

# Programme

as of April 14, 2025

# THE MEDTECH FORUM 2025

An event by  MedTech Europe  
from diagnosis to cure

**13 – 15 May > Lisbon**

#MTF2025 | [themedtechforum.eu](https://themedtechforum.eu)

In cooperation with



# WELCOME INTRODUCTION



**Dear participants, Dear speakers,  
Dear sponsors,**

Following the great success of The MedTech Forum 2024 in Vienna, which surpassed all previous records, I am delighted to welcome you to the next chapter of our journey - The MedTech Forum 2025, which will be held in Lisbon from 13 to 15 May.

The 2025 programme will feature leading voices in the medical technology community, including industry experts and key stakeholders. Together, we will tackle the ever-evolving opportunities and challenges for our industry, from innovation and digital transformation to regulatory developments and sustainability.

I encourage you to take full advantage of the many networking opportunities throughout the event. Whether it's sharing ideas, forging new partnerships, or reconnecting with colleagues, these moments are where some of the most valuable insights and collaborations are born.

Best regards,

Oliver BISAZZA  
Chief Executive Officer  
MedTech Europe

# PROGRAMME AT A GLANCE

**TUESDAY 13 MAY 2025**

**PÁTIO DA GALÉ**

**18:30-22:00 Welcome Cocktail Reception**

**WEDNESDAY 14 MAY 2025**

AUDITORIUM I	AUDITORIUM II	ROOM A	ROOM B	AUDITORIUM III
EXHIBITION AREA 08:30-09:00 WELCOME COFFEE				
09:00-09:25 <b>PLENARY</b> Opening Keynote				
09:25-09:50 <b>PLENARY</b> Keynote Speech				
10:00-10:50 <b>SPONSORED SESSION</b> AI Unleashed: Strengthening MedTech Competitiveness in a New Industrial Age Sponsored by VAMSTAR	10:00-10:50 <b>PARALLEL SESSION</b> MedTech Policy Trends: Navigating a Changing Geopolitical Landscape	10:00-10:50 <b>SPONSORED SESSION</b> Future of business interaction: Commercializing Digital Solutions in MedTech Sponsored by DELOITTE	10:00-10:50 <b>PARALLEL SESSION</b> Resilient Procurement, Stronger Healthcare: The ProCure Results	10:00-10:50 <b>ASK THE EXPERT</b> Interactions with healthcare professionals and promotion of medical devices on social media: an EU enforcement update HOGAN LOVELLS
11:00-11:50 <b>PARALLEL SESSION</b> Boosting Europe's Attractiveness for Medtech Innovation	11:00-11:50 <b>PARALLEL SESSION</b> Transforming Healthcare Beyond Hospital Walls	11:00-11:50 <b>SPONSORED SESSION</b> The AI Edge in MedTech Commercial—Insights from BCG's 4th Milkman Study Sponsored by BCG	11:00-11:50 <b>PARALLEL SESSION</b> Paving the Way for the European Health Data Space	11:00-11:50 <b>ASK THE EXPERT</b> Status of digital health reimbursement in the US and European Markets AVANIA
EXHIBITION AREA 11:50-12:20 NETWORKING BREAK				
12:20-13:10 <b>PARALLEL SESSION</b> From Evaluation to Action: The Future of MDR and IVDR	12:20-13:10 <b>PARALLEL SESSION</b> Cancer patient journey how MedTech fosters better and safer care	12:20-13:10 <b>SPONSORED SESSION</b> From Hype to Reality: Unlocking AI's Potential in Medical Devices Sponsored by ZÜHLKE	12:20-13:10 <b>SPONSORED SESSION</b> Navigating global business challenges in MedTech Operations to provide consistent patient care Sponsored by FLEX	12:20-13:10 <b>ASK THE EXPERT</b> AI-Driven Translation in MedTech: The power of Quality Estimation and Human Expertise SEPROTEC
EXHIBITION AREA 13:10-14:10 LUNCH BREAK				
14:10-15:00 <b>PARALLEL SESSION</b> Safe AI, Smarter Care: Transforming European Healthcare Systems	14:10-15:00 <b>PARALLEL SESSION</b> Empowering European Innovators With Early Feasibility Studies	14:10-15:00 <b>PARALLEL SESSION</b> UK - EU: ready for a reset?	14:10-15:00 <b>PARALLEL SESSION</b> From Data to Diagnosis: Digital Tools Transforming Diagnostics	14:10-15:00 <b>ASK THE EXPERT</b> Are You Winning or Losing Market Share? The Value of Precise Market Data
15:10-16:00 <b>PARALLEL SESSION</b> Climate meets Economics: Bridging Green Goals and Competitive Edge in Healthcare	15:10-16:00 <b>PARALLEL SESSION</b> HTAR in Medical Devices - Boosting or Stifling innovation in Europe?	15:10-16:00 <b>PARALLEL SESSION</b> Shaping the Future of Clinical Investigations in Europe	15:10-16:00 <b>PARALLEL SESSION</b> EU and MDSAP - a Dream or a Viable Opportunity?	15:10-16:00 <b>ASK THE EXPERT</b> Navigating U.S. Anti-bribery compliance under the Trump Administration REEDSMITH
EXHIBITION AREA 16:00-16:30 NETWORKING BREAK				
16:30-17:20 <b>PARALLEL SESSION</b> Navigating Sustainable Corporate Governance: Challenges and Opportunities	16:30-17:20 <b>PARALLEL SESSION</b> Let's talk about Women's Health	16:30-17:20 <b>PARALLEL SESSION</b> EUDAMED: The Central Approach for Gathering Data on Medical Devices	16:30-17:20 <b>SPONSORED SESSION</b> Time to Act: The need for Accelerated Value Pathways for Breakthrough Innovations Sponsored by Edwards	16:30-17:20 <b>ASK THE EXPERT</b> The US Regulatory Landscape – Making Sense of the Current Chaos HOGAN LOVELLS
17:30-18:10 <b>PLENARY</b> Keynote Speech				
EXHIBITION AREA 18:10-19:40 NETWORKING RECEPTION SPONSORED BY CRITICAL SOFTWARE				

