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Emerging Technologies Division

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EMERGING TECHNOLOGIES DIVISION EXECUTIVE COMMITTEE (ETD-EC)

Chair
Prof. Sergio BERNARDINI (IT)

Vice Chair
Prof. Paolo FORTINA (US)

Secretary
A/Prof. Ronda GREAVES (AU)

Member
Prof. Damien GRUSON (BE)

Corporate Members
Dr. Markus ROESSLER (DE)
Dr. Peng YIN (US)

ETD Consultants
Prof. Maurizio FERRARI (IT)
Dr. Larry KRICKA (US)
Prof. Jason PARK (US)
Dr. Helen MARTIN (AU)

CHAIRS OF EMERGING TECHNOLGIES DIVISION COMMITTEES AND WORKING GROUPS

11.1. Executive Committee		S. Bernardini (IT)
11.2. Committees		
11.2.1	Committee on Emerging Technologies in Pediatric Laboratory Medicine (C-ETPLM)	T. Lang (UK)
11.2.2	Committee on Mobile Health and Bioengineering in Laboratory Medicine (C-MHBLM)	B. Gouget (FR)
11.2.3	Committee on Omics Translation (C-OT)	S. Bernardini (IT) *ad interim*
11.3 Working Groups		
11.3.1	Volatolomics (WG-Vol)	L. Kricka (US)
11.3.2	Guidance for the Implementation of Custom-made Genomic Panels (WG-GCP)	J. Morrissette (US)
11.3.3	Artificial Intelligence and Genomic Diagnostics (WG-AIGD)	L. Kricka (US)
11.3.4	Single Cell and Spatial Transcriptomics (WG-SCST)	A. South (US)

11. Emerging Technologies Division (ETD)

The IFCC Emerging Technologies Division (ETD) formally commenced on 1st January 2018. Two Task Forces previously under the Executive Committee (Task Force on Paediatric Laboratory Medicine (TF-PLM) and the Task Force on Geriatric Laboratory Medicine (TF-GLM)) were merged into the ETD at this time.

11.1. ETD Executive Committee (ETD-EC)

Membership

Name	Position	Country	Term	Time in Office
S. Bernardini	Chair	IT	2nd	2021 01 - 2023 12
P. Fortina	Vice-Chair	US	2nd	2021 01 - 2023 12
R. Greaves	Secretary	AU	2nd	2021 01 - 2023 12
D. Gruson	Member	BE	2nd	2021 01 - 2023 12
M. Roessler	Corporate M.	DE	2nd	2021 01 - 2023 12
P. Yin	Corporate M.	US	2nd	2021 01 - 2023 12
M. Ferrari	Consultant	IT		
L. Kricka	Consultant	US		
J. Park	Consultant	US		
H. Martin	Consultant	AU		

11.1.1. Mission Statement

The ETD is a functional unit responsible for identifying and assessing emerging technologies and for translating the emerging and disruptive diagnostic and data analysis procedures from academic laboratories to clinical laboratories and from clinical laboratories to market.

11.1.2. Strategy

The ETD initiates and manages projects through its Committees and Working Groups (WG). Work is conducted in strict cooperation with other IFCC units and with relevant national and international organisations. The ETD ensures that each of its Committees and Working Groups are functioning under clear terms of reference together with an agreed upon schedule of activity. The ETD will assist in the development of project proposals and will undertake an annual review of progress and review as well as approve documents arising from such projects.

11.1.3. Responsibilities

- The application of emerging technologies and methods including mass spectrometry, high-throughput genotyping techniques, mobile health technologies and data analysis to clinical diagnostic protocols focused on Precision Medicine.
- Defining for each emerging technology the clinical needs and criteria of education of specialists in Laboratory Medicine and caregivers.
- Defining for each emerging technology and method the appropriate infrastructure and laboratory organization.
- Defining for each emerging technology and method pre-analytical, analytical and post-analytical processes necessary for clinical laboratory applications.
- Defining for each emerging technology and method quality programs and certifications required to meet criteria for accreditation up to ISO151811 standard.

- Assess the clinical value of each test with regard to addressing unmet clinical need.

