



**THE DIGITAL
MEDTECH CONFERENCE**

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APRIL 24-25, 2018
SAN FRANCISCO, CALIFORNIA

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CYBERSECURITY SESSIONS AT THE DIGITAL MEDTECH CONFERENCE

TUESDAY, APRIL 24, 2018

8:45 am – 8:50 am
Robertson Auditorium

Welcoming Remarks

Zach Rothstein, Esq., Associate Vice President, Technology & Regulatory Affairs, *AdvaMed*

8:50 am – 9:15 am
Robertson Auditorium

FDA Update

FDA will share their insights on current cybersecurity activities shaping DC's political and policy landscape.

Seth Carmody, Senior Program Manager for Medical Device Security, *FDA*

9:15 am – 10:15 am
Robertson Auditorium

Safety, Security and the Many Faces of Risk

As technology evolves and the consumerization of health care takes hold, the understanding of risk related to safety and security that we as a society have held is fundamentally changing.

In the face of this changing landscape, panelists will identify and discuss issues faced across the health care value chain and will include some unique perspectives from providers, group purchasing organizations, patients, insurers, product liability, manufacturers and software developers.

Moderator: Anura Fernando, MS, Principal Engineer, *Underwriters Laboratories Inc.*

Ken Hoyme, Director, Product Engineering Systems Security, *Boston Scientific Corporation*

Akilah Kamaria, Founder/CEO, *Bradán Inc./The SoCal ISAO*

Chris Keegan, Senior Managing Director, *Beecher Carlson*

Rob Suarez, Director of Product Security, *BD*

Scott Thiel, MT(ASCP), MBA, RAC, Director, Life Sciences, Disputes, Regulatory, Compliance & Investigations, *Navigant*

10:15 am – 10:30 am
Lobby

Networking Break

10:30 am – 11:00 am
Robertson Auditorium

Legislative Update

Stay in the know regarding the latest developments from Capitol Hill. Congressional leaders are considering numerous pieces of cybersecurity legislation, ranging from innocuous to harmful, that will shape the cybersecurity landscape for years to come. Join us to discuss the challenges and opportunities facing the industry given these critical policy decisions. Additionally, Elizabeth will provide incisive analysis on timely issues including coordinated disclosure, SBOMs and more.

Elizabeth Pika Sharp, Senior Vice President and Managing Director, Federal Affairs, *AdvaMed*

11:00 am – 11:30 am
Robertson Auditorium

Cybersecurity for the Medical Technology C-Suite: A Primer in Preparedness and Breach Response

Marcy Wilder, Partner, *Hogan Lovells*

11:30 am – 12:30 pm
Fisher

Networking Lunch

12:30 pm – 1:00 pm
Robertson Auditorium

Bridging the Gap Between Hospitals and Manufacturers

Medical device manufacturers and hospital are working feverishly to ensure that medical equipment is operating at peak performance and resistant to cyber intrusions. Working together and collaborating to gain increased insight and understanding can benefit both parties and patients alike. We'll explore the current cybersecurity struggles affecting each side and discuss how they can work together to tackle the problems.

Stephanie Domas, Vice President of Research, *MedSec*

1:00 pm – 2:00 pm
Robertson Auditorium

Medical Device Security: A Partnership Between Product Security and Quality

Medical device manufacturers are faced with the challenge of operationalizing against the requirements in the FDA's pre and post market medical device security guidance, as well as aligning with industry leading practices. To address risks throughout the device lifecycle, manufacturers must be able to define and implement processes for security risk management, security event handling, external communications, security education and training, and program monitoring. In order to consistently operationalize these processes across the organization, manufacturers must document and formalize their medical device security processes via policies and procedures.

