



September 23-25, 2019
Boston Convention and Exhibition Center | Boston, MA

US Market Access Seminar

Sunday, September 22 | 12:30 PM - 5:00 PM

Special Program

The U.S. Market Access Seminar is a pre-program for international delegates attending The MedTech Conference. It will address key issues for non-U.S. medtech companies seeking to launch products in the U.S. market. Instructors will cover regulatory and reimbursement pathways, as well as perspectives about the changing landscapes in each of these areas in the U.S.

The Augmented Team: Successfully Implementing AI Technology

Monday, September 23 | 8:00 AM - 9:15 AM

Panel Session

AI technology is coming to health care, moving quickly from promise to reality. In April 2018, the FDA cleared an autonomous AI system that diagnoses diabetic retinopathy, the first device to provide a diagnostic decision without the need for a clinician to interpret the results. What are barriers to successful implementation of this type of AI technology? What additional evidence development and data collection is required to support widespread adoption? We will also discuss how providers can create a different kind of augmented team and overcome clinician resistance to changing roles to reach AI's full potential.

Digital Technology and the Silver Revolution: Realities and Implications

Monday, September 23 | 9:00 AM - 10:30 AM

Super Session

Aging has taken on a persona of its own. It is not just about people getting older, it represents a fundamental paradigm shift about how we live, work and achieve fulfilling lives. It also entails dramatic decreases in the size of the productive workforce, the number of qualified physicians, and the availability of care givers across society. Whether it is called the "Silver Tsunami," the "Longevity Economy," or the "Silver Economy," the realities, opportunities and risks are ever more present. Longevity is an all-encompassing megatrend with social, political, economic and security implications that will impact governments, nations, companies and healthcare.

The percentage of the world's population over 60 years of age will jump from 12% to 22% between 2000 and 2050, and for those over 80 it will quadruple. In the U.S. alone, 15.6% of the population is now over 65 and by 2030 this will increase to 20.6%. Japan, with nearly 100,000 citizens who have reached the age of 100 or older and Finland are two of the fastest "graying" and "super graying" populations, with Europe not too far behind.

Health care systems are watching, acting, and learning. With aging comes geriatric diseases, comorbidities, and loneliness. The need to diagnose these disease states faster and more accurately is critical. Digital technologies have proven to be valuable assets, though more computational horsepower is needed to optimize them and address anticipated future needs.

Physicians are also relying on AI-based automation fueled by automatic tracking of biometric information for certain tasks. AI is also helping patients and their families understand diseases and treatment options. But is the key AI or IA, intelligence augmentation, where machines extend human capabilities instead of replacing them? Human versus machine is a tricky subject. People need to feel comfortable for the technology to work and deliver impact. Referred to as the “uncanny valley,” the balance between man and robot interaction still needs work.

A recent Smithsonian article states, “The tension between what technology can now do and how much older people actually use it is at the heart of what’s become known as ‘connected aging.” Experts in aging, healthcare, policy and technology from Japan, Finland, Australia, the UK and US will discuss this exciting opportunity and how their countries are leveraging digital platforms, AI and other cutting-edge technologies for elderly care and economic benefit.

Coverage and Reimbursement for Diagnostics: The Private Payer Perspective Monday, September 23 | 9:30 AM - 10:45 AM

Panel Session

Within the rapidly evolving health care market, diagnostic test developers face unique challenges in obtaining product coverage and reimbursement as payer perspectives shift over time. This session will feature private insurers and diagnostic leaders to discuss what health plans are seeking when it comes to considering coverage and reimbursement for new diagnostic tests – including topics such as generating evidence and demonstrating value for diagnostic tests.

Efficiently Collect Real World Data: Industry, Policy, and Regulatory Perspectives Monday, September 23 | 11:00 AM - 12:15 PM

Panel Session

The demand for Real World Evidence (RWE) has increased dramatically, with the payers requiring more evidence to make their decisions and the global regulatory bodies looking to real world data for pre- and post-market decisions. Savvy MedTech companies are using real world data sets to their competitive advantage. Historically a practice for disruptive products, today, RWE could be a critical component of successful go to market strategy. This session will look at how to make the collection of this data more efficient, accessible, and compliant. In a panel moderated by Seth Goldenberg, VP of Medical Device and Diagnostics for Veeva, the audience will hear the perspectives from Owen Faris, Clinical Trials Director - CDRH at US Food and Drug Administration, Rachel Rath, NESTcc Deputy Director, Manish Bharara, Regulatory and Clinical Affairs, Siemens Healthineers and Lisa Holt, Sr. VP, Clinical and Medical Affairs, Metavention, on the collection, application and challenges of RWE, ultimately resulting in better outcomes and safer and more efficient use of technology.

