3rd EFLM Strategic Conference
SMART and GREEN LABORATORIES

How to implement IVDR, emerging technologies and sustainable practices in medical laboratories

25-27 May 2022 (Virtual)

http://www.eflm-http://www.eflm-strategic-conference.eu

SCIENTIFIC PROGRAM

Wednesday, 25 May 2022

10:30-12:30 **Session 1** Where is the MedLab industry headed in the next decade? Partnership model for efficient integration and adoption of emerging technologies and innovations (artificial intelligence, machine learning, advanced and integrative diagnostics) in the IVD landscape into Medical Laboratories.

Chairs: ***Sergio Bernardini (IFCC, Emerging Technologies Division, Chair)***

Anna Carobene (EFLM Task Group-Biological Variation Database, Member)

- **Introduction**
- **Rise of the machines – How AI could help making our profession more medical**
  Janne Cadamuro (EFLM WG Preanalytical Phase, Chair)
- **Solutions in haemato-oncology: Exploring the patient's clinical pathway**
  Clare Weir (Senior Expert & Scientific Marketing Manager in Clinical Flow Cytometry, Sysmex Europe)

- **Differential Diagnosis Support via Lab Test Result Interpretation**
  Alejandro Mora (Siemens Healthcare Diagnostics, Head of Global Marketing/Workflow Solution)

- **With each passing day, I place less value on accuracy. Some ideas to go beyond accuracy in evaluating machine-learning AI systems.**
  Federico Cabitza (Associate Editor of International Journal of Medical Informatics)

- **The Importance of Regulation of AI/ML in the Laboratory**
  Jochen K. Lennerz (Medical Director, Center for Integrated Diagnostics, Harvard Medical School)

- **Discussion**

- **Closing Remarks**

12.30-13.30 **Exhibition Visit**

13:30-15:30 **Session 2** Digital transformation towards the laboratory of the future. Perspectives for the next decade.

Chairs: ***Snežana Jovičić (EFLM, Executive Board Member)***

Dalius Vitkus (EFLM, Executive Board Member)

- **Introduction**

- **Importance of Interoperability in Digital Transformation**
  Sabine Dörhöfer (Roche Diagnostics, Vice Chair Roche WG interoperability)

- **From a vending machine to a decision engine, a roadmap for diagnostic transformation**
  Florian Lange (Abbott, Director AlinIQ)

- **Crossing the chasm: Strategies for digital transformation in clinical laboratories**
  Merve Sibel Gungoren (EFLM, WG-Promotion & Publication, Past-Chair, IFCC, Clinical Laboratory Management Committee, Member)

- **Discussion**

- **Closing Remarks**

15:30-16:00 **Exhibition Visit**

16:00-18:00 **Session 3** Big data and how to utilize it to improve service, quality and patient outcomes. Training the next generation to collect/analyze and use lab data in a more efficient manner with more focus on post-analytics than analytics.

Chairs: ***Pilar Fernández-Calle (EFLM, Executive Board Member)***

Pieter Vermeersch (EFLM, WG-Postanalytical Phase, Chair)

- **Introduction**

- **Reports from laboratory medicine: how to increase value for practitioners, patients, and populations**
  Jonathan Kay (Board Member Lab Tests Online, UK. University of Oxford)

- **Big data in Laboratory Medicine – implications for COPD and asthma. Experiences from the German National Medical Informatics Initiative**
  Harald Renz (German Society for Allergology and Clinical Immunology DGAKI, Past-President)

- **Multivariate statistical data analysis in the diagnostic process**
  David Friedecký (Society for Study of Inborn Errors of Metabolism, Member)

- **Application of Big Data in Precision Medicine**
  Tim Hulsen Department of Professional Health Solutions and Services, Philips Research, Eindhoven, Netherlands

- **How innovative technologies can overcome or minimize laboratory testing interferences**
  Els Melis (Ortho Clinical Diagnostics, Manager, Clinical Labs Assays)

- **Discussion**

- **Closing Remarks**

Thursday, 26 May 2022

10:30-12:30 **Session 4** IVD regulation and the road to May 2022 and beyond. Preparation of the profession for the new IVDR.

