



**14-16 MAY**  
2019  
—  
Paris  
**FRANCE**

## FINAL PROGRAMME

Last update 08/05/2019

All sessions are tentative and subject to change.

In cooperation with

snitem

Including



Global MedTech  
Compliance Conference

# WELCOME INTRODUCTION



**Serge Bernasconi**  
**Chief Executive Officer**  
**MedTech Europe**

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## Dear partners,

In 2019, the MedTech Forum will continue in the positive direction it took in 2018. MedTech Europe's annual Forum will start touring Europe. The 2019 edition will stop on 14-16 May in Paris at the Cité des Sciences et de l'Industrie.

The 2019 Forum will include one full day dedicated to start-ups and SMEs - the Start-up Day organised by the French MedTech Association SNITEM on 14 May and two days of conference bringing together the key topics of the MedTech Forum and the legal & compliance programme of the Global MedTech Compliance Conference on 15 and 16 May (the GMTCC, jointly organised by MedTech Europe & AdvaMed).

MedTech Europe focuses on continuously improving networking opportunities and offering top-level programme to our participants and partners to make this event a unique gathering of healthtech stakeholders in Europe.

See you in Paris and thank you for your ongoing support,

# TUESDAY 14 MAY



08:00-18:00

## SNITEM START-UP DAY

Organised by SNITEM (the French association for medical devices) and ranked as the benchmark of the French health startup ecosystem, the fifth edition of the Innovative Medical Device Startup Day will offer exchanges and debates around regulatory strategy, market access, key steps to create a startup and sources of project financing, etc. Key features of the event include:

- Start-up area: as in 2018, the startup jury will select a dozen start-ups showcased at the Espace Innovation, on the same level as the B to B meetings. These 12 companies in the spotlight will pitch their ideas throughout the Day until the jury prize and the public's "coup de coeur" prize are awarded:
- B to B area: a large space dedicated to B to B meetings where the 1000 attendees (start-ups, Medical Device manufacturers, institutions, investors, competitiveness clusters, lawyers, etc.) can discuss their projects together and initiate new collaborations.

The participation is free and the language of the event is French (simultaneous translation in English will be available). Separate registration is mandatory for that day. For more information, visit the start-up day website.

10:00-13:00

## MEDTECH EUROPE ETHICS & COMPLIANCE COMMITTEE (ECC) MEETING (MEMBERS ONLY)



13:00-14:00

## NETWORKING LUNCH

14:00-15:30

## 1ST GMTA GLOBAL COMPLIANCE NETWORK MEETING (MEMBERS ONLY)



15:30-16:00

## COFFEE BREAK

16:00-17:30

## 1ST GMTA GLOBAL COMPLIANCE NETWORK MEETING (CON'T) (MEMBERS ONLY)



18:00-21:00

## MEDTECH FORUM & GMTCC OPENING RECEPTION & COCKTAIL DINNER Sponsored by Medicen



09:00-09:30

## OPENING

Plenary

### SPEAKERS:

- Serge BERNASCONI - CEO, MedTech Europe
- Rob TEN HOEDT - Chairman, MedTech Europe, Executive Vice President and President, EMEA, Medtronic

### MODERATOR:

- Ingmar DE GOOIJER - Healthcare industry observer

09:30-10:30

## CEO #NOFILTER

Plenary

Global leaders from the field of medical devices, diagnostics and digital health will sit together and speak openly about the latest trends, challenges and opportunities they're facing. The audience will have the opportunity to ask direct questions that will be answered with #nofilter.

### SPEAKERS:

- Carlos PASCUAL - CEO, Werfen Group
- Mick FARRELL - CEO, ResMed

### MODERATOR:

- Ingmar DE GOOIJER - Healthcare industry observer

10:30-11:00

## COFFEE BREAK GMTCC



10:40-11:30

## LIFE WITH DIABETES AND DIGITAL HEALTH: ABOUT CONNECTIONS, DATA AND CONTROL

Digital Keynote

Digital health solutions and the sharing of health data promise to empower patients with information and to support them in managing their health. To address concerns about possible abuse of data, the GDPR gives citizens and patients effective control over their data. Yet, both promises, of empowerment and control, have not yet fully materialised. Individual data relevant for health remains locked in silos: the smartphone apps linked to connected medical and health devices, and the proprietary platforms and clouds where they are stored. As long as this fragmented digital ecosystem persists, it will remain difficult for patients, health professionals and researchers to aggregate it, combine it with other sources, and derive meaning. Claus, a technophile and fan of connected devices, will report from the reality of living with diabetes juggling multiple devices, and from his project to develop a truly patient-centred data platform where control of data is given back to where it belongs: the individual.

### SPEAKER:

- Claus NIELSEN - Co-founder, Data for Good Foundation

### MODERATOR:

- Leo LEWIS - Senior Fellow and Head of Research and Development, Integrated Care Foundation

10:40-11:30

## MAKE IT YOUR TRADE DEAL

Business developments

In the last few years the EU has been quietly but effectively negotiating a network of bilateral trade agreements around the world. As more of these trade agreements are being ratified and become a reality they create opportunities for MedTech around the globe - from Canada (CETA) to Japan, Mercosur and China - see how companies small and large can benefit from trade agreements to access markets, protect their overseas investments and their intellectual property. Trade agreements are a powerful but underutilized mechanism which can help build global partnerships can be a decisive factor from companies, especially SMEs to grow and shape their business.

### SPEAKERS:

- Christian CLARUS - Director Government Affairs, Bbraun
- Geraldine EMBERGER - Consistency Officer for FTA Implementation, DG Trade, Trade Strategy and Market Access
- Jerome SICAIRE, DG Trade, Market Access, Industry, Energy and Raw Materials

### MODERATOR:

- Trevor GUNN - Vice-President International Relations, Medtronic

## WILL THE FUTURE EU HTA COOPERATION RESPOND TO COUNTRIES' NEEDS AND IMPACT ACCESS TO MEDICAL TECHNOLOGIES?

Access

HTA and HTA cooperation in Europe is at a crossroads: the current cooperation based on projects is coming to an end and a new EU Regulation on HTA is in the making. This session will look at whether HTA cooperation is turning into reality and if it addresses common countries' needs and how it impacts access to medical technologies. The European Commission's proposal for a Regulation aims to introduce EU Joint Clinical Assessments (JCA) for selected medical technologies with a mandatory uptake by Member States - the remaining part of the HTA (such as cost and economic evaluation) to be done at national level. It also foresees the possibility for voluntary cooperation on clinical assessment of any medical technologies and non-clinical assessments on any technology. The European Parliament has already expressed its position, suggesting i.e. to add the possibility for Member States to carry out additional assessments on the added clinical value. Member States are now expressing their expectations and views and are negotiating a common text.