SME MedTech Innovations that are Transforming Health Care in the US and Abroad Monday, September 23 | 11:00 AM - 12:15 PM

Panel Session

Given the complexities of payment, policy and care delivery ecosystems in low and middle Income countries it should come as no surprise that change agents in these regions are developing innovations with the potential to transform health systems not only in their own

communities but in countries of all sizes around the world. Fostering breakthroughs in health care delivery models, affordable technologies, and more, these organizations are creating new pathways to improving health care quality and access while challenging the paradigm of modern day patient care.

Transforming the World's Largest Integrated Health System

Monday, September 23 | 11:00 AM - 12:15 PM

Panel Session

NHS England has a budget of over \$160 billion and provides care for over 55 million people. By 2024, the NHS's budget will have increased to nearly \$190 billion, new structural innovations (e.g. Integrated Care Systems and Digital Innovation Hubs) will have matured, and the terms of Brexit will have been agreed. Join us for a discussion with NHS England Chair Lord Prior on the UK's plans, challenges and new opportunities to harness technology and data.

Health 2040: Medtech's Role in a Transformed Future

Monday, September 23 | 12:15 PM - 1:30 PM

Super Session

Twenty years from now, the health care system we know today will look completely different. There will be a fundamental shift from "health care" to "health." And while disease will never be completely eliminated, through science, data, and technology, we will be able to identify it earlier, intervene proactively, and better understand its progression. Greater data connectivity and interoperability, open, secure platforms, and increasing consumer engagement will lead to a future focused on wellness and managed by companies that assume new roles to create value. Ten stakeholder archetypes—grouped into three distinct, but interconnected, categories—are likely to emerge and replace and redefine traditional industry roles.

No segment of today's health care ecosystem is immune. Whether it's just one or several of these archetypes, industry leaders need to make choices now about which role(s) they will want to play over the next 5, 10 and 20 years.

This session will challenge medtech executives to think differently about the future – both in the shorter-term and longer-term - and the business model choices that they are making. Results from a Spring 2019 study of medtech, technology, and health care strategists will shed light on what types of products and services medtech will offer and what business models will emerge.

Developing a Framework for Patient Input in Medical Device Clinical Trials

Monday, September 23 | 1:00 PM - 2:00 PM

Panel Session

Industry, FDA and patient groups recognize the importance and value of patient input in the ideation, design, testing and approval of new medical device technologies, but often struggle to elicit and incorporate patient input in a meaningful way. Patients can identify outcomes that are meaningful, risks that they would be willing to tolerate, and practices that can decrease the burden of participation in clinical trials. MDIC is developing a suite of tools to help medical device companies solicit input from patients and patient groups on clinical trial design elements that are aligned with patients' real-world priorities. Attendees at this session

will learn about the development of tools to help medical device companies solicit input from patients and patient groups on clinical trial design elements that are aligned with patients' real-world priorities.

Using Data and Analytics to Demonstrate the Value of Diagnostics

Monday, September 23 | 1:00 PM - 2:00 PM

Panel Session

Applying sophisticated analytics to large clinical and claims databases can generate evidence demonstrating the value of diagnostics. This evidence can in turn be leveraged in market access, maximizing sales and marketing, manufacturing, research and clinical development. Building off of the AdvaMedDx Framework for Comprehensive Assessment of the Value of Diagnostic Tests to guide evidence development, this session will showcase two use cases – oncology and sepsis – generated through data analytics to reinforce the value of diagnostics for patient health and health care.

AdvaMed's New Code of Ethics: Is Your Company Prepared to Comply?

Monday, September 23 | 2:00 PM - 3:15 PM

Panel Session

AdvaMed recently released its updated Code of Ethics on Interactions with Health Care Professionals, which will take effect on January 1, 2020. The updated Code introduces four new topics critical for medical technology companies: Jointly Conducted Education and Marketing Programs, Communicating for the Safe & Effective Use of Medical Technology, Consigned Products, and Company Representatives Providing Technical Support in the Clinical Setting.

Will your company need to adopt new policies to reflect the Code's new sections, notably those relating to communications, technical support and joint programs? Are your company's Industry codes in compliance? This discussion will feature industry experts that will offer practical tips to get into compliance with only a quarter of the year left to prepare.