Chairs: ***Christa Cobbaert (EFLM Task Force-European Regulatory Affairs, Chair)***

Michael Neumaier (EFLM Past-President; EFLM Task Force-Disruptive Technologies, Chair)

- **Introduction**
  Christa Cobbaert

  LEGAL ACCOUNTABILITY FOR MODIFIED COMMERCIAL TESTS: Point-counterpoint discussion(20 min together: 6 min per speaker and 8 min discussion).

- **Modification of a commercial test transforms the test into an in-house test.**
  Oliver Bizassa (MedTechEurope, Director General, Medical Industry Policies)

- **Modification of a commercial test transforms the test into an in-house test**
  Thomas Streichert (EFLM Task Force-European Regulatory Affairs, Member)

HOW TO PRESERVE ESSENTIAL AND/OR INNOVATIVE LDTs IN MEDICAL LABS IN THE IVDR ERA?

- **Is ISO 15189 insufficient for IVDR-compliant LDT implementation, or can it be rescued?** 15 min and 5 min for discussion.
  Florent Vanstapel (EFLM Committee on Quality and Regulations, Chair)

HOW TO MANAGE COMPANION DIAGNOSTICS AND CONSORTIA IN THE IVDR ERA?

- **Monitoring immunotherapies with enhanced FACS analysis: basis for Companion Diagnostics? The Euroflow consortium perspective.** 15 min and 5 min for discussion.
  Jacques J.M. van Dongen (Chairman of EuroClonality, EuroMRD and EuroFlow)

- **Modern molecular oncology based on LDTs? Implications of the IVDR for Cancer Diagnostics**
  15 min and 5 min for discussion.
  Sabit Delic (Senior Scientist & Director, Munich Leukemia Laboratory, MLL)

DETERMINANTS OF OPTIMAL DIAGNOSTIC REGULATIONS FOR MEDICAL TESTS

- **The regulatory framework beyond IVDR. Principles of optimal diagnostic regulation and how those are reflected – or not! - in the IVDR, and what this might mean for the future.** 15 min and 5 min for discussion.
  Anna Hallersten (Roche Diagnostics, Director, Head Regulatory Policy Europe)

- **Does the IVDR need a CORE-MD consortium equivalent for improved clinical investigation and evaluation of innovative/rare/high-risk In Vitro Diagnostic medical tests?** 15 min and 5 min for discussion.

Elizabeth Macintyre (President of the European Hematology Association and Biomedical Alliance in Europe, President-Elect)

- **Discussions & Closing Remarks**
  Christa Cobbaert, Michael Neumaier

12.30-13.30 **exhibition visit**

13:30-15:30 Laboratories **Session 5** Green Labs for improving environmental sustainability. What are the Priorities of Medical under the EU Green Deal?

Chairs: ***Tomris Ozben (EFLM, President, EFLM Task Force-Green Labs, Chair)***

Ana-Maria Šimundić (EFLM, Past-President, EFLM Task Force-Green Labs, Member)

- **Introduction**
- **How to create a culture of sustainability in science: From the benchtop to the boardroom**
  Carlo Battisti (My Green Labs, President, Living Future Europe. Sustainable Innovation Manager & Consultant)
- **Priorities of the medical technologies sector under the EU Green Deal**
  Valérie Rampi (MedTechEurope, Senior Manager Environment & Sustainability)
- **Reducing the Environmental Impact of the Clinical Laboratory**
  Alistair J Gammie (ValuMetrix Global Senior Director, Ortho Clinical Diagnostics)
- **Striking the Right Balance: Sustainability and Innovation**
  Ffion Jackson (Siemens Healthineers, Head of Product Environmental Protection Laboratory Diagnostics)

- **Discussion**
- **Closing Remarks**

15:30-16:00 **Exhibition Visit**

16:00-18:00 **Session 6** Novel technologies and clinical research in enabling precise and personalized medicine.

