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 Universitaetsklinikum Wuppertal, Witten Herdecke University, Germany
Dept. Molecular Biology and Biotechnology, Head Director of Research, IICS-UNA Instituto de Investigaciones en Ciencias de la Salud, Universidad Nacional de Asunción
Managing Transition

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

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

Terms of Reference

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

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
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

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

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.

Publications


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

**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

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**Projects/Achievements**

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<tr>
<th>Agreed work item / target</th>
<th>Achievement</th>
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</table>
| 1. To foster dynamic exchanges between IFCC and molecular diagnostic laboratories and industry | 1. Attendance at Meeting/email  
2. Updated website to include Nomenclature page  
3. Proposal to COLABIOCLI entitled “Quality Considerations for Molecular Diagnostics” was approved  
5. 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 | 1. Completed and circulated survey monkey on EQA, AAP, Critical-Significant-Risk Results, Pharmacogenomics, Technology Molecular Diagnostics  
2. Paper was accepted on harmonization of reports  
3. Models for preemptive Pharmacogenetics under consideration  
4. Opinion or research paper on Alternate Assessment and EQA in progress with survey monkey |
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<td>3. Creation of a network of locus-specific IFCC Molecular Diagnostics Centres</td>
<td>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</td>
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<tr>
<td>4. Increased Support for Molecular Diagnostics in Low Income Countries</td>
<td>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</td>
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2019 Projects

- **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


Feed back and Questions

Thank You

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