11.1.4. Terms of Reference

The ETD is a functional unit of the IFCC involved in the production of publications arising from activities relating to the application of emerging and disruptive technologies to clinical laboratories.
All ETD activities are well-defined projects, which work within a specified time frame, and are intended to result in a document (an IFCC official document or manual, guideline, or a scientific paper in a refereed international journal), in a product (reference system, service or device), or within the framework of an international activity (scientific workshop, symposium or congress).
The ETD is responsible to the EB and Council to ensure the highest standards of work in its units and for the actions of its members.

11.1.5. Projects

The ETD initiates and manages projects with its own resources or through its Committees and Working Groups. Work is conducted in cooperation with other IFCC units and with relevant national and international organizations. The ETD ensures that each of its Committees and WGs are functioning under clear terms of reference together with an agreed upon schedule of activity. The ETD-EC will assist in the development of the project proposals and will undertake an annual review of progress as well as review and approve any documents that result from the work. Project applications should be made on the ETD Project Proposal Form (available from the IFCC Executive Board webpage).

- The ETD Executive Committee, as the overall managing group for the Division, will ensure the progress of each project, will terminate completed or non-productive projects, and will review the contributions of the members of each functional unit, on a yearly basis.
- Work of the ETD units is carried out in cooperation with other IFCC units, with relevant national and international organizations, and with individuals specifically proficient in a defined area of competence.
- Work within ETD units is to be clearly defined in the goals, terms of reference and a specific timetable for each project.
- An annual review will be carried out by each functional unit for every project within its responsibility.
- The ETD Executive Committee will actively seek, under the appropriate guideline(s) and together with the Corporate Representative on the IFCC Executive Board (EB), the necessary funding to achieve the completion of appropriate scientific projects.
- Outside funding for projects is permitted, but only within the IFCC guidelines for this action (see “Guidelines for Funding from Industry and Other Sources”) and must be approved by the Division Executive Committee and by the IFCC EB. Administration of such funds will be through the IFCC Treasurer’s office.
- The ETD Executive Committee will assign a liaison officer to each of its Committees to monitor the progress of the projects under its responsibility.
- All project proposals will be reviewed by the Divisional Executive Committee and submitted to the IFCC EB for concurrence.
- Preparation of all documents must follow IFCC regulations for publications (see “Guidelines for Preparation of IFCC Documents”).
- The ETD Executive Committee will ensure that Committee and WG Chairs are aware of their responsibilities and of the IFCC resources available to them, and that they

communicate promptly and effectively with all corresponding members nominated to their unit.

11.2. ETD Committees

11.2.1. Committee for Emerging Pediatric Laboratory Medicine (C-EPLM)

Membership

Name	Position	Country	Term	Time in Office
T. Lang	Chair	UK	2nd	2021 01 - 2023 12
T.P. Loh	Member	SG	2nd	2021 01 - 2023 12
C.M Mak	Member	CN	1st	2019 01 - 2021 12
I. Papassotiriou	Member	GR	2nd	2021 01 - 2023 12
J. Zierk	Member	DE	1st	2019 01 - 2021 12
Y.B. de Rijke	Member	NL	1st	2021 05 - 2023 12
K. Kohse	Consultant	DE		
S. Geaghan	Consultant	US		
R. Greaves	EC Liaison	AU		

Why Pediatric laboratory medicine?

Children are not simply small adults - this holds especially true when they become patients. Pediatric patients comprise a group with special problems, also with regards to the results of laboratory investigations.

The purpose of this Committee is to develop procedures and processes to improve the diagnosis and management of patients from birth to adolescence. The use of emerging technologies in this area is of particular relevance as it has the potential to deliver real change and improve access to healthcare in the developing and emerging countries.

Terms of reference

- To identify, prioritise and coordinate projects to support the emerging science in pediatric laboratory medicine across the total testing process.
- To review the current concepts in Pediatric Laboratory Medicine and advance laboratory practice through the development and dissemination of position papers and guidelines.
- To develop existing links and establish new links with clinical and scientific societies working in other specialist organizations including neonatology, pediatrics, inherited metabolic diseases and other rare diseases.
- To lead education activities, including the tri-annual congress of Pediatric Laboratory Medicine.
- To coordinate a worldwide network of scientists working in laboratories specialized in Emerging Pediatric Laboratory Medicine (C-EPLM).
- To work to support emerging economies in Pediatric Laboratory Medicine.