**THURSDAY 15 MAY 2025**

AUDITORIUM I	AUDITORIUM II	ROOM A	ROOM B	AUDITORIUM III
EXHIBITION AREA 08:00-08:30 WELCOME COFFEE				
08:30-09:20 <b>PLENARY</b> CEO #nofilter				
09:30-10:20 <b>PARALLEL SESSION</b> Why Europe Matters: Exploring MedTech Investment Potential	09:30-10:20 <b>PARALLEL SESSION</b> Driving secure health data access via the IDERHA IHI Project	09:30-10:20 <b>PARALLEL SESSION</b> Protecting Privacy in the Age of AI-Powered Healthcare	09:30-10:20 <b>PARALLEL SESSION</b> Secure and Seamless: The Next Generation of Technical Documentation	09:30-10:20 <b>ASK THE EXPERT</b> Innovative Payment Schemes – Lessons Learned from Pharma and Medical (Digital) Devices
EXHIBITION AREA 10:20-10:50 NETWORKING BREAK				
10:50-11:40 <b>PARALLEL SESSION</b> Re-imagining Cyber Secure Health	10:50-11:40 <b>PARALLEL SESSION</b> Navigating Litigation: Securing MedTech's Future in Europe	10:50-11:40 <b>PARALLEL SESSION</b> Global Market Focus: Brazil	10:50-11:40 <b>SPONSORED SESSION</b> Aligning PLM & QMS Processes for MedTech Excellence Sponsored by VEEVA MedTech	10:50-11:40 <b>ASK THE EXPERT</b> Everything You Wanted To Know About IHI (But Were Afraid To Ask)
11:50-12:40 <b>PARALLEL SESSION</b> Implementing the EU Green Deal in Healthcare	11:50-12:40 <b>SPONSORED SESSION</b> Closing the Loop: Turning Customer Insights Into Product Excellence Sponsored by SMARTTEVA	11:50-12:40 <b>PARALLEL SESSION</b> Advancing the Assessment of Digital Health to Foster Innovation	11:50-12:40 <b>PARALLEL SESSION</b> Shaping the Future of Wound Care	11:50-12:40 <b>ASK THE EXPERT</b> How AI & PLM Drive Smarter Compliance in MedTech PTC/DELOITTE
EXHIBITION AREA 12:40-13:40 LUNCH BREAK				
13:40-14:30 <b>PARALLEL SESSION</b> Innovating for Planetary and Human Health: Sustainability Trends at Global Level	13:40-14:30 <b>PARALLEL SESSION</b> Cutting Edge: The Future of Robotic Surgery	13:40-14:30 <b>PARALLEL SESSION</b> A New Cardiovascular Health Plan for Europe, a Game Changer for Patients	13:40-14:30 <b>PARALLEL SESSION</b> Fast-track health technology assessment for in vitro diagnostics APIFARMA	13:40-14:30 <b>ASK THE EXPERT</b> Unlocking Health Data: The EU Data Act's Impact on Digital Health REEDSMITH
14:40-15:30 <b>PARALLEL SESSION</b> Navigating the New Article 10a: Lessons Learned and Practical Insights	14:40-15:30 <b>PARALLEL SESSION</b> Engaging with Impact: Stories of MedTech and Patient Collaboration	14:40-15:30 <b>PARALLEL SESSION</b> Navigating Interoperability in the EHDS: Roles and Responsibilities for Manufacturers	14:40-15:30 <b>PARALLEL SESSION</b> Measure Your Readiness with the Self-Assessment Tool	14:40-15:30 <b>ASK THE EXPERT</b> Removing the Guesswork from IVD Market Intelligence
15:40-16:00 <b>PLENARY</b> Conclusions				

18:30-22:00

PÁTIO DA GALÉ

## WELCOME COCKTAIL RECEPTION



We are very pleased to welcome you to Lisbon and to Pátio da Galé, the chosen venue for the Medtech Forum Welcome Reception.

Located in one of Europe's largest squares, Pátio da Galé was once part of the Royal Palace, blending rich history with modern elegance.

With its grand arcades, open-air courtyards, and views of the Tagus river, Pátio da Galé is truly a unique location for cultural exhibitions or corporate events.

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**DIRECTION: GALE PATIO, PRAÇA DO COMÉRCIO, 11 00 LISBON, PORTUGAL**

**By Car /Taxi / Uber (no more than 7€)**

### By public transportation:

To get from the Lisbon Congress Center to Pátio da Galé using public transport, follow these steps:



**Tram:** Walk to the «Centro de Congressos» stop and take tram 15E towards «Praça da Figueira».



**Stop:** Get off at «Praça do Comércio».



**Walk:** From Praça do Comércio, Pátio da Galé is just a 2-minute walk away.

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# WEDNESDAY 14 MAY

08:30-09:00

**WELCOME COFFEE**

09:00-09:25

AUDITORIUM I

**OPENING KEYNOTE**

More details to follow

**SPEAKERS:**

- Oliver BISAZZA (CEO, MedTech Europe)
- Ghada FARAH (Vice-Chair - MedTech Europe, Terumo Europe)

09:25-09:50

AUDITORIUM I

**KEYNOTE SPEECH**

**MODERATOR:**

- Sue SAVILLE (Health Event Facilitator)

**SPEAKER:**

- Richard I. LESSER (Global Chair, BCG)

10:00-10:50

AUDITORIUM I

**AI UNLEASHED: STRENGTHENING MEDTECH COMPETITIVENESS IN A NEW INDUSTRIAL AGE**



vamstar

Explore how AI accelerates MedTech innovation and revenue in Europe's complex healthcare. We'll share real-world strategies to tackle regulatory, sales, market access, and cybersecurity hurdles, while respecting healthcare's human core. Join us to unlock AI's power in the new industrial revolution.

**MODERATOR:**

- Richard CHARTER (Senior Advisor, VAMSTAR)

**SPEAKER:**

- Praful MEHTA (CEO, Vamstar)

10:00-10:50

AUDITORIUM II

## MEDTECH POLICY TRENDS: NAVIGATING A CHANGING GEOPOLITICAL LANDSCAPE

An insightful session exploring how the evolving geopolitical landscape – the 2024-2029 EU mandate, as well as looking West (the US) and East (Russia and China) – is shaping the future of the medtech sector. Dive into the opportunities and risks emerging in this dynamic environment and discover how our industry can adapt and thrive.