This panel will discuss how Product Security and Quality personnel can work together to address both safety and security risk management. By attending this session, attendees should learn:

- *How to integrate their Medical Device Security Program into their QMS;*
- *What the governance structure can look like to drive accountability for the acceptance and rollout of the policies and procedures;*
- *What is the risk of not having a consolidated document hierarchy and consistent documentation of medical device cybersecurity processes;*
- *What the components to effectively implement a medical device security document hierarchy and what the dependencies are; and*
- *Leading practices for integrating medical security processes with the organization's QMS and the ongoing role of Quality in securing connected medical devices.*

Moderator: Nick Sikorski, CISSP, CSSLP, Manager, Deloitte Risk and Financial Advisory

Dave Deaven, Chief Engineer, Quality, *GE Healthcare*

Michelle Jump, Director, Regulatory Affairs Cybersecurity, *Carestream Health Inc*

Michael McNeil, Global Product Security & Services Officer, *Philips*



WIFI NETWORK: UCSF GUEST

TUESDAY, APRIL 24, 2018

2:00 pm – 7:00 pm
Lobby

Registration Open

3:00 pm – 3:15 pm
Robertson Auditorium

Welcoming Remarks

Michael "Mick" Farrell, Chief Executive Officer, *ResMed*

3:15 pm – 3:45 pm
Robertson Auditorium

Fireside Chat with Anne Wojcicki

The explosion of digital health and diagnostic technologies are empowering individuals to take a proactive role in their health. In this conversation, Anne Wojcicki, the CEO of 23andMe, will discuss what this trend means for health care, and how companies can continue to empower patients and providers with insightful information about their health.

Anne Wojcicki, CEO and Co-Founder, *23andMe*

Facilitator: Andrew Fish, Chief Strategy Officer, *AdvaMed*

3:45 pm – 4:45 pm
Robertson Auditorium

Plenary: Future of Digital Health

Distinguished industry leaders will share their views on the future of digital health. As numerous challenges and opportunities exist in the current business environment, these leaders will provide practical and meaningful information about how they impact the industry and patients.

Moderator: Megan Molteni, Science Writer, *WIRED*

Sheri Dodd, Vice President & General Manager, *Medtronic Care Management Services*

Michael "Mick" Farrell, Chief Executive Officer, *ResMed*

Amy McDonough, Chief Operating Officer, *Fitbit Health Solutions*

Rick Valencia, President, *Qualcomm Life*

4:45 pm – 5:15 pm
Robertson Auditorium

Spotlight

Harry Glorikian, Author, *Moneyball Medicine*

5:30 pm – 6:30 pm
Robertson Auditorium

Debate: Benefits vs. Risks of AI and Technology

We've anticipated it for years and now it's becoming reality: Emerging technologies are finally able to emulate and augment the power of the human brain. That has big implications for many industries, including health care. Cognitive technology (broadly termed AI) offers the potential to dramatically improve the accuracy, precision and timeliness of patient diagnoses and treatment. From a population health perspective, cognitive technology promises to enable greater understanding of subtle patterns – behavioral, genetic and biologic - that identify diseases and impact disease outcomes. From the point of view of operational efficiency and customer experience, AI could reduce unnecessary tests/visits, streamline care and administrative activities and increase physician/clinician productivity.

The benefits are many, but there are also risks. Among the questions to consider:

- *Can sensors and AI pick up on the subtle behavioral and appearance nuances that often queue a physician?*
- *Will technology de-personalize the health care experience?*

- *Could technology displace physicians and ancillary health professionals who have trained to be specialists?*

Join us for a debate that will explore both the benefits as well as the dark side of AI, robotics and other emerging cognitive technologies in health care.

Moderator: Glenn Snyder, Medical Technology Segment Leader, *Deloitte*
Howard Landa, VP of Clinical Informatics and Electronic Health Records, *Sutter Health*

Scott Thielman, Chief Technology Officer and Co-Founder, *Product Creation Studio*

Yulun Wang, PhD, Chairman, Founder & Chief Innovation Officer, *InTouch Health*

John Axerio-Cilies, COO and Co-Founder, *Arterys*

6:30 pm – 7:30 pm
Lobby

Welcome Reception

WEDNESDAY, APRIL 25, 2018

8:30 am – 5:00 pm
Lobby

Registration Open

9:15 am – 9:30 am
Robertson Auditorium

Welcoming Remarks

Sara Radcliffe, President & CEO, *California Life Sciences Association*

9:30 am – 10:30 am
Robertson Auditorium

Why Medical Technology Needs Human-Centered Design

The fundamental principles of Human-Centered Design (HCD) are simple in concept, but difficult to apply. They are:

- *Be human-centered. Consider all people involved with a product, clinic or system: Patients, families, physicians, nurses, technical staff, supporting staff, purchase agents, service and maintenance.*
- *Treat the problem as a complex, coherent system. In health care, everything is connected to everything else. When we design in isolation, whether it is a device or a procedure, it actually impacts almost all of the system, often in unexpected ways. Local optimization does not necessarily lead to global optimization: it is the system as a whole that needs to be optimized.*
- *Prototype, Test, Iterate. When dealing with complex systems, with people and procedures, it is unlikely that the first attempts will be right. So learn to develop rapid prototypes (in hours, not months), test them in the real settings and iterate. How do you test something before it is built? Ah, the secret sauce of design – think theater.*
- *Everyone needs to be part of the design process, whether it is an instrument or test or a procedure. Often the best ideas come from patients, caregivers and nurses. Or service and maintenance people. Get everyone involved.*

*Buy-in and understanding are essential by ALL participants.
Remember: it is a system.*

Jim Guszcza, US Chief Data Scientist, *Deloitte*

Don Norman, Professor and Director, Design Lab, *University of California, San Diego*

10:30 am – 11:00 am
Lobby

Networking Break

11:00 am – 12:00 pm
Fisher



MEDTECH
INNOVATOR

MedTech Innovator Pitch Session I

Two of eight outstanding digital health companies will present and receive feedback from a panel of expert judges. At the end of the day, the audience will vote to choose their favorites, and the top companies will advance in this year's \$500,000 MedTech Innovator Competition and Accelerator.

11:00 am – 12:15 pm
Robertson Auditorium

Panel: Building the Health Care Brain Trust: How Digital Platforms Can Support Breakthrough Treatment for Chronic Disease

Health care professionals share a common goal of understanding patients and improving outcomes - but without a digital platform where disease data can be collected and assessed, practitioners are working from partial information at best. By pooling data from medical devices, treatment regimens and patient visits, digital platforms can give health care professionals deeper insights into chronic conditions like diabetes, epilepsy and heart disease, and also help patients manage them more effectively. In the future, chronic disease treatment may depend less on the individual health care practitioner and more on the robustness of the digital platform - and how open or closed it is to inputs from multiple sources. So what are the challenges in building a platform to support the health care brain trust? How can we aggregate and filter chronic disease data? What data governance models will yield the best results? How can we leverage what we learn to improve outcomes for not just some, but all chronic disease patients?

Moderator: Tracy MacNeal, MBA, President, Diagnostics, Ximedica LLC
Rick Altinger, CEO, Glooko

Marco Flavio Marinucci, Director of Digital Products, Ximedica LLC

Matteo Lai, CEO, Empatica

Jessie Juusola, PhD, Head of Outcomes Research, Evidation Health

John Mattison, MD, Chief Medical Information Officer and Assistant Medical Director, Kaiser Permanente

12:00 pm – 1:15 pm
Atrium Lobby

Networking Lunch

12:45 pm – 1:10 pm
Robertson Auditorium

Spotlight: Experience Matters - Understanding Chronicity to Design for Care

The overwhelming growth of chronic disease diagnosis, the burdens on systems of care, and the challenges of self-management that accompany a diagnosis require a paradigm shift in our thinking of how treatments are delivered. To design solutions, it is important to distinguish between chronic disease and chronic illness. Chronic disease refers to a patient's condition but chronic illness considers the overall experience including symptoms and the emotional and social factors of living with a disease. Our research is focused on identifying and reducing barriers to inspire a more holistic view of the patient's experience, giving us the chance to design a truly human-centered approach. Understanding all of the aspects that create a patient's experience allows us to design innovative solutions for doctors, nurses, service providers and medical administrators.

Cameron Murray, Cognizant

Jamie Haggard, CEO & Co-Founder, Green Sun Medical

1:15 pm – 2:15 pm
Fisher



MedTech Innovator Pitch Session II

Two of eight outstanding digital health companies will present and receive feedback from a panel of expert judges. At the end of the day, the audience will vote to choose their favorites, and the top companies will advance in this year's \$500,000 MedTech Innovator Competition and Accelerator.