Local and regional activities exist in which an exchange of ideas and concepts for the role of the laboratory in the care of children's health take place, but in general, these activities are not linked to each other. In spite of a variety of activities in the past years, reference intervals for laboratory test results are often not very well defined for the pediatric population, a situation which is even worse in adolescent medicine. The subject of the C-ETPLM is obviously relevant to large numbers of people – a substantial proportion of our patients are children. Especially in pediatric patients, the role of the laboratory is crucial for diagnosis and follow-up, e.g., in metabolic disorders or genetically determined diseases. The identification and promotion of emerging

technologies will help support the laboratory provide the most appropriate care for its pediatric patients.

Activities of the C-ETPLM will include:

- Establishment of a concept for the next International Congresses of Pediatric Medicine. As the preferred setting, the Congress will be held in conjunction with an IFCC meeting or a meeting taking place under the auspices of IFCC
- Delivery of educational material on topics relevant to the area of emerging technology in pediatric laboratory medicine through a variety of modalities
- In partnership with other IFCC functional groups and specialist interest bodies collate best practice and experiences in common areas or in response to local/worldwide health issues.
- Regularly publish reports on the progress of the Committee's activities and other relevant articles in the field of Pediatric Laboratory Medicine in the IFCC Journal

11.2.2. Committee on Mobile Health and Bioengineering in Laboratory Medicine (C-MHBLM)

Membership

Name	Position	Country	Term	Time in Office
B. Gouget	Chair	FR	2nd	2021 01 - 2023 12
K. Kotani	Member	JP	1st	2019 01 - 2021 12
J. Nichols	Member	US	1st	2019 01 - 2021 12
F. Desiere	Member-Roche	DE	1st	2019 02 - 2021 12
M. Heydlauf	Member-Siemens	US	1st	2019 02 - 2021 12
D. Gruson	EC Liaison	BE		

Mobile health technologies are part of the current transformation of healthcare and refer to digital applications, sensors, and wearables. Mobile health technologies are more and more used for patients' continuous care and empowerment.
Mobile health technologies also appear as an opportunity to create more junctions with healthcare professionals and dynamic care pathways for the management of patients with chronic conditions.
The engineering, evaluation and validation of sensors and wearables is mandatory to ensure patients safety and have to involved different caregivers (laboratorians, physicians, nurses, pharmacists…). In another hand, digital applications and connected devices leverage additional challenges such as secured data transfer to electronic medical records and interoperability as well as meeting the requirements of user (user experience).
Specific focus should also be given to the connectivity with new laboratory informatics interfaces and new generations of hospital informatics systems as well as the powerful applications of artificial intelligence to laboratory medicine.

Terms of reference of the C-MHBLM

- To review the current concepts of e-Health including broadband connectivity, software, digital networking, big data, mobile connectivity, smart infrastructure and even artificial intelligence to support the delivery of health and medical care for individuals and communities.
- To promote the potential of e-health and m-health in laboratory medicine to improve service delivery for patients including more cost-effective models of care, remote monitoring, improved access even over large distances and rapid data analyses and generation of knowledge.

- To establish collaborations and partnerships with the other organisations concerned with e- Health /m-health and clinical societies and international organisations/bodies.
- To promote an environment where digitally enabled and integrated systems help specialists in laboratory medicine to deliver patient-centred health experiences and quality health outcomes.

11.2.3. Committee for Omics Translation (C-OT)

Membership

Name	Position	Country	Term	Time in Office
S. Bernardini	Chair *ad interim*	IT	1st	2021 04 - 2021 12
W. Ping	Member	US	1st	2019 01 - 2021 12
M. de Tayrac	Member	FR	1st	2019 01 - 2021 12
E. Fux	Member-Roche	DE	1st	2021 05 - 2023 12
P. Fortina	EB Liaison	US		

"Omics" refers to the totality of a field of study. Many types of omics have been described, including: glycomics, lipidomics, metabolomics, pharmacogenomics, proteomics, transcriptomics, and volatolomics. Omics information has the potential to lead to improvement in many facets of human life and society, including the understanding, diagnosis, treatment, and prevention of disease; advances in agriculture, environmental science, and remediation; and our understanding of evolution and ecological systems.