### MODERATOR:

- Christian CLARUS (Director Global Government Affairs, B. Braun Group)

### SPEAKERS:

- Benish ASLAM (Lead, Government Affairs and Policy, Asia Pacific Medical Technology Association (APACMed))
- Trevor GUNN (Vice-President International Relations, Medtronic)
- Mathew SHEARMAN (APCO)

ROOM A

## FUTURE OF BUSINESS INTERACTION: COMMERCIALIZING DIGITAL SOLUTIONS IN MEDTECH

**Deloitte.**

### SPEAKER:

- Georg SELLE (Deloitte)

ROOM B

## RESILIENT PROCUREMENT, STRONGER HEALTHCARE: THE PROCURE RESULTS

This session will present the final results of the ambitious EU ProCure project aiming to make current public procurement practices on medtech more resilient and efficient all over the EU, and to ensure that public health systems are ready for whatever crises the future brings.

### SPEAKERS:

- Raquel ARES (Manager, Science and Innovation Link Office (SILO))
- Hans BAX (Senior Advisor Value & Innovation-based Access, MedTech Europe)
- Bérénice CLEUET (European Projects Manager, Réseau des Acheteurs Hospitaliers (RESAH))
- Camille SERRES (European Projects Manager, Réseau des Acheteurs Hospitaliers (RESAH))

AUDITORIUM III

## ASK THE EXPERT: INTERACTIONS WITH HEALTHCARE PROFESSIONALS AND PROMOTION OF MEDICAL DEVICES ON SOCIAL MEDIA: AN EU ENFORCEMENT UPDATE

Hogan  
Lovells

11:00-11:50

AUDITORIUM I

## BOOSTING EUROPE'S ATTRACTIVENESS FOR MEDTECH INNOVATION

Empowering patients, inspiring innovation! Europe is attractive for its innovative research ecosystem, accessible healthcare system and growing efforts towards value-based healthcare. However, action is needed to retain its historic place as global 'epicenter' of medtech innovation. Let's discuss!

AUDITORIUM II

## TRANSFORMING HEALTHCARE BEYOND HOSPITAL WALLS

Outside-of-hospital and hybrid care models have proved their ability to improve patient outcomes, increase access, and reduce the burden on hospitals and healthcare systems. The session will address the healthcare providers' point of view and practical industry initiatives to scale up these models.

### SPEAKERS:

- Nadine JAMOUS (Director, EMEA Market Access, Health Economics & Reimbursement, Zimmer Biomet)
- Frederic NOEL (Vice President WE Enterprise Accounts & EurAsia Integrated Health Solutions, Medtronic)

ROOM A

## THE AI EDGE IN MEDTECH COMMERCIAL—INSIGHTS FROM BCG'S 4TH MILKMAN STUDY



### MODERATOR:

- Goetz GERECKE (Managing Director & Senior Partner, BCG)

### SPEAKERS:

- Thorsten HARZER (Head of Digital Solutions, Qiagen)
- Basir MUSTAGHNI, Managing Director & Partner, BCG)
- Can SCHNIGULA (Partner, BCG)

ROOM B

## PAVING THE WAY FOR THE EUROPEAN HEALTH DATA SPACE

We are at a critical juncture, transitioning from policy development to the active implementation of the European Health Data Space (EHDS). This session will bring together key stakeholders to address the challenges and opportunities presented by the EHDS implementation. Panellists will discuss strategies for achieving interoperability, ensuring data security, and fostering collaboration among all stakeholders while sharing best practices from ongoing initiatives in the Member States and at EU level. The discussion will explore how industry, governments, and healthcare providers can accelerate the adoption and fully realise the transformative potential of the EHDS.

### SPEAKER:

- Enrique MARTINS (Associate Professor in Health Management and Leadership - FCS-UBI and ISCTE-IUL (University of Lisbon))

11:00-11:50

AUDITORIUM III

## ASK THE EXPERT: STATUS OF DIGITAL HEALTH REIMBURSEMENT IN THE US AND EUROPEAN MARKETS



Join market access experts Meike Bomhof and Stephen Hull to explore digital health reimbursement in the USA, UK, France, Germany, and the Netherlands. Get updates on policies, coding, and payer evidence needs for AI, remote monitoring, and robotic tech across hospitals, data centers, and homes.

### SPEAKER:

- Stephen HULL (Senior Vice President, Avania Market Access)

11:50-12:20

## NETWORKING BREAK

12:20-13:10

AUDITORIUM I

## FROM EVALUATION TO ACTION: THE FUTURE OF MDR AND IVDR

As we approach the 8th birthday of the MDR and IVDR and take stock of their targeted evaluation, this timely discussion will examine the consensus between actors and stakeholders for short-term solutions, including implementing acts, and the long-term vision for sustainable regulatory improvements.

### MODERATOR:

- Bassil AKRA (Chief Executive Officer, AKRA TEAM GmbH)

### SPEAKERS:

- Kelvin OKUNDAYE (Accredited assistant to Dr. Peter Liese - Member of the European Parliament, Coordinator for the EPP Group in the Committee on the Environment, Public Health and Food Safety, Group of the European People's Party (Christian Democrats))
- Flora GIORGIO (Head of Unit, European Commission)
- Manoja RANAWAKE (Vice President Regulatory Affairs - EMEA, WWIPD & IP OUS, BD)

AUDITORIUM II

## CANCER PATIENT JOURNEY HOW MEDTECH FOSTERS BETTER AND SAFER CARE

Medical technologies directly affect patient life and are essential for health care professionals in working side by side for cancer prevention, early detection, diagnosis and efficient and safe patient care. In this panel, stakeholders discuss and suggest on how optimizing medtech solutions enables better patient care, accelerates precision oncology and ensures patient safety.