Chasing Value: Understanding How to Work with GPOs to Introduce New Health Care Innovation in the Supply Chain

Monday, September 23 | 2:00 PM - 3:15 PM

Panel Session

Come learn about how to successfully launch new and innovative technology with GPOs. Does a GPO work for your product and market implementation strategies? Hear from GPOs and suppliers who have worked with them on recent experience in medtech, industry trends, new innovation forums, diversity programs and value based initiatives to foster optimal, high quality health care.

This is an excellent opportunity to learn from experts across the supply chain how they have successfully worked together and launched new innovations with group purchasing organizations. Successful partnership and best practices will be explored in this highly informative session.

***Want to learn more and talk to representatives from HealthTrust, Premier and Vizient directly? Join us for a meet and greet on Tuesday morning with GPO contracting, diversity and innovation program leaders from 10:30 am to 12:30 pm. Come meet supply chain leaders*

*who have been working with medtech innovators and learn about how your company can work with a GPO.***

The New World of 510(k)

Monday, September 23 | 2:00 PM - 3:15 PM

Super Session

The 510(k) process has continuously evolved since 1976. FDA has introduced several changes including RTA, QUIK review and the Safety and Performance Pathway. What is on the horizon?

- *Limiting certain devices as predicates?*
- *The new Third Party Review program?*
- *Redefining the data that must be submitted in a 510(k)?*
- *Pre-Cert options?*
- *eSTAR?*

Hear senior FDA management discuss their proposal for the ongoing improvement of the 510(k) process and the industry reaction to the proposals.

Establishing the Value of Your MedTech Innovation - It's Never Too Early

Monday, September 23 | 2:15 PM - 3:15 PM

Panel Session

Before even building the first prototype, medtech innovators should be thinking about how their invention will deliver value to health care customers. The panel will discuss how innovators can define, demonstrate, quantify and communicate the value of their technologies at each stage of development and through early commercialization and scaled growth.

More Value for Patients and Society Through Data-Driven Healthcare: US and International Perspectives

Monday, September 23 | 2:15 PM - 3:15 PM

Panel Session

Due to digitalization and datafication, there is an increasing amount of health data available to develop better care and solutions for patients and health professionals. In this session, the datafication in health care and medtech industry will be discussed and explored especially from the point of view of solutions and platforms, which can integrate health data from various sources. In addition, the session will cover the ethical points how and under which conditions health data can be shared and utilized in order to protect individuals' data. Special focus will be paid to Finland as a case example of how various types of health data can be integrated and utilized to build a revolutionary win-win-win situation for patients, companies and government. This session serves as a forum for dialogue and collaboration between actors from around the society, from growth companies to global corporations and government to academia.

China NMPA (CFDA) Key Updates and Their Implications on Overseas Companies

Tuesday, September 24 | 8:30 AM - 12:15 PM

Panel Session

Overview of NMPA Major Updates and Implementations in 2019 – Complete Product Life Cycle

- 1. Beyond Traditional Pathway Approval in China: Innovation, Priority, HaiNan and Other Alternatives*
- 2. Recent Developments in China Medical and IVD Devices: Submission, Modifications, MAH, Legal Agents and the Implications*
- 3. Recent Developments in China Post Market Compliance: GSP, AE, Domestic, Overseas Audits and the Implications*
- 4. Clinical evidence requirements: clinical trial/evaluation, international clinical data, multi-center trial, etc.*

China Reimbursement & Tender Systems – Era of Evolving Reform

1. Key Commercial Success Factor: Role of Public Reimbursement System 2. China Reimbursement System 101

a. Basic framework and concepts: new product reimbursement and patient cash pay, Greenbook code role, private insurance etc. What are the different types of reimbursement systems in China?

3. China market access 2 key steps overview: public tender platforms and charge codes in the context of reimbursements

a. Process for manufacturers to work with provincial authorities to support from a new patient charge code to reimbursement code

b. Relationship between patient charge code/reimbursement

4. Step by step examples on how to obtain charge code and reimbursement for new products in China

FDA's New Approaches to Software Regulation: Pre-Certification and Artificial Intelligence

Tuesday, September 24 | 9:15 AM - 10:30 AM

Panel Session

Advances in software and data technologies have forced the FDA to reimagine its approach to regulating these products. This panel will explore the Agency's current plan to restructure its software regulations through its pre-certification pilot program and the Agency's proposal to regulate artificial intelligence. Panelists will offer insights into how companies developing medical software are positioning themselves to take advantage of these proposals and other regulatory challenges they face.