Terms of Reference:
The evaluation of new Omic technologies and analyte targets with potential for implementation in a clinical laboratory setting
- To provide guidance for complex multi-analyte omics testing including data integration and interpretation.
- To review omics technology guidelines and position papers in conjunction with other professional organisations.
- To provide guidance on pre-analytical factors for omics applications including consideration of sample matrices
- To provide an in-depth assessment of emerging volatolomics technologies and their impact on the diagnosis, management and understanding of human diseases.

Today, there is an increasing need for researchers and clinicians to understand the scope and results of omics research and incorporate the incorporate this information into diagnostics, therapeutics and studies of disease aetiology.

Objectives
The Omics Committee seeks to assess the diagnostic significance and impact of omics technology. Initially, the committee will focus on Genomics (including the related epigenomics and transcriptomics).

Genomics
One of the best-known examples of omics is genomics. Genomics is defined as: "a branch of biotechnology concerned with applying the techniques of genetics and molecular biology to the genetic mapping and DNA sequencing of sets of genes or the complete gene set of selected organisms, with organizing the results in databases, and with applications of the data (as in medicine or biology)". Indeed, the field of genetics is not only one of the most rapidly advancing areas of the life sciences, but also one that has a major impact on all of our lives because of its central role in medicine and biotechnology. Furthermore, advances in genomics, and more broadly in biomedical

research, have been greatly facilitated by significant and sustained throughput increases, cost decreases, and improvements in ease of use of genomics technology. The ability to assay genomes comprehensively has been made possible by the enormous reduction of costs and development of many informative assays in the past few decades. Technology advances, particularly new sequencing systems, have enabled many research projects that are producing stunning insights into biology and disease. Extending beyond sequence per se, assays have been developed to determine nucleotide modifications, chromatin state, nuclear organization, and dynamics of those features achieving the low costs and high quality needed to use comprehensive genomic information in many research applications or in individual health care.
The Committee proposes to provide an in-depth assessment of emerging genomics tools and their impact on the diagnosis, management and understanding of human diseases.
The initial focus will be on:

- Single cell/small sample genomics,
- High throughput biochemical and other tools to modulate gene expression,
- Foundational technologies (e.g., efficient sample preparation),
- Genome-wide functional analyses,
- Transcriptomics,
- Epigenomics,

Emerging technologies that may add substantial advances beyond existing approaches, and, if successful, significantly propel forward the field of genomics will be evaluated.
Examples of candidate technologies include:

- DNA, RNA, epigenome, transcriptome, and chromatin analysis from the same sample
- High-throughput genome modifications for replacement, activation, and inhibition, with genomic readout
- Technologies for scaling genomic assays to operate on 10,000 samples cost effectively for e.g., single cell/small samples and for large numbers of samples (e.g., sampling of heterogeneity, population studies);
- Hand-held DNA analysers (e.g., based on Smartphones, nanopore technology).

11.3. ETD Working Groups

11.03.01. Guidance for the implementation of custom-made genomic panels (WG-CGP)

Membership

Name	Position	Country	Term	Time in Office
J. Morrissette	Chair	US	1st	2019 06 - 2021 12
OO. Soriyan	Member	NG		
C. Paolillo	Member	US		
M. Ewalt	Member	US		
C. Santonocito	Member	IT		
ME. Marmarelis	Member	US		
M. Carroll	Member	US		
M. Murthy	Member	BW		
YM Martei	Member	BW		
C. Davies	Member	US		
J. Segal	Member	US		
RT. Sussman	Member	US		
C Rushton	Member	US		

The IFCC Emerging Technology Division (ETD) provides current awareness for emerging technologies likely to have important clinical diagnostic applications in the near future. One of those technologies is Next Generation Sequencing (NGS), which allows the detection of variants in large numbers of genes in a massively parallel fashion. The detection of these variants in tumour tissue can be diagnostic, prognostic, and/or predictive for therapeutic response. In many large academic institutions, NGS testing is performed on most tumour samples and when appropriate, the results are linked to therapy as standard of care. However, genomic testing of tumour samples is not well established in the community hospital setting and is largely not performed in emerging nations.

Terms of Reference

Provide a regularly updated perspective on the clinical diagnostic applications of NGS over the next 3 years through both the creation of a webpage and the publication of manuscripts to:

- Assist clinical laboratories in developing in-house NGS programs,
- Model ways to provide mutation detection,
- Improve detection linked to therapies for those in emerging nations.