### MODERATOR:

- Maciej GAJEWSKI (Exact Sciences)

### SPEAKERS:

- Antonella CARDONE (CEO, Cancer Patients Europe)
- Dennis A. OSTWALD (CEO, WifOR Institute)
- Luca QUAGLIATA (Vice-President, Medical Affairs - Thermo Fisher Scientific)
- Paola THELLUNG DE COURTELARY (Policy and Scientific Manager, European Society of Pathology)



12:20-13:10

ROOM A

## FROM HYPE TO REALITY: UNLOCKING AI'S POTENTIAL IN MEDICAL DEVICES



AI offers immense potential for medical devices, from early disease detection to robotic surgery. Yet, clinical deployment remains challenging. This talk explores how best practices, risk-based approaches, and regulatory alignment can unlock AI's benefits while ensuring safety and reliability.

### SPEAKER:

- Gabriel KRUMMENACHER (Director Data Science, Zuehlke)

ROOM B

## NAVIGATING GLOBAL BUSINESS CHALLENGES IN MEDTECH OPERATIONS TO PROVIDE CONSISTENT PATIENT CARE



In today's landscape, healthcare organizations face unique challenges, such as evolving trade policies, supply chain disruptions, technology advancements and global market expansion. Industry leaders will discuss strategies and insights for designing MedTech operations that address these challenges and ensure seamless global patient care.

### MODERATOR:

- Jesus RUEDA RODRIGUEZ (Director General - Strategies, Special Projects & International Affairs - MedTech Europe)

### SPEAKERS:

- Christian CLARUS (Director Global Government Affairs - B. Braun Group)
- Daniele FAZIO (VP & GM, Medical Devices and Drug Delivery, Flex)
- Wilfred VAN ZUILEN (Zimmer Biomet)

AUDITORIUM III

## ASK THE EXPERT: AI-DRIVEN TRANSLATION IN MEDTECH: THE POWER OF QUALITY ESTIMATION AND HUMAN EXPERTISE



Discover how AI-driven translation technology is transforming the Medical Devices industry by ensuring compliance and efficiency. This session explores AI-powered machine translation, automatic quality estimation (AQE), and expert post-editing. Learn how glossaries, quality frameworks, and AI optimize workflows with real-world case studies.

### SPEAKER:

- María ILLESCAS (Director of Innovation and AI Solutions, SEPROTEC)

13:10-14:10

## NETWORKING LUNCH

14:10-15:00

AUDITORIUM I

## SAFE AI, SMARTER CARE: TRANSFORMING EUROPEAN HEALTHCARE SYSTEMS

The panel seeks to bring together stakeholders from across the healthcare ecosystem to discuss how the safe uptake of AI can revolutionise healthcare delivery in Europe.

The panel will gather experts from hospitals, healthcare professionals, industry and academia to provide for a multi-perspective discussion.

### SPEAKERS:

- Mariana MADUREIRA (Coordinator Medical Device Sector, INFARMED)
- Eric SUTHERLAND (OECD)
- Véronique TORDOFF (Image-Guided Therapy Leader Europe, Philips)

AUDITORIUM II

## EMPOWERING EUROPEAN INNOVATORS WITH EARLY FEASIBILITY STUDIES

HEU-EFS is an IHI project which aims at developing an EU harmonised framework to improve the uptake of Early Feasibility Studies (EFS) for medical devices in the European Union. EFS are a crucial part of the evidence-generation cycle for medical devices. Conducting these studies in a coordinated manner across Europe will bring significant benefits to patients, innovators, and the entire healthcare system.

### MODERATOR:

- Niklas BLOMBERG (Executive Director, Innovative Health Initiative (IHI))

### SPEAKERS:

- Alexandra POULSSON (Senior Advisor, Division for Health Services - Norwegian Institute of Public Health)
- Laura SAMPIETRO-COLOM (Innovation Deputy Director - Hospital Clinic Barcelona)
- Rosanna TARRICONE (Associate Dean at SDA Bocconi - Associate Professor at the Department of Social and Political Sciences)
- Fanny VAN DER LOO (Senior Director Government Affairs EMEA, Canada, Latin America - Edwards Lifesciences)
- Yasemin ZEISL (Project Coordinator - European Patient Forum)

ROOM A

## UK - EU: READY FOR A RESET?

A reset in the relationship between the UK and the EU is underway, with agreement that leaders will meet in an EU-UK Summit. What can realistically be expected from the reset and what it could imply for market access for medical technologies? This session will explore the current market access environment in the UK and what opportunities the reset of the bilateral relations could bring for the medtech industry.

### SPEAKER:

- Peter ELLINGWORTH (Chief Executive - ABHI)

14:10-15:00

ROOM B

## FROM DATA TO DIAGNOSIS: DIGITAL TOOLS TRANSFORMING DIAGNOSTICS

Join us to explore the transformative potential of digital solutions in the IVD sector for clinical evidence generation. These technologies enable efficient data collection, analysis, and validation, improving diagnostic accuracy and supporting personalized medicine. Let's discuss how MedTech Europe members can shape these trends.

### SPEAKER:

- Chaohui GUO (Head of Clinical Validation, Roche)

AUDITORIUM III

## ASK THE EXPERT: ARE YOU WINNING OR LOSING MARKET SHARE? THE VALUE OF PRECISE MARKET DATA

Ask the expert session on MTE's flagship publication and golden standard data trackers. The place to ask direct questions coming from all type of data users and stakeholders. Explore the value of precise, actionable market data in shaping business strategies. Learn how MedTech Europe's data services provide companies with the tool to uncover trends, benchmark performance, and identify growth opportunities.

### SPEAKERS:

- Teodora ANGELOVA (Senior Manager Market Data, MedTech Europe)
- Georgiy BOGDANOV (Manager Market Data, MedTech Europe)

15:10-16:00

AUDITORIUM I

## CLIMATE MEETS ECONOMICS: BRIDGING GREEN GOALS AND COMPETITIVE EDGE IN HEALTHCARE

Are decarbonisation and competitiveness friends or foe? Do the Draghi Report and EU Clean Industrial Deal deliver for MedTech? How to leverage the power of medtech for healthcare system transformation and competitiveness?

AUDITORIUM II

## HTAR IN MEDICAL DEVICES - BOOSTING OR STIFLING INNOVATION IN EUROPE

Boosting or stifling innovation in Europe? This session will provide timely insights on the status of implementation of the Health Technology Assessment Regulation (HTAR) four months after its date of application with a focus on its impact on the availability of innovation in Europe.