In that context, some Member States have already expressed their vision and doubts, in particular on the mandatory use of the EU reports, on the inclusion of medical technologies in the scope or when this inclusion should start bearing in mind that the MDR/IVDR are not yet fully implemented.

### SPEAKERS:

- Hannah BRUEHL - Projektgruppe Nutzenbewertung von Gesundheitstechnologien, German Ministry of Health
- Adrian GRIFFIN - VP, HTA and Market Access Policy, Johnson & Johnson
- Mirella MARLOW - Programme Director, Centre for Health Technology Evaluation, National Institute for Health and Care Excellence (NICE)

### MODERATOR:

- Jessica IMBERT - Manager Market Access and Economic Policies, MedTech Europe

11:00-11:15

## KEYNOTE: VIEW FROM THE REGULATORS



This keynote will be discussing the regulators views on the following aspects: what is working and what doesn't with the current anti-bribery & corruption efforts; how can industry help and what are the key points for the industry to be aware of. In addition, considering that the industry is composed of more than 80% of SMEs, are there specific considerations for these companies?

### SPEAKER:

- Patrick MOULETTE - Head of the OECD Anti-Corruption Division

### MODERATOR:

- Ingmar DE GOOIJER - Healthcare industry observer

11:15-11:35

## PLENARY SESSION



The two chairwomen will discuss the AdvaMed and MedTech Europe compliance priorities as well as how these relate to the topics tackled in the MedTech Forum.

### SPEAKERS:

- Anne-Sophie BRICCA - Deputy General Counsel / Chairwoman of the MTE Ethics & Compliance Committee, Terumo BCT
- Dorothy CLARKE - Vice president Healthcare Compliance and chairwoman of the AdvaMed DDCG, Johnson & Johnson

### MODERATOR:

- Ingmar DE GOOIJER - Healthcare industry observer

11:30-12:00

## MEDTECH FORUM COFFEE BREAK AND NETWORKING

11:35-12:50

## TRANSPARENCY: WHAT'S NEXT FOR INDUSTRY?



With the spreading transparency laws around the world, is there a need to start discussing global transparency? How can the debate move from Sunshine laws to publishing with a purpose? To help to debate this topic, it is also interesting to learn from the pharmaceutical industry what they would do better in insight; how did the public react to their disclosure; what were the main questions, and whether there are discussions to also tackle transparency at international level. The practical and operational challenges of national and international rules should also be discussed in this debate.

### SPEAKERS:

- Julie BONHOMME - Legal affairs and Compliance Director, EFPIA
- Pascal SCHMIDT - Compliance Office EMEA/LATAM & RDI, Roche Diagnostics International
- Loretta VAN DER BIE - Global Transparency Officer, Edwards Lifesciences
- Marcin RODZINKA - Project Coordinator, Mental Health Europe

### MODERATOR:

- Ingmar DE GOOIJER - Healthcare industry observer

12:00-12:50

## NOTIFIED BODIES: A KEY PILLAR OF THE NEW EU REGULATORY SYSTEM [Access](#)

In May 2017, the new EU medical technology Regulations for medical devices and for in vitro diagnostics entered into force. Industry welcomes the Regulations' objectives: a modernised framework, transparency and in particular a strengthened Notified Body system. However, as fewer and fewer Notified Bodies have to manage more and more extensive work, under extreme time pressure, manufacturers' ability to keep products on the market beyond the 26 May 2020 and 26 May 2022 deadlines could be seriously jeopardized.

This session "Notified Bodies: A key pillar of the new EU regulatory system" provides insight into the key challenges Notified Bodies and industry are experiencing as the 26 May 2020 / 2022 deadlines of the new Regulations approach. The multi-stakeholder panel will explore solutions which might be put in place to address these challenges.

### SPEAKERS:

- Lionel DREUX - President, GMED
- Robyn MEURANT - Executive Director, Regulatory Services, IVDs and Medical Devices, NSF Health Sciences, a division of NSF International
- Peter ELLINGWORTH - Chief Executive, ABHI
- Salvatore D'ACUNTO - Head of Unit, DG for Internal Market, Industry, Entrepreneurship and SMEs, Health Technology and Cosmetics, European Commission

### MODERATOR:

- Fabien ROY - Partner, Hogan Lovells

## REAL-WORLD APPLICATIONS IN PATIENT CARE AND MEDTECH DECISION MAKING

[Business developments](#)

### Sponsored by IQVIA



HCP Engagement Best Practices in the age of increasing globalization, regulation and data privacy.

Across the globe, regulations regarding HCP engagement are growing in number and in complexity. Life sciences companies are challenged not only by staying up to date, but by making the process more efficient. Leading companies are leveraging technology to streamline processes, reduce costs, increase efficiencies across the organization, and to garner new insights from data to help them make better decisions.

IQVIA Commercial Compliance's Ben Carmel and Chris van Bronckhorst will explore current challenges, emerging trends and best practices that life sciences companies are employing to stay ahead of the compliance game.

### SPEAKERS:

- Yan BEYNON, President & Global Head of Digital Services, Siemens Healthcare AG
- Youssa TOURKI - Algorithms Manager, DIABELOOP
- Celestina BIANCO - Director of Quality and Regulatory Affairs, Clinical Software, The Werfen Group
- Remke BURIE - Managing Director, Technical Medical Centre, University of Twente

### MODERATOR:

- Ben HUGHES, SVP RW Tech Platforms, IQVIA

12:00-12:50

## THE DIGITAL TRANSFORMATION OF HEALTHCARE: MANAGING THE CHANGE

Digital

### Sponsored by Gensearch



The digitalization of the healthcare sector comes with immense opportunities. Access to information empowers citizens and patients. Healthcare professionals benefit from timely information and decision support systems. Medical knowledge and public health improve with advanced data analytics and artificial intelligence.

