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

- Ashleigh Batchen, Regulatory Strategy Principal (UK)/Chair of the Medical Devices & IVD Working Party (MDSWP), TÜV SÜD, United Kingdom

12:10–13:30	**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

- Gert Bos, Executive Director and Partner, QServe Group, The Netherlands

Speakers will include...

- Sabina Hoekstra, Global Director Regulatory Strategy, TÜV SÜD, Germany
- Chiara Orlandi, Policy Officer, European Commission, Belgium

13:30–14:40	**Lunch Break**
14:40–15:20	**MD2/IVD2 – From athlete to patient and back: The true value of a medical device**

In general, medical device development becomes far more effective when stakeholder perspectives are treated as core design inputs, and prosthetic leg development illustrates this especially well. The patient provides essential insight into real world challenges such as long-term comfort, skin irritation, gait stability, cosmetic preferences, and the level of mobility they hope to regain. Patients often reveal nuances that others may overlook, how a socket feels after hours of wear, or how subtle shifts in weight distribution influence confidence while walking. The rehabilitation physician contributes a complementary clinical view focused on biomechanics, rehabilitation progress, long term musculoskeletal health, and the device's ability to prevent secondary injuries. They ensure the prosthetic supports safe movement, aligns with daily life demands, and matches the patient's mobility goals. The prosthetist, however, plays the pivotal bridging role. They translate patient needs into technical adjustments, customize socket fit, fine tune alignment, and provide ongoing modifications as the patient's body and mobility evolve. Their hands-on expertise exposes practical constraints and opportunities that directly shape design feasibility and real-world performance. When all three perspectives are incorporated early and continuously, this multi lens approach transforms a prosthetic leg from a clever engineering achievement into a meaningful tool that restores independence, supports health, and enhances overall wellbeing.

To illustrate this process, you will hear the story of a marathon runner who lost both legs in a car accident yet regained an extraordinary level of mobility. The session will highlight what such a journey requires by showcasing the patient's endurance and the continuous collaboration between the patient, rehabilitation physician, and prosthetist.

Session Leaders coming soon...

- Alwin van den Broek, Director Clinical Operations & Data Protection Officer, BeVinced, The Netherlands
- Paula van Hennik, Vice President Clinical, ProPharma, The Netherlands

Speakers will include...

- Klaas Talma, Patient/Athlete, The Netherlands

- Kas Peters, Certified Prosthetist Orthotist, CPO, De Hoogstraat Orthopedietechniek, The Netherlands

15:20–16:00	MD3/IVD3 – Incorporating Artificial Intelligence into the Daily Life of a Regulatory Professional

This session brings together software providers to explore how artificial intelligence is reshaping the day-to-day work of regulatory professionals in medical technology. Speakers will explore how these new technologies are being adopted through practical examples and how they can empower regulatory functions to deliver greater value, as well as address the barriers to implementation and the changing skillset within the industry.

Session Leaders

- Célia Cruz, Chief Regulatory Affairs Officer, Complear Health, Portugal

Speakers will include...

- Ivan Perez Chamorro, CEO & Founder, MedBoard, United Kingdom
- Fabien Bouhier, Co-Founder & CTO, Phox, The Netherlands

16:00–16:40	Networking Break
16:40–18:00	MD4/IVD4 – How to cope with changing AI/ML requirements

Artificial intelligence and machine learning are transforming medical devices faster than the regulatory framework can keep up. This session brings together legal, clinical, and practical perspectives on developing and maintaining AI/ML-enabled medical devices under the EU's overlapping regimes: the AI Act, MDR/IVDR (and the recent reform proposal), the Digital Omnibus, GDPR, and EHDS. Speakers will unpack the legal implications of the MDR/IVDR proposal, explain how legal proceedings actually run between European member states and EU agencies, share a practical case study on preparing for the AI Act in the absence of concrete guidelines, and examine what robust clinical evidence looks like for AI/ML devices: from data requirements and synthetic data to PMCF and model drift. The closing panel connects the threads: timelines, classification, standards, data governance, and whether the new proposals bring real clarity.