### MODERATOR:

- Andrea RAPPAGLIOSI (Senior Vice President Public Affairs EMECLA, Edwards Lifesciences)

### SPEAKERS:

- Burçak AYDIN (Senior Manager - HAG INSIGHT Consortium)
- Marco MARCHETTI (Vice Chair HTA Coordination Group / Direttore UOC HTA - Agenas)
- Leslie PIBOULEAU (Directorate-General for Health and Food Safety, European Commission)
- Piotr SZYMAŃSKI (Chairman of the Regulatory Affairs Committee at European Society of Cardiology, Consultant Cardiologist and Head of the Clinical Cardiology Department - CSK MSWiA)

15:10-16:00

ROOM A

## SHAPING THE FUTURE OF CLINICAL INVESTIGATIONS IN EUROPE

In light of the pilot coordinated assessment for clinical investigations of medical devices (MDR Art.78) which has been launched in early February by the Member States and the European Commission, this session will take stock of the process so far, clarify the possibilities offered to sponsors by this pilot and answer any remaining questions. The session will also look to the future at next steps.

### MODERATOR:

- Carine COCHEREAU (Integra)

### SPEAKERS:

- Benedicte NUYTENS (Head of Clinical Investigation Entity, Federal Agency for Medicines and Health Products)
- Nebojsa SERAFIMOVIC (Austrian Agency for Health and Food Safety (AGES))

ROOM B

## EU AND MDSAP - A DREAM OR A VIABLE OPPORTUNITY?

The Medical Device Single Audit Program (MDSAP) is arguably the landmark example of international regulatory cooperation. Learn why it is so timely for the EU to join it as a full member, accelerating European patients' access to medical technologies and fostering EU's competitiveness and innovation.

### MODERATOR:

- Olga VAN GROL-LAWLOR (Senior Global Regulatory Intelligence & Advocacy Manager, Boston Scientific)

### SPEAKERS:

- Oliver BOHLE (Consultant Regulatory Affairs, Spectaris)
- Tracey DUFFY (First Assistant Secretary, Australian Government, Department of Health and Aged Care)
- Flora GIORGIO (Head of Unit, European Commission)
- Graeme TUNBRIDGE (Senior Vice President Global Regulatory and Quality, Regulatory Services, BSI)

15:10-16:00

AUDITORIUM III

## ASK THE EXPERT: NAVIGATING U.S. ANTI-BRIBERY COMPLIANCE UNDER THE TRUMP ADMINISTRATION



This session focuses on how multinational companies can manage risk related to the U.S. Anti-Kickback Statute, False Claims Act, and Foreign Corrupt Practices Act in light of the changing priorities under the Trump Administration, and how understanding U.S. enforcement activity can help companies prepare for how similar trends may play out in Europe.

### SPEAKERS:

- Ali ISHAQ (Partner, ReedSmith)
- Rosanne KAY (Partner, ReedSmith)
- Jeff LAYNE (Partner, ReedSmith)

16:00-16:30

## NETWORKING BREAK

16:30-17:20

AUDITORIUM I

## NAVIGATING SUSTAINABLE CORPORATE GOVERNANCE: CHALLENGES AND OPPORTUNITIES

Join us for a session on implementing the CSRD and CSDDD in MedTech. Explore challenges, opportunities, and potential changes amid economic and global competition. Gain insights on staying ahead in sustainability while remaining competitive. Engage with experts on the future of sustainable corporate governance.

### MODERATOR:

- Céline FAEH (Director Government Affairs EMEA - Zimmer Biomet)

### SPEAKERS:

- Alexandre BARROS (Hydrumedical)
- Celia DOUSSINEAU (Siemens Healthineers)
- Greta KOCH (Parliamentary Assistant to MEP Axel Boss, European Parliament)

AUDITORIUM II

## LET'S TALK ABOUT WOMEN'S HEALTH

The session will gather thought leaders to discuss the needs and opportunities when it comes to women's health. What is the role of medical technologies in addressing woman's health? Hear about advanced diagnostics, personalized care, reproductive health, and closing gender gaps, with a focus on collaboration to drive impactful solutions.

16:30-17:20

ROOM A

## EU DAMED: THE CENTRAL APPROACH FOR GATHERING DATA ON MEDICAL DEVICES

The European Medical Device Database EUDAMED will become the mandatory IT system to use for the MDR and IVDR in only 6 months' time after this session. What changes and new considerations will this central approach bring to manufacturers and other users in data submission and data access?

### SPEAKER:

- Silvia OSTUNI (Legal and Policy Officer, DG SANTE, Medical Device Unit)

ROOM B

## TIME TO ACT: THE NEED FOR ACCELERATED VALUE PATHWAYS FOR BREAKTHROUGH INNOVATIONS



Edwards

This panel explores Europe's next steps to accelerate patient access to breakthrough innovations through early evidence, streamlined regulations, adaptive HTA, and innovative procurement using Real-World Evidence.

### MODERATOR:

- Andrea RAPPAGLIOSI (Senior Vice President Public Affairs EMECLA - Edwards Lifesciences)

### SPEAKERS:

- Laura SAMPIETRO-COLOM (Innovation Deputy Director - Hospital Clinic Barcelona)
- Piotr SZYMANSKI (Chairman of the Regulatory Affairs Committee at European Society of Cardiology - Consultant Cardiologist and Head of the Clinical Cardiology Department - CSK MSWiA)
- Rosanna TARRICONE (Associate Dean at SDA Bocconi - Associate Professor at the Department of Social and Political Sciences)

AUDITORIUM III

## ASK THE EXPERT: THE US REGULATORY LANDSCAPE - MAKING SENSE OF THE CURRENT CHAOS



Hogan Lovells

17:30-18:10

AUDITORIUM I

## KEYNOTE SPEECH

### SPEAKERS:

- Leonor BELEZA (President, Fundacao Champalimaud)
- Oliver BISAZZA (CEO, MedTech Europe)


18:10-19:40

## NETWORKING RECEPTION



# THE MEDTECH FORUM 2025 APP

The official MedTech Forum App will be available end of April and only for registered participants.



