



Terms of Reference

3

To foster dynamic exchanges between IFCC and molecular diagnostic laboratories and industry

To produce guidelines on clinical validation of tests, conduct and reporting of molecular diagnostic tests

To create a network of locus-specific IFCC Molecular Diagnostics Centres



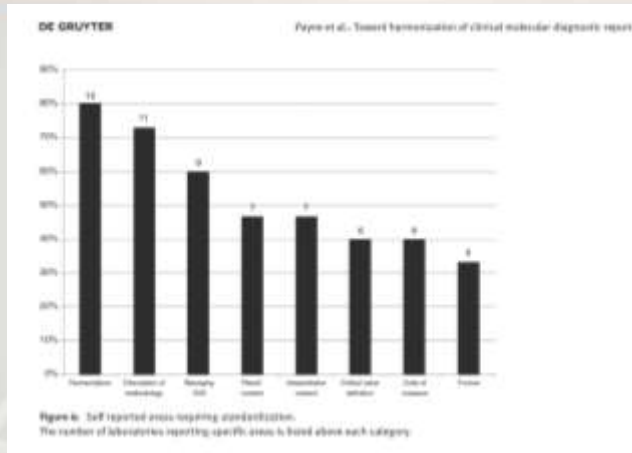
Advancing excellence in laboratory medicine for better healthcare worldwide





Terms of Reference: To foster dynamic exchanges between IFCC and molecular diagnostic laboratories and Industry

4



Deborah A. Payne, Katarina Baluchova, Graciela Russomando, Ph.D.¹, Parviz Ahmad-Nejad², Cyril Mamotte³, Francois Rousseau⁴, Ron H. van Schaik⁵, Kristin M. Marriott⁶, Masato Maekawa⁷, K.C. Allen Chan⁸, on behalf of the IFCC Committee for Molecular Diagnostics (C-MD) Toward Harmonization of Clinical Molecular Diagnostic Reports: Findings of an International Survey. CCLM doi:10.1515/cclm-2017-1080 (in press)



Terms of Reference: To foster dynamic exchanges between IFCC and molecular diagnostic laboratories and Industry

5

Participation with other Committees and Industry

Nomenclature:

As part of the survey completed by the C-MD, the needs assessment identified "Nomenclature" as one topic that many laboratories needed guidance and assistance.

- The C-MD communicated via email and in person with the Nomenclature committee chair Karin Toska regarding potential joint projects.
- An additional page to our website dedicated to links associated with Nomenclature

Education:

- C-MD member Katarina Baluchova was local coordinator for Molecular Course sponsored by the C-CMBC in Slovakia.

Industry and Metrology:

- Helen Parkes presented to the C-MD committee in Budapest regarding updates and opportunities to further collaboration in the field of Metrology.
- Additional efforts were made by emailing two companies associated with molecular diagnostics
 - Promega
 - Oxford Gene Technology



Terms of Reference: To foster dynamic exchanges between IFCC and molecular diagnostic laboratories and Industry

6

Survey Monkey Initiatives in English and Spanish

[2018 IFCC C-MD Survey on External Quality Assessment, Alternate Assessment Programs, Critical- and Significant-Risk Tests, Testing Methodologies and Pharmacogenomic testing offerings](https://www.surveymonkey.com/r/ZP67FD2)
<https://www.surveymonkey.com/r/ZP67FD2>

[2018 IFCC C-MD Encuesta sobre Evaluación Externa de la Calidad, Programas Alternativos de Evaluación, Pruebas Críticas y Significativas de Riesgo, Metodologías de Prueba:](https://www.surveymonkey.com/r/ZHXDJH6)
<https://www.surveymonkey.com/r/ZHXDJH6>

Over 40 laboratorios have responded and survey is still open!!! Please help us increase participation in Africa, Asia and Latin America.

Improved Website

The committee reviewed the website and has submitted updates for the EQA page.

- Additional pages for the website were submitted to the IFCC office and are awaiting approval
 - One page is dedicated to the IFCC Molecular Expert Laboratories
 - The second page is dedicated to links associated with Nomenclature for infectious diseases and genetics.



