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UNMET CLINICAL NEEDS ASSESSMENT FOR BIOMARKER EVALUATION - A PRACTICAL TOOLBOX FOR LABORATORY MEDICINE

Speaker: Phillip Monaghan (UK)
Moderator: Christa Cobbaert (NL)

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ABSTRACT

The translation of promising biomarkers to clinical application is a critical opportunity for laboratory medicine; to provide information that enables clinicians to make better decisions about the care of their patients. The realisation of this goal is itself critically dependent on the appropriate evaluation of novel biomarkers for use in the clinical setting. Inherent to this concept is consideration of the unmet clinical need that a laboratory test is aiming to address. However, as testing guides downstream clinical interventions to improve patient outcomes, the link between testing and outcomes is often indirect. As such, a full mapping of the clinical care pathway to define the purpose and role of the laboratory test and importantly, the clinical management decisions that the test will inform, thus enables the unmet clinical need to be addressed and furthermore complemented by the anticipated impact on patient outcomes. The corollary from this approach is the early specification of analytical and clinical performance criteria to subsequently evaluation studies in a cyclical manner, keeping the clinical care pathway and outcomes as the key drivers in the process. In doing so, biomarker development can be aligned to address existing gaps in clinical care and mitigate research waste and inappropriate utilisation of laboratory tests where clinical benefit is uncertain or at worst potentially harmful. There is a major opportunity here for laboratory professionals to play a key role in the development and implementation of clinical care pathways for new and existing laboratory tests. Stakeholder involvement; working together to overcome the conventional silos across disciplines is paramount to drive the adoption of innovative tests with robust implementation planning, so that test results are available and acted upon in an appropriate and timely manner, with a strong link to clinical intervention and outcomes. To realise the value of laboratory medicine in this context, the EFLM Working Group for Test Evaluation (WG-TE) has developed a 'practical toolbox' providing a Test

	<p>Evaluation Framework and Interactive Unmet Clinical Needs Checklist (hosted on the EFLM eLearning platform) to assist laboratories and other key stakeholders in clinical translational research, to undertake clinical needs assessment and clinical care pathway development.</p>
<p>ABOUT THE SPEAKER</p>	<p>Phillip Monaghan is a consultant clinical scientist at The Christie Pathology Partnership. He is honorary lecturer at the University of Manchester in the Faculty of Medical and Human Sciences, Institute of Inflammation and Repair. Dr. Monaghan is a member of the EFLM Working Group for Test Evaluation. He is Deputy Chair of the ACB Scientific Committee: Working Group on Traceability and Harmonisation of Calibration. He was awarded the Silver Research Medal from the Royal College of Pathologists for work on cortisol.</p>
<p>HOW TO REGISTER</p>	<p>Registration at: https://elearning.eflm.eu/enrol/index.php?id=43</p> <p>The participation is free of charge</p>