Current projects

- Create and add content to a current awareness webpage on genomics:
  1. Genomics educational section
     a. Seminal papers: Genomics review articles; Circulating Tumor DNA; Tumor heterogeneity; Fusion Detection; Minimal Residual Disease; Tumor Mutational Burden; Immunotherapy; Clonal Hematopoiesis of Indeterminate Potential
     b. Webinars, Podcasts and Educational resources
     c. Guidelines
  2. Industry partners and technologies of interest
     a. FDA approved/cleared molecular diagnostic test
     b. Industry partners
  3. Clinical Validation of a NGS assay
     a. Manuscripts delineating best practices
     b. Tools to determine assay performance
  4. Best practice: links to common equipment used in NGS
     a. Wet Lab
     b. Bioinformatics
     c. Reporting
     d. Clinical treatment guidelines
- Manuscript of best practices for validation of clinical NGS and reporting, based on the seminal papers in the field, with links to the IFCC website.
- Manuscript based on IFCC survey results on current needs and best practices for moving genomics into emerging nation settings
- Identification of an appropriate hospital or clinic in an emerging nation(s) to implement genomic testing associated with targeted therapy in the oncology setting.

11.03.02. Volatolomics (WG-Vol)

Membership

Name	Position	Country	Term	Time in Office
L. Kricka	Chair	US	1st	2019 06 - 2021 12
P. Fortina	Member	US		
J. Wiencek	Member	US		

The IFCC Emerging Technology Division (ETD) provides current awareness for emerging technologies likely to have important clinical diagnostic applications in the near future. One of those technologies is volatolomics (breathomics) i.e., breath analysis.

Terms of Reference
- To develop a survey of the diagnostic applications of volatolomics (breath analysis).
- To develop periodic updates of the volatolomics survey over the next 3 years.

Current projects
- Applications of breath analysis in detecting COVID-19
- Survey of the diagnostic applications of volatolomics (breath analysis) including recent literature, companies, clinical diagnostic products, and clinical trials.
- Solicit industry and academia input to the planned updates of the volatolomics survey.

11.03.03. Artificial Intelligence and Genomic Diagnostics (WG-AIGD)

Membership

Name	Position	Country	Term	Time in Office
LJ Kricka	Chair	US	1st	2021 01 - 2023 12
LM Baudhuin	Member	US		
A. Ertel	Member	US		
P. Fortina	Member	US		
T. Hope	Member	US		
C. McCudden	Member	CA		
JY Park	Member	US		
S. Polevikov	Member	US		
D. Satchkov	Member	US		

Terms of Reference
- To evaluate and monitor emerging trends and directions of research and development in the field defined by the intersection of artificial intelligence, genomics, and clinical diagnostics.
- To develop an in-depth assessment of the application of AI (deep learning, machine learning) in genomic (molecular) diagnosis.
- To develop periodic updates of the applications of AI in clinical genomic testing.
- To assess the accessibility and the barriers to routine implementation of AI in clinical genomic testing.
- To develop a resource that will inform the IFCC community on developments and trends in the applications of artificial intelligence in clinical genomic

Current projects
- Survey of the clinical diagnostic applications of AI in genomics, including recent literature, companies, clinical diagnostic products, and clinical trials.
- Solicit industry and academia input into the AI in clinical genomics survey.
- Assess the role of AI in genomic tests for detecting COVID-19.
- Explore the utility of AI-based search engines in searching the AI and genomics literature for emerging diagnostic applications
- Formulate consensus definitions of AI and other terms relevant to the application of AI in clinical laboratories

11.03.04. Single Cell and Spatial Transcriptomics (WG-SCST)

Membership

Name	Position	Country	Term	Time in Office
AP South	Chair	US	1st	2021 01 - 2023 12
RJ Cho	Member	US		
G. Kumar	Member	US		

Terms of Reference

Provide a regularly updated perspective on the clinical diagnostic applications of single-cell and spatial transcriptomic technologies as they evolve and become more accessible over the next 3 years through both the creation of a webpage and the publication of manuscripts to:

- Assist clinical laboratories in developing in-house single-cell and spatial transcriptomics
- Provide up to date information on potential therapy matches through identification of effector cell types in different disease states
- Provide up to date information on technologies and approaches as they become commercially available

Current projects

- Begin work on a manuscript delineating the prerequisites required for the implementation of single cell in the clinical setting
- Review the current genomic testing platforms available in the clinic
- Investigation of new platforms for rapid single cell and spatial genomics
- Explore technologies for single cell somatic mutational profiling in tumour, inflammatory, and normal tissues

11.4. Corporate Member Activities

The Corporate Members bring relevant industry expertise, experience, and support to the Division to facilitate more involvement, voice, support from IFCC industry members and help drive Executive Committee's missions and projects. IFCC Corporate Members may propose projects.

11.5. List of addresses

ETD EXECUTIVE COMMITTEE

Chair
Prof. Sergio BERNARDINI
University Tor Vergata
Viale Tito Labieno 122
00174 Rome - Italy
E-mail: bernardini@med.uniroma2.it

Vice-Chair
Prof. Paolo FORTINA
Sidney Kimmel Cancer Center
Sidney Kimmel Medical College
Thomas Jefferson University
Philadelphia, PA 19107 – USA
E-mail: paolo.fortina@jefferson.edu

Secretary
A/Prof. Ronda GREAVES
Biochemical Genetics
Victorian Clinical Genetics Services
Murdoch Children's Research Institute
Parkville, VIC 3052 - Australia
E-mail: ronda.greaves@vcgs.org.au

Members
Prof. Damien GRUSON
Cliniques Universitaires Saint Luc,
Département des Laboratoires Cliniques
Biochimie Médicale
1200 Bruxelles - Belgium
E-mail: damien.gruson@uclouvain.be

Corporate Representatives

Dr. Markus ROESSLER
Roche Diagnostics GmbH
Roche Diagnostics Solutions
Early Development & Reagent Design
Nonnenwald 2
82377 Penzberg - Germany
E-mail: markus.roessler@roche.com

Dr. Peng YIN
Abbott Diagnostic Division
4F, 4-3 Caohejing SBP Phase III
1036 Tian Lin Road, Minhang District
200233 Shanghai, China
E-mail: peng.yin@abbott.com

Consultants

Prof. Maurizio FERRARI
University Vita-Salute
IRCCS San Raffaele
Milan – Italy
E-mail: magenfe@yahoo.com

Dr. Larry KRICKA
Department of Pathology & Lab. Medicine
University of Pennsylvania Medical Center
3400 Spruce Street
Philadelphia, PA 19104 - USA
E-mail: kricka@pennmedicine.upenn.edu

Prof. Jason PARK
Department of Pathology,Children's Medical Center1935 Medical District Drive
Dallas, TX 75235 - USA
E-mail: Jason.Park@childrens.com

Dr. Helen MARTIN
Chemical Pathology
SA Pathology
1 Frome Road, Adelaide
SA -Australia
E-mail: Helen.Martin2@sa.gov.au

ETD COMMITTEE CHAIRS

Dr. Tim LANG
Clinical Biochemistry Department
University Hospital of North Durham
North Road
Durham, DH1 5TW - UK
E-mail: tim.lang@nhs.net

Dr. Bernard GOUGET
President-Healthcare Division Committee
Comité Français d'accréditation (Cofrac)
75012 Paris - France
E-mail: b.gouget@icloud.com

ETD WORKING GROUP CHAIRS

Dr. Larry KRICKA
Department of Pathology & Lab. Medicine
University of Pennsylvania Medical Center
3400 Spruce Street
Philadelphia, PA 19104 - USA
E-mail: kricka@pennmedicine.upenn.edu

Prof. Jennifer J.D. Morrissette, Ph.D., FACMG
Scientific Director, Clinical Cancer Cytogenetics
Clinical Director, Center for Personalized Diagnostics
Associate Professor of Clinical Pathology and Laboratory Medicine
Division of Precision and Computational Diagnostics
Department of Pathology, University of Pennsylvania
3020 Market Street
Philadelphia, PA 19104
E-mail:
jemorris@pennmedicine.upenn.edu

Dr. Andrew P. South
Thomas Jefferson University, 233 S. 10th Street, BLSB 406
Philadelphia USA PA19107
E-mail: Andrew.south@jefferson.edu