But digitalization will disrupt the way healthcare is delivered. All stakeholders are acquiring new roles and responsibilities. Buyers come with new expectations from the industry, while the market is seeing new entrants (app developers, consumer device makers). This disruption needs to be managed. Change managers will be reflecting on the challenges and opportunities.

### SPEAKERS:

- Sebastien STOITZNER - CEO, Gensearch
- Andre HEINZ - Head of global Human Resources, Siemens Healthineers

### MODERATOR:

- Joan CORNET PRAT - Digital Health Transformation, Barcelona Hub

12:50-13:40

## THE HEALTHTECH TRANSLATION ADVISORY BOARD

Business developments

Meet the HealthTechTAB ([www.healthtechtabs.eu](http://www.healthtechtabs.eu)), the first European translational accelerator to provide free close access to HealthTech industry experts to accelerate HealthTech development and provide the HealthTach community, both from industry and academia, with the right tools to bring their innovations to patients. Join the TAB experts and fellow HealthTech innovators for lunch in this "Ask the experts" session designed to create the opportunity for you to interact with industry experts who have successfully brought innovations from bench to bedside and share your struggles and questions about the next step towards translation.

### SPEAKER:

- Rui SOUSA - Program Manager, HealthTech TAB

12:50-14:15

## LUNCH BREAK AND NETWORKING



13:20-14:10

## MONETIZING INNOVATION IN MEDTECH - CAPTURING THE FULL OFFER VALUE IN A NEW ERA

Sponsored session



### Sponsored by Simon Kucher

Product innovation has long been the engine for profitable growth in the medical technology industry. However, with constrained healthcare budgets, HTAs and procurement professionalization, capturing reasonable returns on R&D and L&A investments is becoming an increasing challenge. Successful medical technology companies make market access a top strategic priority in guiding portfolio, clinical development and launch decisions. They furthermore explore new business models in the context of better addressing customers' clinical and budgetary challenges as well as monetizing the value of customer services and digital solutions.

Join Simon-Kucher & Partners where our experts along with an external industry speaker will present insights and practical food for thought on:

- Why finding new ways to monetize innovation is key for the industry
- How to successfully manage market access for product innovations
- How to optimally monetize digital opportunities
- How to best capture the value of customer services
- How to develop and deploy winning customer solutions

### SPEAKERS:

- Joerg KRUETTEN - Global Head of Healthcare and Life Sciences, Board Member, Simon-Kucher
- Maria RUIZ-ESCRIBANO - Boston Scientific

## BLUEPRINTING AGILE TRANSFORMATIONS - VALUE AT STAKE AND PRACTICAL APPLICATIONS OF ENTERPRISE AGILITY IN MEDTECH

Sponsored session

McKinsey&Company

### Sponsored by McKinsey

Historically, big beat small. Now, fast and adaptive beats slow and steadfast. New technologies, evolving customer preferences and changing employee expectations are fundamentally challenging established ways of working in more and more sectors. Agile organizations combine the efficiencies of scale with the speed, flexibility and resilience to compete and win in today's world.

During this session, Shail will talk through the cutting-edge use cases of Enterprise Agility in Healthcare and Medical Devices, and what successful companies do to take their organizations beyond the pilot.

### SPEAKER:

- Shail THAKER – Senior Partner, McKinsey

13:20-14:10

## ENGAGEMENT BEST PRACTICES IN THE AGE OF INCREASING GLOBALIZATION, REGULATION AND DATA PRIVACY

Sponsored session

Sponsored by IQVIA



Across the globe, regulations regarding HCP engagement are growing in number and in complexity. Life sciences companies are challenged not only by staying up to date, but by making the process more efficient. Leading companies are leveraging technology to streamline processes, reduce costs, increase efficiencies across the organization, and to garner new insights from data to help them make better decisions.

IQVIA Commercial Compliance's Chris van Bronckhorst will lead a panel of industry professionals who will explore current challenges, emerging trends and best practices that life sciences companies are employing to stay ahead of the compliance game.

### SPEAKERS:

- Ben CARMEL - Global Head of Business Development, IQVIA
- Chris VAN BRONCKHORST - Head of Go-To-Market Europe & Asia, IQVIA

14:15-15:30

## WORKSHOP: IN VIVO ANALYSIS OF THE MEDTECH EUROPE CODE



**Important notice:** Registration to the workshop is mandatory and is only possible if both business and compliance representatives register at the same time. Registration is only open to participants duly registered to the GMTCC / MTF 2019. Thus registration will be confirmed by GMTCC Secretariat. A first-come, first-served basis policy will apply.

**Description:** This workshop is open to a maximum of 12 companies. Each company will have two representatives: one EMEA/European business leader and one EMEA/European compliance officer. The group will discuss how this ambitious project has been working out, what areas need improvements or adjustments and the practical challenges encountered over the last years (e.g. speaker support, medical societies, company organized events, travel agencies, Poster presenter, CVS assessment of international events, national implementation) with regards to the MedTech Europe Code. The workshop will be moderated by chair persons of the Ethics & compliance Committee (ECC) and Code Committee to make sure that key take aways are integrated in the future work on the Code.

### MODERATORS:

- Anne-Sophie BRICCA - Deputy General Counsel / Chairwoman of the MTE Ethics & Compliance Committee, Terumo BCT
- Roeland VAN AELST - VP Healthcare Compliance EMEA & Canada / Chairman of the MTE Code Committee, Johnson & Johnson

14:15-15:30

## DISTRIBUTORS SESSION

### Sponsored by The Red Flag Group



This session aims at addressing aspects such as:

- How do companies manage distributors and agents with practical implementation of the new regional codes, as well as policing of these same codes?
- Best practices in third party screening as well as engagement of new business partners Sub-distributors/agents - what level of due diligence is being applied by companies.