Chairs: ***Klaus Kohse (EFLM, Executive Board Member)***

Michel Langlois (EFLM Science Committee, Chair)

- **Introduction**
- **The present and future of precision medicine using Human Genetics laboratories**
  Philippe Froguel (Genome Wide Association Study, GWAS; Board of the French Genethon Genomic Centre, Member)
- **The personalized medicine research pipeline: methodological and regulatory challenges**
  Jacques Demotes (Director General of the European Clinical Research Infrastructure Network, Coordinator of the project CSA PERMIT, PERsonalised MedicIne Trials)
- **Greater expectations: meeting clinical needs through broad and rapid genomic testing**
  Jennifer J.D. Morrissette (Scientific Director, Clinical Cancer Cytogenetics; Clinical Director, Center for Personalized Diagnostics
- **Digital Twins for predictive, preventive and personalised medicine**
  Mikael Benson (Swedish Digital Twin Consortium, Linköping University)

- **Integrated bioinformatic tools in the clinical of polytreated patients for precision medicine routine use**
  Maurizio Simmaco (Sapienza University, Professor of Molecular Biology - Director of Laboratory Medicine Clinical Biochemistry Unit)

- **Discussion**

- **Closing Remarks**

Friday, 27 May 2022

10:30-12:30 **Session 7** Strategic vision for laboratory services that add value.
Cost-effective and clinically effective laboratory services– enhancing the value of laboratory testing with focus on major (acute and chronic) public health problems.

Chairs: ***Andrea Rita Horvath*** (***EFLM Past-President, EFLM Task-Group Performance Specifications Based on Outcome Studies, Chair)***

Mario Plebani (EFLM, President-Elect)

- **Introduction –** Strategic vision for laboratory services that add value
  Andrea Rita Horvath

- **Central Role of Laboratory Medicine & Laboratory Professionals in Public Health and Patient Care**
  Khosrow Adeli (IFCC President)

- **Managing Patient Risk with Precision Quality Control**
  Robert Schmidt (Director: Center for Effective Medical Testing & Quality Optimization, University of Utah)

- **Clinical utility of medical tests – how can we demonstrate it?**
  Patrick Bossuyt (EFLM Task Force-European Regulatory Affairs, Member)

- **Cost-effectiveness through laboratory testing - Win or fail in the last metres?**
  Paul Julicher (Senior Director Medical Affairs, Abbott Laboratories)

- **Test implementation – the last step in realising the value proposition**
  Andrew StJohn (IFCC Value Proposition for Laboratory Medicine, C-VPLM, Chair)

- **Discussion**
  Mario Plebani

  ***Invited contribution**.*

- **Building more effective Test Utilization Management leading to improved diagnostic processes**
  Marielle Kaplan (Task Group: EFLM Syllabus Course, Member & Coordinator)

- **Quality indicators as a tool for providing evidence of efficiency in the tTTP**
  Laura Sciacovelli (Italian Society of Clinical Biochemistry and Clinical Molecular Biology-SIBioC, Past-President)

- **Closing remarks**
  Andrea Rita Horvath

12.30-13.30 **exhibition visit**

13:30-15:30 **Session 8** Direct to Consumer Testing - what role should laboratory medicine have?

Chairs: ***Sverre Sandberg (EFLM, Past-President)***

***Tommaso Trenti (Italian Society of Clinical Biochemistry and Clinical Molecular Biology-SIBioC, President*)**

- **Introduction**
- **Regulatory and legal aspects in Europe**
  Erik Vollebregt (affiliation will be inserted)
- **A viewpoint from industry.**
  Rolf Hinzman (IFCC Task Force Corporates member, Past Chair, Roche Diagnostics)
- **Covid-19 self-testing: An example of self-testing out of control?**
  Mette Christophersen Tollånes (Global Public Health and Primary Care, Director)
- **We must speak up: The role of laboratory medicine in direct-to-consumer testing**
  Mathias Orth (EFLM Task Force-European Regulatory Affairs, Member)
- **Discussion**
- **Closing Remarks**

15:30-16:00 **exhibition visit**

16:00-18:00 **Session 9** **NETWORKING ON THE PLATFORM**
What do you expect from EFLM in the next years? Open discussion for the participants to join the discussion and speak openly about the latest trends, challenges and opportunities they are facing?

Chairs: ***Graham Beastall (IFCC, Past-President)***

Tomris Ozben (EFLM, President, EFLM Strategic Conference, Chair)

- **Introduction**

- **Discussion**
  Roundtable with Session Chairs and Audience

- **Closing Remarks**
  Tomris Ozben