



SYMPOSIUM 2026 UTRECHT

Medical Devices & IVD Programme

Monday 19 October 2026 – Wednesday 21 October 2026

Beatrix Building, Royal Jaarbeurs, Utrecht, The Netherlands



Please note, the programme may be subject to change.

Monday 19 October 2026 – DAY 1

Time	Session
11:00-12:00	Registration
12:00-12:10	Welcome Speech
	Speakers <ul style="list-style-type: none"> • Ashleigh Batchen, Regulatory Strategy Principal (UK), TÜV SÜD, United Kingdom
12:10-13:40	MD1/IVD1 - MDR/IVDR 2.0 – Kickstarting Further Structural Improvements
	This session focuses on the regulatory actions and activities that the EU is considering to further optimize the regulatory approval processes under the MDR and IVDR in Europe, by streamlining and optimizing the processes in general, and to make the system more cost-effective in general. Key elements of improvement focus on innovation, breakthrough devices, orphan devices and well-known legacy devices, to support both large industry and SMEs. In addition, the notified body processes may be streamlined further, initiating time-constraint for various conformity assessment steps and introducing clock stops. Perspectives will be shared from the viewpoint of a regulator, a key notified body, and an industry perspective. The session is a combination of short presentations and panel discussions that are interactive with the audience.
	Session Leaders <ul style="list-style-type: none"> • Ashleigh Batchen, Regulatory Strategy Principal (UK), TÜV SÜD, United Kingdom • Gert Bos, CSO, QServe Group, The Netherlands
	Speakers coming soon...
13:40-14:40	Lunch Break
14:40-15:20	MD2/IVD2 – Patient and Physician Perspective – Why Our Profession Matters
	Information coming soon...
	Session Leaders coming soon...
	Speakers coming soon...
15:20-16:00	MD3/IVD3 – Coming Soon
	Information coming soon...
	Session Leaders coming soon...
	Speakers coming soon...
16:00-16:40	Networking Break
16:40-18:00	MD4/IVD4 – How to cope with changing AI/ML requirements
	With significant obligations coming into force with the EU AI Act in August 2026, the Digital Omnibus looking to streamline many pieces of horizontal legislation and with the MDR and IVDR moving from Section A to Section B of the regulation, this session will explore the impact of the upcoming legislative changes on AIaMD/SaMD.
	Session Leaders <ul style="list-style-type: none"> • Leon Doorn, CEO & Co-Founder, MedQAIR, The Netherlands
	Speakers coming soon... <ul style="list-style-type: none"> • Cécile van der Heijden, Attorney-at-Law, Axon Lawyers, The Netherlands



SYMPOSIUM 2026 UTRECHT

Medical Devices & IVD Programme

Monday 19 October 2026 – Wednesday 21 October 2026

Beatrix Building, Royal Jaarbeurs, Utrecht, The Netherlands



	<ul style="list-style-type: none"> Bingshuo Li, Senior Consultant & AI Lead, QServe, Germany
18:00–18:05	Closing Speech

End of Day 1

Tuesday 20 October 2026 – DAY 2

Time	Session
08:55–09:00	Welcome to Day 2
09:00–10:20	MD5/IVD5 – Use of Reliance to Expedite Market Access, Optimise Resource Allocation, Automate Safety Reporting, and so on
	<p>Why has the topic of reliance been chosen? Exponential growth in regulatory requirements including new standards & guidance which are evolving at a fast pace. Consequences of this exponential growth has resulted in much higher costs of bringing a medical device to market and retaining the medical device on the market as well as reduction in the diversity of medical devices available and medical device supply.</p> <p>The use of reliance, consisting of different application types depending on the level of trust and other factors, is one approach to lessen the burden of bringing and maintaining medical devices on the market.</p> <p>Implementation of reliance is not restricted to pre-market application but is also being implemented post-market through the use of e.g. common adverse event coding allowing for safety events to be quickly identified either by the legal manufacturer or national regulatory authorities (NRAs). Similarly, reliance may be applied in other areas: clinicals, auditing, inspection, QMS, and change management.</p> <p>Benefits of reliance in general for the legal manufacturers, NRAs, patients, and other stakeholders include:</p> <ul style="list-style-type: none"> Faster access to safe, quality innovations from patient perspective & optimisation of resources and investment from legal manufacturer perspective Process efficiency: reduction in effort duplicity, cost & resource savings, shorter response time Optimized resource allocation Enhanced convergence of regulatory frameworks <p>In conclusion, looking into the crystal ball, the future perspectives of the use of reliance internationally will be presented, including referencing the MDR revision, which includes the word reliance.</p>
	<p>Session Leaders</p> <ul style="list-style-type: none"> Stephanie Grassmann, Managing Director, MedTechXperts LLC, Switzerland
	<p>Speakers coming soon...</p> <ul style="list-style-type: none"> Stephanie Grassmann, Managing Director, MedTechXperts LLC, Switzerland
10:20–11:00	Networking Break
11:00–12:20	MD6/IVD6 – Coming Soon
	Information coming soon...
	Session Leaders coming soon...
	Speakers coming soon...
12:20–14:00	Lunch Break