1:15 pm – 1:35 pm
Robertson Auditorium

Spotlight: Health Care Innovators Need to Open Their Aperture

Health care has traditionally approached a patient condition head-on, innovating based upon a tightly-defined understanding of the problem to be solved. While this approach has, to date, yielded leaps forward that have eradicated disease, extended life and improved quality of life, we should position ourselves for a different challenge: patients whose profile includes not one but multiple diseases and whose multi-condition reality is sub-optimally understood and managed outside of acute facilities. These patients represent upwards of 30% of the US population and drive more than 70% of US health care costs – and they need something different from health care innovators. The multiple singular disease solutions and approaches are overly-burdening the health care system to catch, coordinate and manage the complexity of these patients. Furthermore, we have assigned lofty aspirations of providers and to technology to deliver clinical and economic value creation but have been remiss to address the reality of difficult clinical execution, disaggregation of information, or misaligned economics. It's time for health care technology innovators to open their aperture, driving developments towards a whole patient, reduce the complexity of care and tie clinical and economic value together.

Sheri Dodd, Vice President & General Manager, Medtronic Care Management Services

1:35 pm – 1:55 pm
Robertson Auditorium

Spotlight

The vision to enable individualized health care decision and thus improve outcomes across the spectrum of patients has gathered tremendous interest and investment. The opportunity to leveraging technology to create high-value, on-demand, predictive, and distributed platforms to improve outcome and decrease cost of care is vast and non-controversial. One can argue that this is the "holy grail" of personalized digital medicine. However, the progress towards this vision has been slow and, with many "false starts", a bit frustrating. The key barrier has been the lack of real-time, clinical-grade, personalized data that can inform therapeutic choices and facilitate real-time physician engagement. In this presentation, we will share the technology platform developed by Profusa which overcome the key physiological barrier for long-term, continuous sensing of an individual's biochemistry. By overcoming the biological barrier to long-term sensing, we have demonstrated sensing longevity for more than 4 years, generating clinical-grade data to inform physician's therapeutic choices, and are approved for our first application in Europe. We will describe the approach, technology solution, readiness of the platform for deployment, and application potential

Ben Hwang, PhD, Chairman and Chief Executive Officer, Profusa, Inc.

1:55 pm – 2:15 pm
Robertson Auditorium

Spotlight: How Can Rules and Norms Make Way for Software?

The capabilities of clinical decision support software are rapidly improving. Commentators offer various predictions for when, not if, software-based diagnostic tools will match the judgment, decision or knowledge of a clinician, depending on the specialty and the condition. Yet today's legal, regulatory and professional paradigms are premised on the need for a clinician to intercede between these solutions and the patient's treatment decisions. What will happen when CDS is capable of matching a clinician's diagnosis or when "black box" CDS does not lend itself to human assessment? A new paradigm is needed, and we will need to look outside health care as we re-balance the role of technology and the role of clinicians in diagnosing and treating patients.

Nathan A. Brown, Partner, *Akin Gump*

2:15 pm – 2:45 pm
Lobby

Networking Break

2:45 pm – 3:45 pm
Fisher



MedTech Innovator Pitch Session III

Two of eight outstanding digital health companies will present and receive feedback from a panel of expert judges. At the end of the day, the audience will vote to choose their favorites, and the top companies will advance in this year's \$500,000 MedTech Innovator Competition and Accelerator.

2:45 pm – 3:45 pm
Robertson Auditorium

Panel: Market Outlook and Opportunities

The digital health industry continues to see increased venture funding and M&A interests. This panel of experts will discuss and analyze the digital health ecosystem's market activity and business environment.

Moderator: Megan Zweig, Director of Research, *Rock Health*
Greg Caressi, Senior Vice President, Transformational Health, *Frost & Sullivan*
John Gardner, Founder, *NGP Ventures*
Chase Hensel, CEO, *Welkin Health*
Jared Seehafer, CEO & Co-founder, *Enzyme*

3:45 pm – 4:00 pm
Lobby

Networking Break

4:00 pm – 5:00 pm
Fisher



MedTech Innovator Pitch Session IV

Two of eight outstanding digital health companies will present and receive feedback from a panel of expert judges. At the end of the day, the audience will vote to choose their favorites, and the top companies will advance in this year's \$500,000 MedTech Innovator Competition and Accelerator.