Advancing excellence in laboratory medicine for better healthcare worldwide



Terms of Reference: To produce guidelines on clinical validation of tests, conduct and reporting of molecular diagnostic tests

7

Publications

Deborah A. Payne, Katarina Baluchova, Graciela Russomando, Parviz Ahmad-Nejad^d, Cyril Mamotte^e, Francois Rousseau^f, Ron H. van Schaik^g, Kristin M Marriott^h, Masato Maekawaⁱ, K.C. Allen Chanⁱ, on behalf of the IFCC Committee for Molecular Diagnostics (C-MD) Toward Harmonization of Clinical Molecular Diagnostic Reports: Findings of an International Survey. CCLM doi:10.1515/cclm-2017-1080 (in press)

Meetings/Presentations

Title: Standardization in Molecular Diagnostics: Outcomes and Perspectives: DA Payne, PhD IFCC General Conference Budapest, Hungary

Title: Quality Considerations for Molecular Diagnostics 2019 COLABIOCLI meeting in Panama symposium chaired by Dr. Graciela Russomando of Paraguay from IFCC-CMD

1. What is going on in Molecular Diagnostics in Central and South America? What do we need to do to improve it?
 Dr. Graciela Russomando (Paraguay) C-MD Full Member 2019.
2. An Update of Molecular Analytes: Current and Future Directions.
 Dr. Parviz Ahmad-Nejad from Germany (C-MD Chair appointed for 2019).
3. Pre and Post Examination Factors for Molecular Diagnostics.
 Dr. Debs Payne (USA)
4. EQA and Alternate Assessment Strategies in Molecular diagnostics.
 Dr. Patricia Esperon (Uruguay)



Advancing excellence in laboratory medicine for better healthcare worldwide





Terms of Reference: To create a network of locus-specific IFCC Molecular Diagnostics Centres

8

Expert Laboratories:

Added nine new expert laboratories: Argentina, Austria, Canada, Germany, Iran, Japan, Mexico, Uruguay and USA

Network and Expert Laboratories

Future plans to expand expert lab and network laboratories in Africa, Asia and Latin America



Advancing excellence in laboratory medicine for better healthcare worldwide



Projects/Achievements

9

Agreed work item / target	Achievement
1. To foster dynamic exchanges between IFCC and molecular diagnostic laboratories and industry	<ol style="list-style-type: none"> Attendance at Meeting/email Updated website to include Nomenclature page Proposal to COLABIOCLI entitled "Quality Considerations for Molecular Diagnostics" was approved Contacted two companies: Promega (https://www.promega.com/) and Oxford Gene Technology (https://www.ogt.com/) regarding harmonization and standardization projects for lower income countries Sent email to Chair of Nomenclature committee regarding C-MD efforts
2. To produce guidelines on clinical validation of tests, conduct and reporting of molecular diagnostic tests	<ol style="list-style-type: none"> Completed and circulated survey monkey on EQA, AAP, Critical-Significant-Risk Results, Pharmacogenomics, Technology Molecular Diagnostics Paper was accepted on harmonization of reports Models for preemptive Pharmacogenetics under consideration Opinion or research paper on Alternate Assessment and EQA in progress with survey monkey



Advancing excellence in laboratory medicine for better healthcare worldwide





Projects/Achievements

10

Agreed work item / target	Achievement
3. Creation of a network of locus-specific IFCC Molecular Diagnostics Centres	<ol style="list-style-type: none"> 1. Changed acceptance criteria for Expert laboratories and increased expert laboratories 2. Engaged C-MD members to review articles in for CCLM 3. Adding additional expert laboratories to separate page of website 4. Seeking more network and expert laboratories in Africa and Asia
4. Increased Support for Molecular Diagnostics in Low Income Countries	<ol style="list-style-type: none"> 1. Session for COLABIOCLI accepted for Panama 2019 2. Added Expert Laboratories in Latin America 3. Submitted Survey Monkey that was translated into Spanish 4. Solicit support from two companies 5. Need greater representation of Africa, Asia and Latin America in surveys regarding standardization in molecular diagnostics



2019 Projects

11

- **Expand** IFCC Network and Expert laboratories in Africa, Asia, Latin America to address bias in Survey Monkey results and to improve support for standardization and harmonization
- Publish result of Survey Monkey on EQA, AAP, Pharmacogenomics, Critical Results and Methods
- Checklist document on Molecular Diagnostic Test Validation
- Survey Monkey on Alternate Assessment Procedure
- Expanding contents of the webpage EQA list
- Collaboration with C-CMBC and Nomenclature Committee



Participation from C-MD committee in Budapest

12



T. Ashavaid IN, H. Parkes UK,
J. Anetor NG, K. Baluchova SK,
P Ahmad-Nejad DE, G. Russomando PY,
D. Payne US, H. Van Son VT



Feed back and Questions

13

Thank You

Please visit our website
<http://www.ifcc.org/ifcc-scientific-division/sd-committees/c-md/>