Session Leaders

- Leon Doorn, CEO & Co-Founder, MedQAIR, The Netherlands

Speakers

- Cécile van der Heijden, Senior Legal Counsel / Attorney-at-law, Axon Lawyers, The Netherlands
- Davidsdochter Coenraad, Team Manager Regulatory Medical Devices, QServe, Germany
- Sarina Zillikens, Clinical Affairs Expert & Team Lead, Escentia, Germany
- Victor Plat, Policy Officer, Ministry of Health, Welfare & Sport, The Netherlands

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

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.

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.

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.

Benefits of reliance in general for the legal manufacturers, NRAs, patients, and other stakeholders include:

- 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

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.

Session Leaders

- Stephanie Grassmann, Managing Director, MedTechXperts LLC, Switzerland

Speakers will include...

- Stephanie Grassmann, Managing Director, MedTechXperts LLC, Switzerland
- Jie Zhou, Technical Lead, TGA, Australia [*Online*]
- Francisco Delgado, Head of Medical Device Pathways, MHRA, United Kingdom
- Mia Spiegelmann, Vice President Regulatory, Quality and Environmental Affairs, MedTech Canada, Canada [*Online*]

10:20–11:00	**Networking Break**
11:00–12:20	**MD6/IVD6 – Is the CE mark alone sufficient to enter European markets including the UK?**

This session will focus on if the CE mark alone is sufficient to enter a European market or if there are local or other applicable legislation that must be fulfilled before launch to market.

Session Leaders coming soon...

- Natasha Bankowski, Independent Director and RA/QA/Vigilance consultant - Medical Devices/IVDs and Pharma, Ireland

Speakers will include...

- Neil Plumridge, Independent IVD Consultant, United Kingdom
- Meike Bomhof, Vice President Europe, Avania, Spain

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**

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.

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.

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.

Learning Objectives

- 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.

Session Leaders

- Amber McNair, Associate Director, Clinical Trials Regulatory, IQVIA, United Kingdom
- Margareth Jorvid, Chief Executive Officer, Methra Uppsala, Sweden

Speakers will include...

- Deepa Subramaniyan, Senior Clinical Trial Regulatory Lead, F.Hoffmann La Roche, Switzerland
- Maurice Steenhuis, Medical Technology Assessor, CCMO, The Netherlands
- Olga Tkachenko, Policy Officer, European Commission, Belgium
- Stiina Aarum, Scientific Officer, EMA, The Netherlands

15:20–16:00	**Networking Break**
16:00–17:20	**MD8 – Medical Devices: Beyond Regulatory Borders**

Successful development of Medical Technology is not solely dependent on the right regulatory strategy. The pathways from innovation to patient access is shaped by the right funding, the right (global) development strategy and the reimbursement reality.
This session, ***Beyond Regulatory Borders***, will give you incredible valuable insights into these elements and will look outside the regulatory border.
It will explore how medtech companies could align the financial challenges and give the perspective of a global Medical Device Company on Medical Device Development and will be concluded with insights from a reimbursement specialist from the Netherlands.

All together, these perspectives will show that successful medtech innovation is not defined by a regulatory approval alone, but by the ability to navigate the investment logic and complexity, the global development challenges and the reimbursement pathway.

Session Leaders

- Alwin van den Broek, Director Clinical Operations, BeVinced, The Netherlands

Speakers will include...

- Jón Ingi Bergsteinsson, Founder & MP, LIFA Ventures, Iceland
- Robin Toorneman, Health Innovation Advisor, Innovamore, The Netherlands
- Michael Konings, Global Head of Regulatory Affairs - IGT- Systems, Philips, The Netherlands

16:00-16:50	**IVD8 – Living in the Future: What Can We Expect for IVDs?**

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.

Learning Objectives

- 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.

Session Leaders

- Stuart Angell, Director of Regulatory Affairs, BIVDA, United Kingdom

Speakers will include...

- Alex Laan, Head of the Notified Body, BSI, The Netherlands
- Monique Greijmans, Business Developer and Principal Consultant, MedQAIR, The Netherlands

16:50-17:20	**IVD9 – Commercialisation of In-House Tests: From Lab to Market, the In-House Testing Journey**

With the increasing uptake of personalised medicine, early disease detection and precision diagnostics, this session will look at the key considerations needed when bringing in-house tests to market, such as the legal requirements, practicalities and pathways available for manufacturers.

Session Leaders coming soon...

- Stuart Angell, Director of Regulatory Affairs, BIVDA, United Kingdom

Speakers will include...