4:00 pm – 4:20 pm
Robertson Auditorium

Spotlight: How Medical IoT and Advanced Connected-Devices Must Transform Patient Monitoring and Diagnostics

It's no secret what the trends imply. With the exponential rise in elderly patients, chronic disease, health care costs and subsequent pressure on Medicare/Medicaid solvency, the health care industry is eyeing Medical IoT and Advanced Connected Devices as the solution to make widespread use of low-cost remote patient monitoring and alert diagnostics beyond the hospital a reality. As IoT evolves from consumer-facing trackers to medical diagnostics, advanced connected devices will need to traverse regulatory, evidenced-based outcomes, payment scheme, supply chain and cybersecurity hurdles so that easy-to-use, reliable and affordable health care diagnostics and preventative care becomes the new standard in health care.

Venk Varadan, Co-Founder & CEO, *Nanowear*

4:20 pm – 4:40 pm
Robertson Auditorium

Spotlight: Developing a Creative and Flexible Regulatory Strategy

Optimizing regulatory efficiency requires thinking creatively about regulatory classifications and controls, approaching the FDA as a collaborative partner, and working proactively to define the regulatory landscape.

Yarmela Pavlovic, Partner, Hogan Lovells

4:40 pm – 5:00 pm
Robertson Auditorium

How to Leverage Connected Devices to Differentiate and Succeed in a Value-Based World

The proliferation of the Internet of Things in healthcare is accelerating, with the estimated number of connected medical devices expected to increase from 10 billion to 50 billion over the next decade. The global shift toward value-based reimbursement models is driving much of the connected medical device market as medtech companies look to digital technologies to fuel new business models and services. By harnessing the data from smart medical devices and applying machine learning and artificial intelligence, medtech companies have the opportunity to show improved patient outcomes, reduce healthcare system costs and offer new digital-enabled services to their customers. Kal Patel, MD, will explore the new business models that connected medical devices are enabling and the positive impact digital health can have on improving overall health of patients and the healthcare system itself.

Kal Patel, MD, SVP of Digital Health, Flex

5:00 pm – 5:15 pm
Robertson Auditorium

AdvaMed's Take: Key Policy Issues Shaping the MedTech Industry

Janet Trunzo will highlight today's issues that will influence the future of medtech regulation.

Janet Trunzo, Senior Advisor to the President & Senior Executive Vice President, Technology & Regulatory Affairs, AdvaMed

5:15 pm – 5:35 pm
Robertson Auditorium

Spotlight: Software Pre-Certification Update

Bakul Patel, FDA's Associate Director for Digital Health, will provide a critical update on FDA's work concerning the development of the Agency's software pre-certification program.

Bakul Patel, Associate Director for Digital Health, FDA CDRH

5:35 pm – 5:45 pm
Robertson Auditorium

Closing Remarks

Andrew Fish, Chief Strategy Officer, AdvaMed

5:45 pm – 6:00 pm
Robertson Auditorium

MedTech Innovator Lightning Round

Paul Grand, CEO, MedTech Innovator



AdvaMed Digital Health represents innovators of safe and effective digital health technologies that improve patient health and wellness and enable more effective health care delivery. Our organization

strives to create a business and health care environment that fully supports digital health technology innovation and patient access to these incredible technologies. To do this, AdvaMed Digital Health acts as a thought leader, convener and advocate for digital health technologies; supports and promotes continued digital health technology innovation; and secures public policies that enable digital health technology innovators to better serve consumers, patients, clinicians and the health care system.

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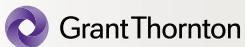
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Our Global Digital Health Team includes more than 40 life sciences and health care lawyers who take a technology-based approach to counseling on digital health products and services, helping you to leverage opportunities for growth, minimize legal barriers, comply with rules, protect your data, and realize its value.



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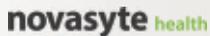
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