



Date & time: 16 January 2025, 10:00 – 18:00 CET
Place: Online Session
Responsibility: EMN for Traceability in Laboratory Medicine

Time	Topic	Speaker
10:00 -10:10	Introduction and Welcome	Vincent Delatour & Gavin O'Connor Chair & Vice Chair of EMN TraceLabMed
10:10 - 10:40	How can metrology support regulation in Health : the viewpoint of the IFCC	<i>Christa Cobbaert*</i> <i>Chair of the Scientific Division Executive committee (SD-EC) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC)</i>
10:40 - 11:20	Standardization of clinical measurements : the viewpoint of an Industry representative	Christian Vogl <i>Roche Diagnostics, Corporate representative at the IFCC SD-EC</i>
11:20 - 11:40	Innovation in the Health Sector	Speaker to be confirmed
11:40 -12:00	Discussion	All participants
12:00 - 13:00	Lunch break	
13:00 -13:30	Metrology to enable accurate AMR Surveillance with a One Health Approach	Esmeralda Valiente (PTB) <i>External stakeholder to be defined</i> Questions & short discussion
13:30 -14:00	Metrology for genomic profiling to support early cancer detection and precision medicine	Carla Divieto (INRIM) & Carole Foy (NML) Daniela Drandi (University of Torino) Questions & short discussion
14:00 - 14:30	XMet	Mike Messenger, (British In Vitro Diagnostics Association BIVDA) Questions & short discussion
14:30 - 15:00	Intracellular delivery	Max Ryadnov (NPL) <i>External stakeholder to be defined</i> Questions & short discussion
15:00 - 15:15	Break	
15:15 - 15:45	Reference measurements for cardiac markers	Claudia Swart (PTB) <i>External stakeholder to be defined</i> Questions & short discussion
15:45 - 16:15	Metrology for Neurodegenerative Diseases	Chiara Giangrande (LNE) Henrik Zetterberg (Univ. Göthenburg) Questions & short discussion
16:15 - 16:45	Metrology for Metabolomics	Gavin O'Connor (PTB) Elie Fux (Roche Diagnostics, Chair of the IFCC WG on Metabolomics)

		Questions & short discussion
16:45 - 17:15	Metrology to support sustainable development of nanotherapeutics	<i>Dorota Bartczak/Heidi Goenaga (NML)</i> <i>Zahra Rattray (Strathclyde University)</i> Questions & short discussion
17:15 - 17:45	Discussion	All participants
17:45	End of event	All participants

Metrology to enable accurate AMR Surveillance with a One Health Approach

Summary: This project aims to develop reference measurement methods and materials as well as artificial intelligence modelling to support accurate surveillance of antimicrobial resistance (AMR) and prediction of emerging AMR genes using a One Health approach. We will focus on bacterial model (s) that pose significant global challenges in disease management and infection.

GenomeMet 2

GenomeMET initiated development of new reference measurement systems (RMS) to support clinical genomics and improve standardization of advanced genomic testing for precision medicine and cancer. GenomeMET 2 will build on these foundations to deliver metrological traceability to key areas where applied genomic analyses are made internationally, such as oncological molecular Minimal/Measurable Residual Disease (MRD) testing where early detection of disease recurrence is critical for enabling effective intervention and extending patient survival.

XMet

Outbreaks can cause huge health and economic shocks: COVID-19 caused >2 million European deaths and globally cost >€300,000,000,000. Diagnostic tests are widely cited as being critical to outbreak response. Yet metrology to underpin accuracy is not widely available questioning how critical a test can be if it is poorly standardised. Xmet will deliver metrological traceability to ensure the accuracy of the diagnostic tools used for tracking and responding to outbreaks.

Metabolomics

Quantitative metabolomics methods have the potential to revolutionise routine clinical diagnosis and prognosis through the provision of complete metabolic profiles. However, the metabolomics data currently generated is not comparable between laboratories and across the large timeframe required to generate the data from large clinical studies. Therefore, standardisation is required to ensure that the results are traceable to a higher order reference and to meet current in vitro diagnostic regulatory standards. Full engagement with European and international metabolomics community driven harmonisation activities is required, as well as the provision of the reference standards and reference materials needed to assure patient data

CardioMet2

With 1.19 million deaths per year, heart diseases remain a major cause of morbidity and mortality in the EU. Results for clinical markers (both blood based and other risk factors) used for risk assessment and diagnosis are still hardly comparable between different sites. Linking them to

reference points and using digital tools for evaluation will allow clinicians a more holistic and personalised risk assessment.

NEuroBioStand 2

Recent research on biomarkers is revolutionizing the field of neurodegenerative diseases. As assays become more refined, blood biomarkers could be used in routine clinical settings to guide personalized treatment strategies and enable earlier interventions. AI, imaging, and digital tools can be deployed for greater precision in care, including predicting risk, early diagnosis, matching patients to new therapies, and monitoring safety.

Metrology to support sustainable development of nanotherapeutics

The global nanomedicine market is projected to be worth \$350 billion by 2025, with the potential to revolutionise European healthcare through development of safer and more efficacious treatments, addressing most pressing societal needs. However, there are neither validated methods for the quantification of the drug concentration within the nanotherapeutics systems, the variability of the drug concentration between the individual delivery particles, nor the drug stability/transformation upon encapsulation and storage. Such methods are critically needed by regulators, public sector, and the industry to support safe and sustainable development of nanotherapeutics.