#### SPEAKERS:

- Vasso Mangou KRITICOS - Sales Manager, Mega Lab AR
- Christian WAGNER - Group Leader Compliance, Improvement, Corporate Governance EMEA, Olympus Europa
- Bruno BOLDRIN - Executive Director, ABRAIDI
- Casper VENBJERG HANSEN - Head of Business Ethics & Compliance Project, Compliance Officer Emerging Markets & Global Operations, Coloplast

#### MODERATOR:

- Scott LANE - Chief Executive Officer & Chairman, The Red Flag Group

## THE DIGITAL TRANSFORMATION & COMPLIANCE: ROUNDTABLE DISCUSSION WITH CHIEF PRIVACY OFFICERS



This session aims at discussing issues arising from the new digital age and the changing business models, such as:

- What are the new risks coming for the new digital age;
- Should the compliance office become digital?
- How to ensure data stewardship, in order to deliver new products? What type of governance set up should companies think about?
- What are the privacy/data protection/GDPR considerations to keep in mind?
- Is there a role for compliance when we talk about Artificial Intelligence?
- How could open data and new technologies help to fight corruption and anti-bribery?

#### SPEAKERS:

- Jamie O'DONNELL - EU Vice President and General Counsel, ResMed
- Peggy L. BODIN - Senior Legal Counsel and Global Privacy Offer, Zimmer Biomet
- David FRAZEE - Technical Director, Corporate Research Systems Lab, 3M
- Gunda SCHUMANN - Senior Legal Counsel, European Legal Department, Haemonetics S.A.

#### MODERATOR:

- Mary Devlin CAPIZZI - Partner, Drinker Biddle & Reath LLP

14:20-15:20

## VALUE: DRIVER OF CHANGE IN HEALTHCARE

Plenary

Over the past years, Value Based Health Care has been proposed as the way forward to reform health care systems. This new concept comes with opportunities but also brings challenges regarding its implementation. In this session, key healthcare stakeholders will provide their perspectives on the reality of implementing Value driven health systems in Europe. Hear from international organisations such as OECD, National Authorities, health system representatives, providers and the industry. The session will dive into the concept of value, initiatives from International organizations in the field of reforming healthcare with a focus on patient relevant outcomes (PaRIS), considerations by health systems under reform pressure and providers seeking for investment. MedTech Europe will share its view on how it can effectively contribute to the opportunities that a value driven healthcare environment can bring to all stakeholders.

### SPEAKERS:

- Andrzej RYS - Health Systems and Medical products and Innovation Director, DG Sante, European Commission
- Alba VERGES I BOSCH - Minister of Health, Ministry of Health, Catalunya
- Michael VAN DEN BERG - Policy Analyst, Health Division, Directorate for Employment, Labour and Social Affairs, OECD

### MODERATOR:

- Ingmar DE GOOIJER - Healthcare industry observer

15:30-16:00

## COFFEE BREAK GMTCC



15:30-16:20

## MEDTECH AND VALUE: WILL VALUE-BASED PROCUREMENT BECOME A REALITY?

Value

Value is almost an omni-present term when people speak of healthcare transformation, but "what does it mean and how is it applicable to MedTech Europe and our partners" are questions we will address in this session. We will start by setting the context with an overview of how MedTech Europe is anchoring value in its access model, aiming to translate value-driven decision-making into daily practice. We will give special emphasis to the evolution of value-based procurement, highlighting progress as well as challenges, in our journey since launching the MEAT Value-Based Procurement framework in 2015. Results and learnings from a recent survey on value-based procurement will be shared for the first time, including perspectives from both industry and procurers. The session will conclude with highlights from the procurer's mindset, including views on incorporating value-based decision-making into the reality of day-to-day tendering.

### SPEAKERS:

- Yves VERBOVEN - Director Access & Economic Policies, MedTech Europe
- Goetz GERECKE - Senior Partner, Boston Consulting Group
- Hans BAX - Sr. Advisor, MEAT Value-Based Procurement

15:30-16:20

## GENOMIC TESTING AND PERSONALISED MEDICINE

Business developments

### Supported by SIDIV



Personalised medicine has become a key subject in the vision of many on the future of health-care. But what is it that we are talking exactly? What kind of an answer is personalized medicine to the current challenges of providing better and safer affordable healthcare? IVDs are a major key to the development of personalized medicine as is the monitoring and communication capacities of and increasing number of devices. Companion diagnostics is a very interesting entrance into personalized medicine and what about Genomic testing? During the discussion a few expert will attempt to respond to such important questions.

#### SPEAKERS:

- Antoine DISSERT - Genomic Health
- Marie DEHEM - Agendia
- Olivier PERCHE - Roche

#### MODERATOR:

- Patrick KORMAN - Myriad

## MDR - IS THE SYSTEM READY FOR BUSINESS?

Access

Only 12 months remain before the Medical Devices Regulation enters into application. How should you be spending the last remaining 12 months left of the transition period in order to best position your business? What can you do, and how can you manage business uncertainties as the regulatory system is still being built? Hear the perspectives of this multi-stakeholder panel, consisting of representatives from the national competent authorities, the European Commission, hospitals and industry

#### SPEAKERS:

- Helena DZOJIC - Head of department Medical devices & Chair of the Competent Authorities for Medical Devices (CAMD) Executive Group, Swedish Medical Products Agency
- Pascal GAREL - Chief Executive, HOPE
- Salvatore D'ACUNTO - Head of Unit, DG for Internal Market, Industry, Entrepreneurship and SMEs, Health Technology and Cosmetics, European Commission
- Joachim WILKE - Director Regulatory Intelligence EMEA / Chair of the Medical Devices Regulatory Affairs Committee, Medtronic /MedTech Europe

#### MODERATOR:

- Ashley YEO - Healthcare editor, Informa - In Vivo/MT

15:30-16:30

## MEET THE PARIS REGION HEALTHTECH COMMUNITY

Sponsored session

### Sponsored by MEDICEN



This session will allow you to get a 360° overview of the key trends and figures in the Paris Region in the field of healthtech. Learn more about the latest initiatives that can act as true business and collaboration opportunities with our innovative stakeholders.

You will also get the chance to hear several pitches from innovative medtech start-ups seeking international exposure and outreach.

This session is coordinated by Medicen Paris Region, a leading European health cluster federating 400+ members from research to industry and dedicated to accelerate innovation.