Bridging Commercial and Military Market Needs to Advance Medical Device Development

Tuesday, September 24 | 9:25 AM - 9:55 AM

MedTech Exec Talks

In any economy, R&D executives must maximize their resources in order to advance next generation medical technologies and product lines. The US Department of Defense (DoD) annually funds development of specialized medical technologies to meet specific military needs in particular use environments. These programs can provide medical device manufacturers non-dilutive resources to advance technologies that are planned or already in development, or that may be too expensive or too risky to self-fund. However, many companies do not take advantage of these opportunities because they: perceive the government contracting process as daunting and resource-intensive; believe the military market is limited; and are unsure how to leverage these efforts into products for the civilian market to ensure

productive revenue streams. This session will explore a business model that successfully bridges industry's need to develop commercially-viable devices and desire to achieve this using augmented resources, with the DoD's need for dependable sources of innovative, military-ready medical technology.

CMS Town Hall

Tuesday, September 24 | 9:45 AM - 11:00 AM

Super Session

This session will feature an open Q&A discussion amongst senior leaders from the Centers for Medicare and Medicaid Services (CMS). Topics covered will include developments pertaining to medical technologies including Medicare coverage, new payment models and patient access to new technologies.

The New World of Medtech M&A Valuation: Strategies to Adapt and Thrive

Tuesday, September 24 | 9:45 AM - 11:00 AM

Panel Session

Continued strong sector fundamentals, improving end markets and new product launches and healthy pipelines has led to a significant run up in valuations of private and public medtech assets. As a result, organizations have been forced to adopt new and more advanced valuation techniques to appropriately evaluate acquisition targets.

Officials from some of the most successful medtech organizations will share insights and best practices for capturing and analyzing the most relevant aspects in designing a comprehensive valuation for M&A and what challenges remain, including the following:

- *How are companies succeeding in competitive situations for attractive targets?*
- *What are the right analytical tools for evaluating complex economics globally, including payer dynamics and commercial risks?*
- *What levels of strategic and operational diligence are required to properly value deal targets?*
- *How is the capital markets environment—cheap credit, activist shareholders—affecting resource allocation for transformative M&A?*

Preparing for Medical Device Cybersecurity in 2020

Tuesday, September 24 | 10:00 AM - 10:20 AM

Solutions Showcase

Over the last decade, technology has played a central role in advancing quality of care, creating new delivery mediums and changing access for patients, in large part due to the development of new medical devices. Device cybersecurity is a shared responsibility between device vendors, HDOs and others. Recent medical device regulatory guidance confirms the need to prepare for anticipated changes. This session will explore the evolution of cybersecurity as a HIPAA compliance mitigation into a patient safety enabler. It will delve into cybersecurity processes and functions that are expected to be performed and tools available to support.

Phase Zero: How to be Resource-Efficient with New Product Opportunities

Tuesday, September 24 | 10:30 AM - 10:50 AM

Solutions Showcase

New products can change the outlook for companies and the right product can create a new market segment. But even in the regulated device space, a comprehensive development process can be too burdensome for many early opportunities. Learn how to identify the need for a Phase Zero effort, rationalize the approach to collaborators and scope the necessary activities. Scott Thielman will share how a design firm thinks about targeted projects to reduce in risk in the domains of technical functionality and product vision.

Connected Ecosystems for Smarter Decisions

Tuesday, September 24 | 10:30 AM - 11:00 AM

MedTech Exec Talks

The emergence of the Internet of Things (IoT) – where physical devices are instrumented to capture and transmit data covering everything from environmental conditions to usage patterns and user behaviors – is arguably the next wave of digital advancement. The “things” in IoT can refer to a wide variety of devices such as subcutaneous drug delivery units, continuous glucose monitors and vitals monitoring equipment. The expanded sensing and communication capabilities of these “things” is a harbinger of new business possibilities. Not surprisingly, IoT is making inroads in the medical devices industry. Medical devices and diagnostic companies are transforming themselves from not only devices/consumables providers but also disease/care management organizations to achieve better health outcomes. In the hospital, manufacturers are connecting devices to enable health care professional to make the smarter decisions on care delivery and treatments. And with increasing outpatient and at-home treatment, connected devices enable remote patient monitoring to ensure safety, accuracy and timeliness of treatment.

IoT promises to transform how medical device companies operate — from product design and development, to manufacturing, sales, performance monitoring and service. The IoT's global network of sensors and touchpoints is already raising the bar across health care — allowing device manufacturers, labs, health care providers and patients to reap more benefits from the increasingly digital, closely connected and highly competitive medical-device market. This session will explore the latest on IoT and connected devices and how to realize the three key benefits of a differentiated user experience, streamlined operations and lower cost and instant feedback.