- Jan-Bart Hak, Director Medtech Regulatory Sciences EU, ProPharma, The Netherlands

End of Day 2

Wednesday 21 October 2026 – DAY 3

Time	Session
08:55–09:00	**Welcome to Day 3**
09:00–10:20	**MD9 – Advancing Clinical Evidence Generation: Strategy, Regulation, and Real-World Data**
Discover how to advance clinical evidence generation—from practical study-design considerations to high-level strategic insights. This session will draw on five years of MHRA clinical investigation data, revealing clear patterns in study design, device risk classification, approval timelines, and the regulatory and operational challenges most commonly encountered. It will also explore how to define and select robust clinical evidence sources to meet post-market requirements. Attendees will gain strategic insight, practical guidance, and data-driven perspectives to strengthen clinical planning, streamline regulatory pathways, and build credible, trusted evidence across the device lifecycle.	
Session Leaders • Maaike Labots, Manager Medical Writing, Avania, The Netherlands	
Speakers • Daniel Hill, Deputy Head of Clinical Investigations, MHRA, United Kingdom • Bianca Lutters, Head of Clinical Affairs, Principal Consultant, QServe, The Netherlands • Nikhil Khadabadi, Chief Medical Officer, ECLEVAR, United Kingdom	
09:00–10:20	**IVD10 – Innovation Before Regulation – How has IVDR Met the Brief of Supporting SMEs?**
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 is 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.	
Learning Objectives • What impact have IVDR had on SMEs • What was the desire for supporting SMEs as part of the regulation • What is the reality	
Session Leaders • Stuart Angell, Director of Regulatory Affairs, BIVDA, United Kingdom	
Speakers will include... • Jan-Bart Hak, Director Medtech Regulatory Sciences EU, ProPharma, The Netherlands • Steve Reeder, Chief Operating Officer, SMI Systems, United Kingdom • Alex Laan, Head of the Notified Body, BSI, The Netherlands	
10:20–11:00	**Networking Break**
11:00–12:20	**MD10 – EUDAMED: Strategic Opportunities, Implementation Status and Lessons Learned**
In this session we will learn of the strategic opportunities available with the rollout of EUDAMED and how organisations can keep this “shopwindow” into the company clean and presentable. We will also hear a status update on the rollout of EUDAMED, and what lessons have been learnt thus far.	
Session Leaders • Natasha Bankowski, Independent Director and RA/QA/Vigilance consultant - Medical Devices/IVDs and Pharma, Ireland	
Speakers will include... • Ronald Boumans, Strategic Consultant, Boumans Regulatory Consulting B.V., The Netherlands	

- Richard Houlihan, Chief Executive Officer, EirMed, Portugal

11:00–12:20	IVD11 – IVD Development & Performance Studies Session

Information coming soon...

Session Leaders

- Rebecca Hird, Head of Approved Body and Global Authorisation Manager, TÜV SÜD, United Kingdom

Speakers will include...

- Liz Gommans, IVD technical file reviewer / RA specialist, DEKRA Certification B.V., The Netherlands
- Carlos Galamba, CEO & Head of Diagnostics (IVD / CDx), MDx CRO, United Kingdom
- Pieter Bogaert, Senior consultant regulatory affairs - in vitro diagnostics, QbD Group, Belgium

12:20–14:00	Lunch Break
14:00–15:20	MD11 - Built to Last? Designing Regulation for Next-Generation SaMD

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).

Learning Objectives

- 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

- Gabbie Cesvet, Head of Government Relations, Scarlet, United Kingdom

Speakers will include...

- MiRa Jacobs, Head of Digital Health, MHRA, United Kingdom

14:00-15:20	IVD12 – PMS, Vigilance and Lifecycle Management Through Real-World Experience

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. An overview of the recent IVDR changes and their impact on PMS systems will be discussed, alongside how to utilise lifecycle management as a strategic tool

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.

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.

The session aims to bridge the gap between regulatory requirements and real-world implementation, offering participants actionable insights based on direct experience.

Session Leaders • Natasha Bankowski, Independent Director and RA/QA/Vigilance consultant - Medical Devices/IVDs and Pharma, Ireland	
Speakers will include... • Marta Carnielli, Head of Certification IVD, TÜV SÜD, Germany	
15:20–15:25	**Closing Speech**

End of the Medical Devices & IVD Symposium