Contents :

- Presentation of the healthtech ecosystem in the Paris Region
- Presentation of key initiatives accelerating health innovation
- Pitch session : short presentations of some of the most active and innovative start-ups & SMEs in our ecosystem
- Networking

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### MODERATOR:

- Medicen Paris Region

# WEDNESDAY 15 MAY

16:00-18:15

## ASK THE EXPERTS SESSION



This session will be set up in roundtable discussions. The time allocated will allow them to get to the heart of key issues. Attendance is limited to 12 persons per table. After 40 minutes, the participants are invited to switch tables. Each table lead will prepare in advance a one-pager with key topics/trends that they plan to address. After the discussions, key discussion points/outcome will be added to this one-pager and circulated to all participants.

- Best practices in investigations - Rosanne KAY, Partner, Reedsmit
- Data Protection & GDPR: one year on - Peter BLENKINSOP, Partner, Drinker Biddle & Reath LLP
- MTE Code - Pablo ROJAS ABAD, Manager Legal & Compliance, MedTech Europe
- Conference Vetting System - Christine SAINVIL, Compliance officer, Ethical MedTech - Marcella PAVONE, Compliance Assistant, Ethical MedTech
- Transparency in the Middle East - Ghadeer AL YACOUB, Regional Healthcare Compliance Officer, Turkey, Middle East & Africa, Johnson & Johnson - Arwa ASIRI, Compliance Officer, Mecomed
- Applying the MTE Code in France - Benedicte GARBIL, General Manager France, Edwards Lifesciences
- Advamed new code & key take aways for the future - Nancy TRAVIS – Vice President, International Compliance Governance, AdvMed
- Placement of equipment - Adem KOYUNCU, Partner, Covington & Burling LLP
- European class action/collective redress - Ekkart KASKE, Executive Director; European Justice Forum
- The future of independent medical education - David B. VODUŠEK, Professor Emeritus, Faculty of Medicine, University of Ljubljana, Slovenia, Chair of the CME Experts Committee, BioMed Alliance - Michel BALLIEU, Executive Director, BioMed Alliance
- Qualies: A Compliance System Maturity Evaluation Program developed in Brazil - Carlos GOUVEA, Executive Director, Instituto Ética Saúde and CBDL - IVD Brazilian Chamber
- Distributors - Scott LANE, Chief Executive Officer and Chairman, The Red Flag Group
- COCIR Code of Conduct - Magali LEROUX, Legal Counsel, COCIR
- Challenges to medtech companies in 'New Era' China - Kent KEDL, Senior Partner, Greater China and North Asia, Control Risks

### MODERATOR:

- Matthew COUILLARD - Director, TDI Compliance

16:10-16:40

## MEDTECH FORUM COFFEE BREAK AND NETWORKING

16:40-17:30

## VIRTUAL HOSPITALS: THE NEW REALITY?

Business developments keynote

Several trends in the healthcare industry are driving virtual hospitals: hospital consolidation, advances in remote-monitoring technology, and new payment structures. In this session you'll hear from an seasoned hospital CEO and university professor what the current status is and what to expect in the future.

### SPEAKER:

- Mark VAN HOUDENHOVEN - Chair of the Board of Directors (CEO), Sint Maartenskliniek

### MODERATOR:

- Ingmar DE GOOIJER - Healthcare industry observer

## NEW BUSINESS MODELS FOR DIGITAL HEALTH: A LOOK AT VALUE

Digital



### Sponsored by ZS

In today's landscape, market access for digital technologies is often hampered by the lack of adequate financing methods. The most common reimbursement models in Europe usually finance health providers delivering services and procedures. But the emergence of digital technologies that improve outcomes, ease of access and quality of life outside the normal healthcare setting pose a challenge to these reimbursement models. Innovative Medtech companies continue to develop and bring new digital health technologies to market, by partnering in new ways with payers or by finding new revenue streams. This session will offer reflections and case studies of successful business models for digital health, in Europe and beyond.

### SPEAKERS:

- Matt SCHEITLIN - Partner, ZS
- Lucile BLAISE - Vice president, Western Europe, ResMed
- Agnes SIMON - Sr Business EMEA, Medtronic Patient Monitoring & Diagnostics, Medtronic

### MODERATOR:

- Nick GULDEMOND - Associate Professor Integrated Care and Technology, Erasmus School of Health Policy & Management Erasmus University

## VALUE DRIVEN FINANCING OF INNOVATION - A NEW ERA OF DIALOGUE BETWEEN PAYERS AND INDUSTRY?

Value

While health systems are looking for new opportunities to transform and are considering value driven approaches, the following key challenges have been identified:

- Few health systems reward value
- Siloed budget approach does not optimize value throughout the patient pathways and
- Payment decision based on value is a new concept.

While there are multiple schemes there is a clear need for a good taxonomy, good practice principle and learnings. Some latest developments within Europe and other jurisdictions will be discussed.

### SPEAKERS:

- Dafne SCHROER - Health Economics Evidence Generation Manager EMEA, Johnson & Johnson
- Ernesto M. NOGUEIRA - Managing Director, ValueConnected

### MODERATOR:

- Yves VERBOVEN - Director Market Access and Economic Policies, MedTech Europe



# WEDNESDAY 15 MAY

16:40-17:30

## REGULATORY COMPLIANCE, ENFORCEMENT AND LITIGATION

Sponsored by COVINGTON



COVINGTON

This session aims at discussing the interconnection of applicable legal and regulatory requirements for MedTech companies from an international perspective. The discussion will address U.S. legal requirements, including FDA regulation and fraud/abuse issues, and comparable EU issues, such as compliance with IVDR/MDR and anti-bribery issues. The session will discuss the interrelationship these legal and regulatory requirements and enforcement trends.

17:40-18:30

## GLOBAL TRENDS AND REGULATORY CHANGES IMPACTING MEDTECH SECTOR IN US AND ASIA

Plenary

Sharing perspective on key trends shaping Medtech development in key growth regions US and Asia (ie. China). This will include changes and evolution in customer, technology, patient care and regulatory requirements in these markets and how Medtech companies are coping and innovating in response.

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### SPEAKER:

- Ivy TEH - Global Managing Director, EIU Healthcare

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### MODERATOR:

- Ingmar DE GOOIJER - Healthcare industry observer

18:30-20:00

## NETWORKING COCKTAIL

09:00-10:00

## CEO #NOFILTER

Plenary

Global leaders from the field of medical devices, diagnostics and digital health will sit together and speak openly about the latest trends, challenges and opportunities they're facing. The audience will have the opportunity to ask direct questions that will be answered with #nofilter.