14:00–15:20	HM6/MD7/IVD7 - The Future of Combined IMP/IVD Trials in Europe: COMBINE, CTIS Integration, and the Emerging Regulatory Model
	<p>The regulatory landscape for combined clinical trials involving investigational medicinal products (IMPs) and in vitro diagnostic medical devices (IVDs) is undergoing significant transformation. Building on the analysis published in the 2026 February edition of the Regulatory Rapporteur, this session will provide an updated perspective on the latest developments in the European Commission's EC COMBINE initiative, including progress on harmonisation pilots, early CTIS integration concepts, and potential future models for unified IMP/IVD submission pathways.</p> <p>With the introduction of the new EU Biotech Act, additional changes are expected that may reshape requirements for supporting evidence packages, oversight processes, and the interaction between the Clinical Trials Regulation (CTR) and the In Vitro Diagnostic Regulation (IVDR). Particular attention will be given to how Request for Information (RFI) pathways could evolve under this new legislative framework, and what these changes may mean in practical terms for clinical trial sponsors, especially those conducting biomarker driven or co-development trials.</p> <p>The session intends to offer a cross-industry view of emerging regulatory and operational expectations, incorporating lessons learned from ongoing engagement across sponsors, competent authorities, and notified bodies. Operational and authority perspectives will be shared by co presenters enabling a multi stakeholder discussion on practical challenges, anticipated system behaviour, and opportunities for greater procedural alignment. Attendees will gain an up to date understanding of current developments, near term industry implications, and forward-looking considerations for planning and executing combined IMP/IVD trials in the EU.</p>
	<p>Learning Objectives</p> <ul style="list-style-type: none"> • Understand emerging EU requirements for combined IMP/IVD trials under CTR, IVDR, and the COMBINE initiative. • Analyse how COMBINE outputs and the proposed EU Biotech Act may reframe RFI roles, sequencing, and authority interactions. • Consider the implications for future regulatory governance and procedural alignment under CTR and IVDR.
	<p>Session Leaders</p> <ul style="list-style-type: none"> • Amber McNair, Associate Director, Clinical Trials Regulatory, IQVIA, United Kingdom • Margareth Jorvid, Chief Executive Officer, Methra Uppsala, Sweden
	<p>Speakers coming soon...</p>
15:20–16:00	Networking Break
16:00–17:20	MD8 – Health Technology Assessment & Funding Session
	<p>Most successful Medtech start-ups develop their regulatory plans and evidence generation with alongside market access strategy and align those with their funding needs. A clear plan with realistic timelines will clearly de-risk the development of your device and facilitates the discussions with the important stakeholders, like investors.</p> <p>This session will address some important thought lines for MedTech Start-ups and will include insights from a MedTech focused VC, the current world of a start-up and a HTA expert.</p>
	<p>Session Leaders</p> <ul style="list-style-type: none"> • Alwin van den Broek, Director Clinical Operations & Data Protection Officer, BeVincend, The Netherlands
	<p>Speakers coming soon...</p>
16:00–16:40	IVD8 – Living in the Future: What Can We Expect for IVDs?



SYMPOSIUM 2026 UTRECHT

Medical Devices & IVD Programme

Monday 19 October 2026 – Wednesday 21 October 2026

Beatrix Building, Royal Jaarbeurs, Utrecht, The Netherlands



	<p>This session brings key stakeholders together to discuss the evolution of IVD regulation and what we can plan for moving forward. In a time of IVDR 2.0 it's crucial that everyone involved in the IVD landscape understands what these changes may mean for the sector.</p>
	<p>Learning Objectives</p> <ul style="list-style-type: none"> • Have a base understanding of the history and current landscape relating to IVD regulation. • Be clear on expectations and what is to come in this space. • Allow for engaging and open dialogue between attendees and panellists in the form of a Q&A, giving the opportunity for individuals to have their own specific questions asked.
	<p>Session Leaders</p> <ul style="list-style-type: none"> • Ashleigh Batchen, Regulatory Strategy Principal (UK), TÜV SÜD, United Kingdom
	<p>Speakers coming soon...</p>
16:40-17:20	<p>IVD9 – Commercialisation of In-House Tests: From Lab to Market, the In-House Testing Journey</p>
	<p>Information coming soon...</p>
	<p>Session Leaders coming soon...</p>
	<p>Speakers coming soon...</p>

