



Workshop:
Clinical Evidence Requirements and Data Management over the Medtech Product Lifecycle 28 May 2024 | London, UK

Preliminary Program

13:00	Welcome Coffee
13:10	Welcome Address & Introduction Helene Quie (<i>CSMD2024 Conference Chair</i>) Amie Smirthwaite (<i>Pre-Conference Workshop Lead</i>)
13:30	<p>Interactive Workshops, 1st Round (30 min each, attendees pick 2 out of 4 topics)</p> <p>Stream 1: New Product Development - Defining Clinical Evidence Requirements Based on "State of the Art" Facilitators: Sally Sennitt (<i>Medical Director, RQM+ Trial Services</i>) Dirk Steenmans (<i>Global Head, Clinical and Post Market Practice</i>) Tunvez Boulic (<i>Product Manager, Giotto.ai</i>) <i>Attendees will explore tools and techniques to define clinical evidence requirements based on user needs and state of the art treatment options. Includes hands-on use of AI literature search tools to optimize efficiency.</i></p> <p>Stream 2: Clinical Study Design for Regulatory Approvals and Market Access Facilitators: Danielle Giroud (<i>CEO, MDClinicals</i>) Helene Quie (<i>CEO, QMed Consulting</i>) <i>Strategies to ensure clinical investigations meet requirements for regulatory and market access purposes, based on example case studies</i></p> <p>Stream 3: Enhanced Clinical Evidence Generation Through PMCF Studies Facilitators: Rich Holborow (<i>Global Head of Clinical Compliance, BSI Notified Body</i>) Amie Smirthwaite (<i>SVP, Scientific Affairs, RQM+</i>) <i>Using PMCF as an opportunity to answer key research questions to address residual risks and unanswered questions arising from the clinical evaluation.</i></p> <p>Stream 4: Post Market Surveillance, Reporting and Risk Management Facilitators: Guido Rieger (<i>Medical Advisor, Kottman GmbH</i>) Sarah Contu (<i>Product Manager, Giotto.ai</i>) <i>Designing and managing an effective system for postmarket surveillance, adverse event reporting, and risk management for medical devices to ensure patient safety and regulatory compliance.</i></p>
15:00	Coffee Break (Delegates Change Stations)
15:30	Interactive Workshops, 2nd Round
17:00	Panel Discussion with the Leaders of the Workshop Summarizing the Results / Key Points
17:45	Closing Remarks
18:00	Drinks Reception
19:00	Dinner Event with Keynote Speaker Danielle Giroud (not included in the Pre-Conference Workshop fee)