### SPEAKERS:

- Claude DARTIGUELONGUE - President, Microbiology, Thermo Fisher Scientific
- Eric THEPAUT - Senior Vice President and President, EMEA, Boston Scientific
- Sophie DUTILLOY - EMEA President, Alcon

### MODERATOR:

- Ingmar DE GOOIJER - Healthcare industry observer

10:05-11:10

## MEDTECH AS SOLUTION PROVIDERS: COMPLIANCE CHALLENGES



The industry has been discussing the concept of value in healthcare systems as well as what it means in terms of new commercial models for a few years, but the legal and compliance challenges that these bring along are numerous and vary depending on which part of the world you are looking at. This session aims at discussing the significant organisations, legal and compliance challenges in the transition from a product-driven industry to one focused on services. To help that discussion, the panel will be looking at some hypotheticals.

### KEYNOTE SPEAKER:

- Patrizio ARMENI, Associate Professor of Practice of GHNP division, SDA Bocconi School of Management

### SPEAKERS:

- Anthony MCQUILLAN - Vice President Legal & Compliance EMEA, Medtronic
- Regina PULS - VP/Head of Rules and Procedures, Siemens Medical Solutions
- Donna HLIL - Vice President & General Counsel North America, Draeger

### MODERATOR:

- Ingmar DE GOOIJER - Healthcare industry observer

10:10-11:00

## IVDR: HUNGRY FOR DATA

Access

As we enter 'year 3' of the IVD Regulation's transition period, most manufacturers will have assessed the safety and performance data they have for their products. The next major step is to plan and launch studies that might be needed to fill any remaining evidence gaps. How are the studies going, how will they affect the industry? How can we leverage big data? Is industry using third parties to gather data or conducting studies in-house? Attend this session to learn more about the different business models out there, so that you can benchmark your own investment decisions.

### SPEAKERS:

- Peter ROSE - Managing Director, Europe, Maetrics
- David EGBOSIMBA - Solutions Delivery Manager, Maetrics

### MODERATOR:

- Volker FRANZEN - Director Regulatory Affairs, QIAGEN & Co-Chair, MedTech Europe Clinical Evidence Working Group (IVD)

10:10-11:00

## CREATING A 3D PRINTING ECOSYSTEM TO TRANSFORM HEALTH FOR HUMANITY

Business developments



### Sponsored by Johnson & Johnson

3D printing technology has the potential to radically change patient care, enabling customized solutions delivered at or near the hospital. The development of an entirely new business model at point of care incorporating personalized solutions and services provides real-time, on-demand connectivity at key patient touch points. Leaders from Johnson & Johnson, Wrightington Hospital and 3D Systems will discuss how an ecosystem of 3D surgical modeling and on-demand solutions may improve outcomes, enable personalized care and shorten surgical time.

#### SPEAKERS:

- Gautam GUPTA - Vice President of Business Development, Healthcare division of 3D Systems
- Sam ONUKURI - Head & Senior Fellow, 3D Printing Center of Excellence, Johnson & Johnson
- Henry JONES - Consultant Orthopaedic and Trauma Surgeon, NHS

#### MODERATOR:

- Furio GRAMATICA - Director, Development & Innovation, Fondazione Don Gnocchi

## ADVANCING DIGITAL HEALTH IN EUROPE'S REGIONS: VISION, LEADERSHIP, INVESTMENT

Digital

Digital health deployments require that people and institutions work together: citizens and patients trust the system with their personal data; healthcare providers embrace the contribution of digital systems, and industry delivers the technologies.

But this works only when healthcare authorities set the technical, legal and financial frameworks for the exchange of data.

Careful observers in Europe know that small regions and countries are much better at delivering this framework than bigger ones, while industry often dismisses them as too small for scale. But it pays to pay attention to small regions and countries, if only because they are the laboratories of change.

#### SPEAKERS:

- Werner LEODOLTER - KAGES
- Mette HARBO
- Marco MARSELLA - Head of Unit for eHealth, Well-being and Ageing, DG CNECT

#### MODERATOR:

- Michael STRÜBIN - Director Digital Health, MedTech Europe

11:00-11:30

## COFFEE BREAK AND NETWORKING

11:30-12:20

## A 1.5€ BILLION RESEARCH & INNOVATION EU FUNDING OPPORTUNITY! ARE YOU WILLING TO TAKE ADVANTAGE OF IT AND HOW TO DO SO? THE NEW EU HORIZON EUROPE 7 YEARS PROGRAMME TO SUPPORT HEALTHTECH DEVELOPMENT PROJECTS FROM RESEARCH TO MARKET

Business developments

The European Commission wants to partner with our industry and is committed to fund the Medical Technology Industry from Research to Innovation development all the way to ease market access to explore new healthcare models. The EU «Horizon Europe» 2021-2027 programme is anticipating to invest billions of euros especially to support a new Private Public Partnership on Health Technologies which MedTech Europe and a few other partners are engaged to set up with them.

What does this really mean for your company? What health trends will the PPP focus on? Who can really benefit from such support? How to leverage such opportunities for our industry and your organisations? What engagement will need to be committed to?

All these questions and many more will find answers from a panel of «experts» and will be illustrated through real case examples.

### SPEAKERS:

- Patrick BOISSEAU, VP European Affairs, CEA
- Philippe CLEUZIAT - Research Program Senior Director, Clinical Unit, Open Innovation & Partnerships, BioMérieux
- Serge BERNASCONI - CEO, MedTech Europe

### MODERATOR:

- Ingmar DE GOOIJER - Healthcare industry observer

## IS DIAGNOSTIC INFORMATION OF VALUE IN HEALTH CARE PRACTICE?

Value

Health systems around the world seek to address patients' unmet health needs and governments strive to keep healthcare spending sustainable, while providing equal access to care. This has fuelled debate around what constitutes a valuable healthcare intervention in a health system. Until recently, the value of information and especially the value of information by IVD was not explicitly included as part of this discussion. However, investment in diagnostic information is key to improve clinical decision making.

The value of diagnostic information "VODI" concept was recently published and European organisations from different chronic and acute disease areas will debate the concept and its relevance within the management of their disease. VODI is a holistic framework within Value Driven Health Systems.