**Download the app to maximise your time and experience during the event!**

## CONNECT WITH THE COMMUNITY

Start a conversation using direct messages and use this opportunity to network with your peers. Meet them in the exhibition hall at the booth of your choice.

## EXHIBITORS DIRECTORY

Discover all the exhibitors and locate them on the map.

## CREATE YOUR PERSONALISED AGENDA

Add your sessions of interest to My Programme and receive notifications before they begin.

## INTERACT DURING SESSIONS

Interact and vote during the sessions with other on-site.

## SHARE YOUR FEEDBACK

Use the app to leave your comments about the sessions.



08:00-08:30

**WELCOME COFFEE**

08:30-09:20

AUDITORIUM I

**CEO #NOFILTER**

**MODERATOR:**

- Sue SAVILLE (Health Event Facilitator)

**SPEAKERS:**

- Annette BRÜLS (Corporate Vice-President, EMEACLA, Edwards Lifesciences)
- Roland GOETTE (Executive Vice President EMEA, BD)
- Urmi Prasad RICHARDSON (President EMEA, Thermo Fisher Scientific)
- Gavin WOOD (Company Group Chairman, Johnson & Johnson MedTech EMEA)

09:30-10:20

AUDITORIUM I

**WHY EUROPE MATTERS: EXPLORING MEDTECH INVESTMENT POTENTIAL**

How can Europe remain an attractive destination for MedTech investments? Hear from top investors as they explore the sector's potential and what it needs to thrive in a competitive global market.

**MODERATOR:**

- Stephen LEVIN (Editor in chief, MedTech Strategist)

**SPEAKERS:**

- Craig COOPER (Partner, Serpentine ventures)
- Janke DITTMER (General Partner, Gilde Healthcare)
- Giovanni MONTI (Founder, Option 5 Health Ltd)

AUDITORIUM II

**DRIVING SECURE HEALTH DATA ACCESS VIA THE IDERHA IHI PROJECT**

The IDERHA (<http://www.iderha.org/>) consortium will create a federated data space for secure health data access and develop policy recommendations for RWE acceptance in regulatory decision making. The panel will explore the importance and opportunities of health data access to enable innovative healthcare solutions.

**MODERATOR:**

- Hugh LAVERTY (Head of Scientific Operations, Innovative Health Initiative (IHI))

**SPEAKERS:**

- Flora GIORGIO (Head of Unit, European Commission)
- Philip GRIBBON (Fraunhofer ITMP)
- Christian MUEHLENDYCK (Scientific Partnerships Lead Europe, Middle East and Africa (EMEA) J&J MedTech, Johnson&Johnson MedTech EMEA, Germany)
- Gözde SUSUZLU (Senior Programme Manager, The European Patient Forum)



09:30-10:20

ROOM A

## PROTECTING PRIVACY IN THE AGE OF AI-POWERED HEALTHCARE

Delve into the critical role of privacy in the rapidly evolving landscape of AI-driven healthcare. This session will explore the intersection of cutting-edge digital health innovations and robust privacy frameworks, including the EU AI Act and GDPR. Learn how to implement ethical AI practices and privacy-preserving technologies to build trust and drive compliant innovation.

### MODERATOR:

- Peter BLENKINSOP (Partner Faegre Drinker)

### SPEAKERS:

- Noemi ALONSO CALVO (Exact Sciences)
- Chantal VETS (Sr. Legal Program Director, Digital Regulations - Medtronic)

ROOM B

## SECURE AND SEAMLESS: THE NEXT GENERATION OF TECHNICAL DOCUMENTATION

This panel will delve into modernising Technical Documentation through a harmonised, item-level approach, enabling secure, system-agnostic data exchange with standardised formats and nomenclature. The discussion will highlight the importance of supporting SMEs by removing financial barriers, while preserving flexibility for manufacturers, paving the way for sustainable and forward-thinking regulatory practices.

### MODERATOR:

- James SHEARN (Director Regulatory & Quality Compliance, STERIS)

### SPEAKER:

- Tanja KNAUER (Vice President, Regulatory Affairs & Standards and Digital Operations and Strategy, Siemens Healthineers)

AUDITORIUM III

## ASK THE EXPERT: INNOVATIVE PAYMENT SCHEMES – LESSONS LEARNED FROM PHARMA AND MEDICAL (DIGITAL) DEVICES

MedTech Europe's Reimbursement and Funding Working Group has carefully developed twenty 'Key Success factors' and relevant metrics to operationalise and allow the qualitative assessment of the suitability and effectiveness of IPS across Europe. During the session, the speakers will present the key findings.

### SPEAKERS:

- Hatim ABDULHUSSEIN (Chief Executive Officer - Health Innovation Kent Surrey Sussex, NHS)
- Oriana CIANI (Associate Professor of Practice, SDA Bocconi School of Management)
- Jorge Juan FERNÁNDEZ GARCÍA (Innovation Officer Hospital Clínic de Barcelona)

10:20-10:50

## NETWORKING BREAK

10:50-11:40

AUDITORIUM I

## RE-IMAGINING CYBER SECURE HEALTH

Multistakeholder panel discussion: representatives from hospitals, industry and regulators will debate cybersecurity in healthcare, aiming to share best practices and insights on how to re-imagine the health ecosystem to make sure it is cybersecure.

### MODERATOR:

- Miroslav PALAT (President, CzechMed)

### SPEAKERS:

- Manan HATHI (Senior Manager, Digital Health Regulatory Policy and Intelligence, Stryker)
- Saila RINNE (Head of Unit, eHealth, Well-Being and Ageing, Directorate-General Communications Networks, European Commission)
- Lino SANTOS (National Coordinator, Portuguese National Cybersecurity Centre (CNCS))

AUDITORIUM II

## NAVIGATING LITIGATION: SECURING MEDTECH'S FUTURE IN EUROPE

Explore Europe's evolving litigation landscape, from class actions under the Representative Actions Directive to the impact of Third Party Litigation Funding. Learn proactive strategies to navigate these challenges and ensure resilience in a rapidly changing legal environment.