Wednesday 21 October 2026 – DAY 3

Time	Session
08:55–09:00	<p>Welcome to Day 3</p>
09:00–10:20	<p>MD9 – Clinical Investigation & Clinical Evaluation Session</p>
	<p>Information coming soon...</p>
	<p>Session Leaders</p> <ul style="list-style-type: none"> • Maaike Labots, Manager Medical Writing, Avania, The Netherlands
	<p>Speakers coming soon...</p>
09:00–10:20	<p>IVD10: Innovation Before Regulation – How has IVDR Met the Brief of Supporting SMEs?</p>
	<p>SMEs are critical to the IVD sector, with over 80% of IVDs being placed on the market by SMEs. The IVDR was designed to support SMEs, but what mechanisms are there in reality to do this? The session should discuss the state of play, what is done to improve market enablement, and what are the chances of success for SMEs to place devices on market.</p>
	<p>Learning Objectives</p> <ul style="list-style-type: none"> • What impact have IVDR had on SMEs • What was the desire for supporting SMEs as part of the regulation • What is the reality
	<p>Session Leaders</p> <ul style="list-style-type: none"> • Stuart Angell, Managing Director, IVDealogy, United Kingdom
	<p>Speakers coming soon...</p>
10:20–11:00	<p>Networking Break</p>
11:00–12:20	<p>MD10 – EMDN Coding & EUDAMED Session</p>



SYMPOSIUM 2026 UTRECHT

Medical Devices & IVD Programme

Monday 19 October 2026 – Wednesday 21 October 2026

Beatrix Building, Royal Jaarbeurs, Utrecht, The Netherlands



	Information coming soon...
	Session Leaders coming soon...
	Speakers coming soon...
11:00–12:20	IVD11 – IVD Development & Performance Studies Session
	Information coming soon...
	Session Leaders
	<ul style="list-style-type: none"> Stuart Angell, Managing Director, IVDealogy, United Kingdom
	Speakers coming soon...
12:20–14:00	Lunch Break
14:00–15:20	MD11 - Built to Last? Designing Regulation for Next-Generation SaMD
	<p>Technological development is known to move faster than the legislative and regulatory frameworks intended to govern it. Regulation is required to be evidence-based, risk-proportionate, and legally certain. Regulatory change requires lengthy consultation and long lead times. Meanwhile, product development - particularly in the SaMD context - follows shorter, iterative cycles, and often ends up in a form that's very different to where it started. This discrepancy can create regulatory lag and enforcement challenges. The discussion focuses on regulatory design mechanisms intended to manage technological uncertainty, including technology-neutral drafting, outcome-based requirements, and the use of secondary instruments such as harmonised standards, guidance, and common specifications. Recent EU regulatory experience is used to illustrate how these mechanisms function in practice. It covers regulatory enforcement challenges - including case studies relating to general purpose LLMs, "wellness" products, and chat bots. Finally, from the manufacturer's perspective, it draws out the challenges of building in a) an ambiguous, and b) a constantly evolving regulatory environment (such as in the context of the AI Act).</p>
	Learning Objectives
	<ul style="list-style-type: none"> Understand key challenges in regulatory design and enforcement, especially where rules need to apply to products not yet invented. Explore principles of future-proof regulation (e.g. technology neutrality, outcome-based requirements, and adaptive mechanisms). See how regulatory choices shape innovation in practice, using real-world examples and highlighting areas of friction.
	Session Leaders
	<ul style="list-style-type: none"> Felicity Ellis, Head of Legal, Scarlet, United Kingdom
	Speakers coming soon...
14:00-15:20	IVD12 – PMS, Vigilance and Lifecycle Management Through Real-World Experience
	<p>This session addresses the practical implementation of IVDR requirements with a focus on Post-Market Surveillance (PMS), vigilance and lifecycle management in the context of IVD manufacturers and SMEs. While IVDR requirements are well defined, their operational application remains challenging, particularly for organisations with limited regulatory resources. The session will begin with an overview of recent IVDR updates and evolving regulatory expectations, highlighting their direct impact on PMS systems, vigilance activities and the management of corrective actions. Particular attention will be given to the increased need for data integration, trend analysis and proactive risk management throughout the device lifecycle.</p>



SYMPOSIUM 2026 UTRECHT

Medical Devices & IVD Programme

Monday 19 October 2026 – Wednesday 21 October 2026

Beatrix Building, Royal Jaarbeurs, Utrecht, The Netherlands



	<p>A real FSCA case will be presented to illustrate how PMS signals can escalate into vigilance activities, including decision-making processes, interaction with competent authorities, communication strategies and implementation of corrective actions. The case study will demonstrate common pitfalls, regulatory expectations and lessons learned, with emphasis on documentation, timelines and cross-functional coordination.</p> <p>The final part of the session will focus on lifecycle management as a strategic tool to ensure ongoing compliance, linking PMS outputs, vigilance findings and regulatory updates into a coherent system. Practical recommendations will be provided to support SMEs in building proportionate, sustainable and inspection-ready processes under IVDR.</p> <p>The session aims to bridge the gap between regulatory requirements and real-world implementation, offering participants actionable insights based on direct experience.</p>
	<p>Learning Objectives</p> <ul style="list-style-type: none">• Interpret recent IVDR updates and their impact on post-market obligations.• Apply PMS and vigilance requirements using a real FSCA case study.• Integrate lifecycle management principles to improve regulatory compliance in SMEs
	<p>Session Leaders</p> <ul style="list-style-type: none">• Luigi Cipolleschi, QA/RA Manager, Biochemical Systems International S.p.A., Italy
	<p>Speakers coming soon...</p>
15:20–15:25	Closing Speech

End of the Medical Devices & IVD Symposium