### SPEAKERS:

- Ken MASTRIS - Board Member, European Cancer Patient Coalition
- Isabelle TONGIO - SIDIV representative and Director of Public and Governmental Affairs, BioMérieux
- Ken MASTRIS - Board Member, European Cancer Patient Coalition
- Bernarda ZAMORA - Senior Economist, The Office of Health Economics

### MODERATOR:

- Hans MARTENS - Martens International Consulting

11:30-12:20

## MEDTECH FORUM ASK THE EXPERTS

Ask the experts

- Liability of economic operators under the MDR and IVDR: navigating the EU Member States requirements - Charles Henri CARON, Counsel, Hogan Lovells & Matthias SCHWEIGER, Partner, Hogan Lovells
- 3D printing of medical devices - Joerg SCHICKERT, Partner, Hogan Lovells
- Reimbursement in France - Anne-Aurélien EPIS DE FLEURIAN, Market Access Director, SNITEM
- Practical blockchain in healthcare - Ain AAVIKSOO, Chief Medical Officer Guardtime Health, General Manager Estonia, Guardtime
- Digital Health Interoperability - Karima BOURQUARD, Director of Interoperability, Integrating in the Healthcare Enterprise (IHE) Europe - Petra WILSON, European Director, Personal Connected Health Alliance
- Digital Therapeutics - Jessica SHULL, Advisor, Digital Therapeutics
- The continuum of care - a new MedTech-driven concept for healthcare. How key enabling technologies help MedTech to manage future data-dominated healthcare? - Klaus-Michael WELTRING, Managing Director, Bioanalytik Muenster - Kathleen SPRING, Project staff, Bioanalytik Muenster
- Turning Sensitive Data into Competitive Advantage in the Medical Device Market - Luk ARBUCKLE, Chief Methodologist, Chief Technology Officer, Privacy Analytics
- Australia: an update on MedTech regulatory policy - Val THEISZ, Director Regulatory and Clinical Affairs, at the Medical Technology Association of Australia
- Antimicrobial resistance - Anna Rita COSSO, Vice President, Cittadinanzattiva

11:30-12:50

## WHAT ROLE FOR INDUSTRY IN SUPPORTING MEDICAL EDUCATION?



This session aims at discussing industry's role in supporting continuing medical education. What type of measures and programmes can be put in place to safeguard the provision of high quality, balanced medical education? What level of industry involvement is appropriate in order to allow essential interaction between the medical profession and the medical technology industry?

### SPEAKERS:

- David B. VODUŠEK - Professor Emeritus, Faculty of Medicine, University of Ljubljana, Slovenia, Chair of the CME Experts Committee, BioMed Alliance
- Berit GOETHEL-PAAL, Senior Expert CoE Clinical & Therapeutical Governance Projects, Care Value Management, Fresenius Medical Care Deutschland GmbH
- Mike ROBY - Senior Director Learning & Innovation Value Based Healthcare, Medtronic
- Zach HORNSBY - Chief Compliance Officer North & Latin America, Elekta

### MODERATOR:

- Christian CUNEO, Senior Director Regional Compliance, Stryker

# THURSDAY 16 MAY

11:30-12:50

## COMPLIANCE EFFECTIVENESS & RISK MANAGEMENT



This session aims at discussing:

- How to harness data inside of the organisation in order to support the compliance function?
- How to leverage the activities of other business parts within the same organisation?

Best practice exchange on how to measure effectiveness of key elements of compliance programs and initiatives with the data and analytics.

### SPEAKERS:

- Sapan SINGH - Director Compliance, Global Indirect Channels and Data Analytics Programs, Stryker
- Jacques FONTAS - Compliance Lead Europa, GE Healthcare
- Stephen NGUYEN-DUC, Global Head of Ethics & Compliance, Medday Pharmaceuticals
- Louis VAN DEN BOGAARD - Legal Compliance Program Team Lead, Philips

### MODERATOR:

- George FIFE - Partner, Forensic & Integrity Services, EY

## BEST PRACTICE EXCHANGE WHEN PROVIDING EDUCATIONAL GRANTS: 1,5 YEARS AFTER THE PHASE OUT OF DIRECT SPONSORSHIP



This session is aimed at allowing companies to exchange of best practices in providing Educational Grants in Europe, following the ban of direct sponsorship at the beginning of 2018. How is this being managed within the different companies? How are companies monitoring compliance?

### SPEAKERS:

- Linda SNEDDON, Compliance MPD EMEA, WL Gore & Associates
- Sandrine BOUILLLOT - Compliance Officer EMEA, Varian
- Philippa MONTGOMERIE - Senior Director Legal and Compliance EMEA, Medtronic
- Elisabeth WRZESINSKI - Compliance, Smith and Nephew

### MODERATOR:

- Thomas K. HAUSER - Navigant, Life Sciences Governance, Risk Management and Compliance

12:30-13:30

## HANDS-ON TRANSLATION | HEALTHTECHTAB Q&A SESSION

Business developments

Pitch your HealthTech innovation to the TAB experts and receive live assessment and feedback and discuss possible avenues for translation.

### SPEAKERS:

- Rui SOUSA - Program Manager, HealthTech TAB
- Sandra FRANCISCO - Director Finance & Business support, Medevice

12:20-13:50

## LUNCH BREAK AND NETWORKING

13:00-13:50

## MILKMAN 3.0 - DIGITIZING THE MEDTECH COMMERCIAL MODEL

Sponsored session



### Sponsored by Boston Consulting Group (BCG)

BCG will provide "hot off the press" insights from their ongoing global medtech commercial benchmarking study (Milkman 3.0) on how to accelerate sales growth and improve go-to-market efficiency by leveraging the power of AI and analytics. During this interactive session, Goetz and Basir will walk you through specific use cases on next generation sales, digital marketing and dynamic pricing to illustrate the business potential for medtech and how to realize it in an agile way.

#### SPEAKERS:

- Götz GERECKE - Senior Partner and Managing Director, Boston Consulting Group (BCG)
- Basir MUSTAGHNI - Partner & Managing Director, Boston Consulting Group (BCG)

## INNOVATIVE PAYMENT SCHEMES: AN ALTERNATIVE FUNDING FOR MEDTECH?

Sponsored session



### Sponsored by ValueConnected

Most reimbursement and funding mechanisms in Europe prioritize evidence levels as a decision-factor. This is a challenge for many companies with medical technologies that can generate value to healthcare systems, but did not have sufficient time to collect the demanded clinical and economic outcomes. What mechanisms exist in Europe that can create pathways for such medical technologies, at the same time considering their uncertainty of outcomes? And how can the medtech industry explore them?