### SPEAKERS:

- Carolyn BLAKE (U.S. Chamber of Commerce, Institute for Legal Reform)
- Brian KRUID (Senior Litigation Counsel, International - Stryker)
- Patrick REILLY (Partner Faegre Drinker Biddle & Reath LLP)
- Sofia VAZ SAMPAIO (Morais Leitão)

ROOM A

## GLOBAL MARKET FOCUS: BRAZIL

Brazil is projected a solid growth of medical technology market over the next five years. Its evolving healthcare market, particularly for innovative technologies presents a wealth of opportunities for medtech manufacturers. In this session, experts will explore the trends and policies driving the growth of the medtech market, discuss the challenges and opportunities and what it takes to succeed in Brazil.

### MODERATOR:

- Carlos GOUVEA (Executive President, Câmara Brasileira de Diagnóstico (CBDL))

### SPEAKERS:

- Kristin CIRIELLO POTHIER (Life Sciences Sector Leader, Global Deal Advisory and Strategy Leader, Healthcare and Life Sciences, KPMG LLP)
- Nataly TREJOS (Associate Director, LATAM Regulatory Policy Johnson&Johnson MedTech)

10:50-11:40

ROOM B

## ALIGNING PLM & QMS PROCESSES FOR MEDTECH EXCELLENCE

 Veeva MedTech

Unlocking product lifecycle excellence starts with aligning PLM and QMS. Learn how MedTech companies streamline operations, enhance product integrity, and accelerate time-to-market with a process-first approach balancing innovation, safety, and efficiency.

### SPEAKERS:

- Mandy BLOCHER (Head of PLM Digitalization & Regulatory Intelligence, B.Braun (Division Aesculap))
- Arielle FAKHRAEE (Director, MedTech Quality Strategy, Veeva Systems)

AUDITORIUM III

## ASK THE EXPERT: EVERYTHING YOU WANTED TO KNOW ABOUT IHI (BUT WERE AFRAID TO ASK)

IKOP, IKAA, Financial Contribution, 3A? If it does not ring a bell, join this session! IHI projects offer many benefits such as funding and networking, to name a few. People participating in the first projects will highlight why they have joined this public-private partnership on health innovation.

### SPEAKERS:

- Hugh LAVERTY (Head of Scientific Operations, Innovative Health Initiative (IHI))
- Peter ZANDBERGEN (Director Public-Private Partnerships, Innovation Partnerships Europe Innovation & Strategy, Philips)

11:50-12:40

AUDITORIUM I

## IMPLEMENTING THE EU GREEN DEAL IN HEALTHCARE

Tackling Challenges, Seizing Opportunities - How is the medical technology sector navigating the Green Deal maze? How to connect sustainability dots for better health and patient outcome? What's coming next?

AUDITORIUM II

## CLOSING THE LOOP: TURNING CUSTOMER INSIGHTS INTO PRODUCT EXCELLENCE

 smarleeva

Join us to explore the transformative potential of digital solutions and AI for enhanced product performance, customer experience, safety, and post-market surveillance. Discover impactful projects and discuss how the MedTech Industry can shape these trends.

### SPEAKERS:

- Michael SCHAETZLE (Head of Data Insights and Process Excellence Post-Market Quality, Roche Diagnostics)
- Raffel ZUBER (Data Scientist, Roche Diagnostics)

11:50-12:40

ROOM A

## ADVANCING THE ASSESSMENT OF DIGITAL HEALTH TO FOSTER INNOVATION

The focus of this session will be to shine a spotlight on EU-level initiatives currently supporting the development of inclusive and fit-for-purpose European assessment frameworks for digital health technologies. Understanding the interplay between different initiatives and their potential to be effectively applied in practice is expected to advance the assessment of digital health to foster timely access to innovation for European patients.

### MODERATOR:

- Katarzyna MARKIEWICZ-BARREAUX (AI Strategic Intelligence Lead, Philips)

### SPEAKERS:

- Rubén CASADO ARROYO (Healthcare Professional, Université Libre de Bruxelles-Erasme Hospital)
- Marco MARCHETTI, Vice Chair HTA Coordination Group / Direttore UOC HTA, Agenas
- Juan Carlos REJON PARRILLA (Researcher, Andalusian HTA Agency (AETSA))
- Emmanouil TSIASIOTIS (Academia representative, Graduate school of health economics and management (ALTEMS), Università Cattolica del Sacro Cuore)

ROOM B

## SHAPING THE FUTURE OF WOUND CARE

The session will examine the burden of wounds on the healthcare systems and policy trends impacting wound management. How better wound care policy can address inequalities in healthcare and drive sustainable healthcare.

AUDITORIUM III

## ASK THE EXPERT: HOW AI & PLM DRIVE SMARTER COMPLIANCE IN MEDTECH



Explore how AI and PLM technologies transform compliance from burden to asset. Learn to build smarter frameworks, enhance decision-making, and ensure comprehensive compliance throughout the product lifecycle with practical insights from Deloitte and PTC.

### SPEAKER:

- René ZOELFL (Senior Director, Global Advisor of MedTech PTC)

12:40-13:40

## NETWORKING LUNCH

13:40-14:30

AUDITORIUM I

## INNOVATING FOR PLANETARY AND HUMAN HEALTH: SUSTAINABILITY TRENDS AT GLOBAL LEVEL

Environmental challenges do not halt at national or regional level while supply chains in the medical technology sector are globally intertwined. As many governments are looking to advance sustainability in the healthcare sector, this session aims at providing a snapshot of common trends.

AUDITORIUM II

## CUTTING EDGE: THE FUTURE OF ROBOTIC SURGERY

The value of Robotic-assisted surgery (RAS) will be the centre of the discussions among experts and stakeholder organisations. Speakers will evaluate the unmet healthcare needs of European citizens and discuss strategic policy initiatives to address them.

### MODERATOR:

- Laura HAMPUNEN (Stryker)

### SPEAKERS:

- Dirk GHADAMGAHI (Head of Medical Affairs - Johnson&Johnson MedTech)
- James PORTER (Chief Medical Officer Robotic Surgery and Digital Technology, Medtronic)

ROOM A

## A NEW CARDIOVASCULAR HEALTH PLAN FOR EUROPE, A GAME CHANGER FOR PATIENTS

The session will be entitled "A new Cardiovascular Health Plan for Europe, a game changer for patients", and will bring together key representatives from the cardiovascular community, patient organizations, industry, and policymakers. The discussion will explore how to accelerate early detection, innovation, and equitable access to treatment, and how these elements can be integrated into the upcoming EU Cardiovascular Health Plan.