#### SPEAKERS:

- Ernesto M. NOGUEIRA - Managing Director, ValueConnected
- Ben MODLEY, Director of Operations, ValueConnected

## HOW REGULATION CAN HELP TO REALIZE YOUR STRATEGIC BOLD PLAYS

Sponsored session



### Sponsored by DELOITTE

Yes, we did say help not hinder. Bold strategic moves are made or broken by their implementation. Across the medtech industry, groups are spending huge amounts of time, effort and cash implementing bold strategies and they are doing the same meeting new regulatory requirements. The two can feel like they are divergent.

In this session, we explore the ways that these bold strategies and regulatory goals can align across talent, digital transformation and growth, helping deliver wins across both and saving time, energy and cost.

#### SPEAKERS:

- Michel DE RIDDER - Partner Regulatory compliance for lifesciences, Deloitte
- Emma BAIRSTOW - Partner UK Medtech lead, Deloitte

13:50-14:40

## BREXIT IS REAL

Access

A few weeks prior to The MedTech Forum 2019, the deadline for the UK leaving the EU will have passed. Whether an agreement has been reached and a transition period is in place, or the UK leaves the EU without an agreement in a hard Brexit scenario, Brexit will be real. After years of speculation this session will inform on the realities that the Medtech Industry has to face when dealing with Brexit. As we know more we will let you know!

### SPEAKERS:

- David LUFF - Partner, Appleton Luff
- Mark LLOYD DAVIES - Senior Director, Government Affairs & Policy, Medical Devices EMEA and Johnson & Johnson Western Markets Lead, Johnson & Johnson
- Cristian CLARUS - Director Government Affairs, Bbraun

## CYBERSECURITY AND HEALTHCARE: BLOCKCHAIN AND OTHER ANSWERS

Digital

Ensuring medical devices are safeguarded from cybersecurity risks is a shared responsibility across the medical device ecosystem. The EU has recently strengthened its cybersecurity framework, but the rules for connected medical devices and their links to health IT systems will remain set by national regulators. While their approaches and choices will reflect local conditions and preferences, they also need to coordinate to avoid market fragmentation and costs. Blockchain technology has recently emerged as a possible technology solution to address cybersecurity, privacy, and patient control. But does it work for European healthcare systems and the medtech industry?

This session will convene a senior EU official to outline the European agenda for cybersecurity; a blockchain entrepreneur who knows the healthcare system in Estonia (by some considered the most digitally advanced in Europe); and a Ministry official and cybersecurity policy expert from an advanced Member State.

### SPEAKERS:

- Ain AAVIKSOO - Chief Medical Officer Guardtime Health, General Manager Estonia, Guardtime
- Martina BARTELIN - Former Senior Policy Advisor, Ministry of Health, Welfare and Sport, Netherlands
- Marco MARSELLA - Head of Unit for eHealth, Well-being and Ageing, DG CNECT

### MODERATOR:

- Alain MERLE - Strategic Marketing Manager - Security, CEA Leti



13:50-14:40

## NEW HORIZONS IN VALUE DRIVEN PROCUREMENT, WILL THE EU ACCELERATE CHANGE?

Value

With the new EU public procurement directive now transposed in all the Member States and given the interest at EU level to drive innovation, this session will look at the European Commission's initiatives in the field of value-based procurement for healthcare and at how these might foster a change in practice in Most Economic Advantageous Tendering and Procurement of Innovative Solutions.

Several new EU initiatives and the development of Coordination and Support Actions funded by the EU will be highlighted. A specific focus will be put on the deliverables and the learning from a project conducted by a consortium of leading procurement organizations in Europe coordinated by MedTech Europe. In this project, the organizations are teaming up around a novel approach of value-based procurement of innovative solutions in the field of rapid diagnostics and integrated care. Attendees will also have the opportunity to hear and debate about the drive towards value-based cross border procurement and about the tangible impact of all these initiatives in procurement practices.

### SPEAKERS:

- Virginie DOR - Partner, CMS DeBacker
- Carmen LAPLAZA SANTOS - Deputy Head of Innovative and Personalised Medicine Unit, European Commission
- Götz GERECKE - Senior Partner and Managing Director, Boston Consulting Group (BCG)

### MODERATOR:

- João PEREIRA DA COSTA - Legal & Compliance Counsel III, Legal EMEA, Medtronic Portugal

14:00-14:40

## PLENARY SESSION: CLOSING REMARKS & DISCUSSION



This closing discussion aims at reviewing the key take-aways from the last two days; how the integration of GMTCC into the MedTech Forum worked? What are the key challenges for the year ahead.

### SPEAKERS:

- Anne-Sophie BRICCA - Deputy General Counsel / Chairwoman of the MTE Ethics & Compliance Committee, Terumo BCT
- Dorothy CLARKE - Vice President Healthcare Compliance and chairwoman of the AdvaMed DDCG, Johnson & Johnson

### MODERATOR:

- Ingmar DE GOOIJER - Healthcare industry observer

14:50-15:40

## CREATIVE THINKING IN A DIGITAL WORLD

Plenary

In June 2008, Chris Anderson, then editor-in-chief of Wired Magazine, published an article titled "The End of Theory. The Data Deluge Makes the Scientific Method Obsolete." This revolutionary notion raised some philosophers' awareness. Could we really work without concepts and without theories? Is Plato and Aristotle's legacy suddenly threatened? The answer is complicated and this presentation will enable participants to see how, since the Internet appeared, the nature of the creativity challenge has changed. If "thinking outside the box" remains essential for new ideas, imagining "new digital boxes" becomes even more important.

### SPEAKER:

- Luc DE BRABANDERE - Fellow, Boston Consulting Group (BCG)

### MODERATOR:

- Ingmar DE GOOIJER - Healthcare industry observer

15:40-16:00

## CONCLUSIONS

Plenary

### SPEAKER:

- Serge BERNASCONI - CEO, MedTech Europe



A MedTech Europe event

# The MedTech Forum

bringing HealthTech stakeholders together

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