### MODERATOR:

- Alexander OLBRECHTS (Director Digital Health, MedTech Europe)

### SPEAKERS:

- Birgit BEGER (CEO, European Heart Network)
- Marta BRAGAGNOLO (EU Projects Manager / Patient & Stakeholder, Global Heart Hub)
- Frederic CLEMENT (Patient Care Solutions: International Chief Marketing & Strategy Officer, GE Healthcare)
- Aoife DELMAS (Chief Development Officer - European Society of Cardiology)

13:40-14:30

ROOM B

## FAST-TRACK HEALTH TECHNOLOGY ASSESSMENT FOR IN VITRO DIAGNOSTICS



The evolution of in vitro diagnostics (IVDs) underscores the need for an optimized health technology assessment (HTA) framework. A BMJ Innovations study used design thinking to engage stakeholders, proposing a fast-track HTA system to enhance IVD evaluation, adoption, and healthcare efficiency.

### MODERATOR:

- Fernando ALMEIDA (President, INRJ)

### SPEAKERS:

- André BISCAIA (President, USF AN)
- Carlos CATALÃO (Medical and Health Policy Director, Roche)
- Tamara MILAGRE (EVITA)
- Guilherme VITORINO (Vice-Director of NOVA IMS, UNIVERSIDADE NOVA)

AUDITORIUM III

## ASK THE EXPERT: UNLOCKING HEALTH DATA: THE EU DATA ACT'S IMPACT ON DIGITAL HEALTH



The EU Data Act aims to foster fair and secure data sharing across the EU. It will affect any connected medical device or health wearable that generates or collects data from its users and where those services are supported by the cloud, could implicate cloud portability requirements under the Act. In this presentation, we will explore the main features and implications of the Data Act for the digital health sector, as well as the key issues and challenges that need to be addressed, such as deadlines, obligations towards patients/users, compliance requirements.

### SPEAKERS:

- Friederike WILDE-DETMERING (Counsel, ReedSmith)
- Cynthia O'DONOGHUE (Partner, Reed Smith LLP)

14:40-15:30

AUDITORIUM I

## THE MDR/IVDR 5-YEAR RECERTIFICATION: URGENT QUESTION, STRATEGIC CHOICES

As MDR and IVDR certificates near expiry, a system-wide bottleneck looms. Can the current framework withstand the pressure, or are we heading toward gaps in patient access to life saving devices? This high-level panel explores the strategic and urgent questions behind the 5-year recertification cycle, at the heart of the EU's ongoing regulatory evaluation.

### MODERATOR:

- Amanda MAXWELL (European Regulatory Affairs Editor, Citeline)

### SPEAKERS:

- Bassil AKRA (Chief Executive Officer - AKRA TEAM GmbH)
- Frank MATZEK (Vice President, Biotronik)
- Alexey SHIRYAEV (President - Team-NB)

AUDITORIUM II

## ENGAGING WITH IMPACT: STORIES OF MEDTECH AND PATIENT COLLABORATION

This plenary session highlights powerful examples of how medtech companies are engaging with patients and patient associations to drive innovation and improve outcomes. Hear firsthand from company representatives and patient advocates as they share their stories, challenges, and the power of working together to shape a patient-centered future.

### SPEAKERS:

- Kalina BOZHKOVA (Director, European Alliance for Patient Access)
- Hugh LAVERTY (Head of Scientific Operations, Innovative Health Initiative (IHI))
- Sandra SA (Patient Experience and Partnership Lead, Roche)
- Roi SHTERNIN (Founder & Chief Patient Officer, Chronically)

ROOM A

## NAVIGATING INTEROPERABILITY IN THE EHDS: ROLES AND RESPONSIBILITIES FOR MANUFACTURERS

This session will focus on the evolving regulatory landscape under the EHDS, particularly the expanded definition of «EHR systems». The broad scope of this definition impacts a wide range of digital health products, including those not traditionally considered as EHR systems by care providers or manufacturers. Panelists will discuss the implications of these regulatory changes for manufacturers, the strategies required to ensure compliance, and the importance of collaboration with standard developing organisations such as Integrating the Healthcare Enterprise (IHE) to achieve interoperability.

### MODERATOR:

- Shweta BHARDWAJ (Director, Global R&D and Digital Policy, Johnson and Johnson, Johnson & Johnson)

### SPEAKERS:

- Alexander BERLER (Strategic Business Development Director at IHE Catalyst AISBL, HL7 Hellas)
- Sabine DÖRHÖFER (Business Owner Standardization - Roche Diagnostics International)
- Janos VINCZE (Vendor Co-Chair, IHE Europe)

14:40-15:30

ROOM B

## MEASURE YOUR READINESS WITH THE SELF-ASSESSMENT TOOL

This session will introduce a self-assessment measurement tool for medical technology suppliers to assess their internal readiness, co-developed by prof. Laing (Swansea University) and a MedTech Europe ad hoc working group.

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### MODERATOR:

- Klaus ANDERSEN (Managing Partner, Aquilo Consulting)

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### SPEAKERS:

- Stephanie FRIDD (Director Value Based Care, Philips)
- Dominique GILSOUL (Global Market Access Leader, Solventum)
- Hamish LAING (Director, Swansea University - Value-Based Health and Care Academy)

AUDITORIUM III

## ASK THE EXPERT: REMOVING THE GUESSWORK FROM IVD MARKET INTELLIGENCE

Ask the expert on the best in-class report and data collection for the IVD industry. Participants can discover the transformative value of precise, actionable market data in driving business success. Gain insights into how MedTech Europe's data services empower companies to uncover emerging trends, benchmark performance against peers, and identify untapped growth opportunities—all while shaping effective, forward-thinking strategies. Don't miss this opportunity to learn from the leaders in market data excellence!

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### SPEAKER:

- Teodora ANGELOVA (Senior Manager Market Data, MedTech Europe)

15:40-16:00

AUDITORIUM I

## CONCLUSIONS

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### SPEAKERS:

- Oliver BISAZZA (CEO, MedTech Europe)



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