How Data Will Transform Patient Outcomes, Medtech and Practice of Health, Why It Hasn't Happened

Tuesday, September 24 | 11:00 AM - 11:45 AM

CEOs Unplugged

How can medtech firms take a cue from big tech companies that are tapping data to transform products, capabilities, business models and entire markets? Collected from sources like devices, EMRs and patient surveys, data can provide valuable feedback to improve surgical practice, speed regulatory approval, improve reimbursement and definitively prove value. It can improve medical technology, help patients avoid institutions, reduce medication dependence and improve safety. It can extend medtech's relationship with patients well outside the realm of one-time interventions. This panel will focus on how medtech uses data—the barriers, the success stories and the future to come.

Diverse Perspectives on Developing and Deploying Digital Technologies

Tuesday, September 24 | 11:15 AM - 12:15 PM

Panel Session

The advent of technologies which use digital platforms and artificial intelligence has the potential to significantly impact the health outcomes of patients and to change the way that health care is delivered. This session will explore the various considerations that should be factored into the development and use of these types of technologies. Experts will discuss the process for developing and positioning these devices, data protection and risk considerations, regulatory and legal compliance issues, market positioning and payment.

It Takes a Village: How the Health Care Community is Working Together to Tackle Cybersecurity

Tuesday, September 24 | 11:15 AM - 12:15 PM

Super Session

Managing cybersecurity in the health care community is a shared responsibility, all participants must proactively do their part. This panel will explore the various ways in which the health care space is jointly tackling these issues, including perspectives from FDA, medical device manufacturers and health care providers.

Small Companies Selling Big Ideas to Huge Corporations

Tuesday, September 24 | 11:15 AM - 12:15 PM

Panel Session

What does it take for a startup to sell to corporate giants? The panel will examine ways for small size companies to pitch big ideas to hardly accessible clients. As commerce becomes more virtual and distances shrink, what are the new ways for small enterprise from the medtech and digital health industries to perform their larger peers.

Through the analysis of success stories and failures, the panelists will discuss on what it takes to make it big when you're small.

Emerging Issues Regarding the HCPCS Coding Process for Medical Devices

Tuesday, September 24 | 2:10 PM - 2:50 PM

MedTech Exec Talks

In the midst of first-of-its kind litigation challenging a Healthcare Common Procedure Coding System (HCPCS) coding decision, the Centers for Medicare & Medicaid Services (CMS) recently announced a number of changes to the coding process for 2019. This session will address these changes, the litigation and the implications of these recent developments for companies.

Leadership Views on Diagnostics

Tuesday, September 24 | 2:15 PM - 2:55 PM

CEOs Unplugged

CEOs of leading diagnostics companies from the AdvaMedDx Board of Directors share perspectives on the opportunities they see for future innovation and growth in the field and the policy and market changes that must be altered or embraced to ensure advancement.

Going Viral: Best Practices in Social Media

Tuesday, September 24 | 2:15 PM - 3:30 PM

Panel Session

Twitter. Facebook. Instagram. Social media platforms have transformed how individuals and corporations are communicating and sharing information. These and other burgeoning social media tools can provide medtech companies new opportunities to effectively interact with patients, physicians, employees and other stakeholders. However, as a highly-regulated industry, medtech companies must consider new evolving media in the context of the regulatory environment and rules of the road amidst rapid change in today's communications in advertising and promoting their products.

In this session, participants will gain an overview of how FDA regulates medtech company communications in the age of social media. Attendees will also learn about AdvaMed's recently updated Direct-to-Consumer Advertising Industry Principles and how they can help companies establish processes in compliance with current regulations. Next, a leading communications consulting firm will outline social media best practices both for companies with an established on-line presence and those just starting to explore the social media landscape. Finally, representatives from a large and a small medtech company will provide case studies on how they have successfully utilized these new communications platforms. A Q&A session with all panel participants will conclude the session.

Pulse of the Industry 2019

Tuesday, September 24 | 2:15 PM - 3:30 PM

Super Session

A decade since the financial crisis, the medtech industry has re-established steady growth rates and record levels of venture capital investment. However, medtech has yet to fully realize the potential of new digital technologies to transform the industry. Connected devices will capture and analyze data to deliver personalized care and improved outcomes, while presenting new challenges in customer engagement, data management and cybersecurity. EY's 13th annual Pulse of the Industry Medical Technology report examines each of these topics and will be the foundation for the panel conversation where we'll explore how medtech companies can best seize the opportunities and avoid the dangers ahead.

International Digital Testbeds: Perspectives on Partnerships and Organic Investment Models

Tuesday, September 24 | 2:30 PM - 3:45 PM

Panel Session

As monetization of big data and the trend away from the traditional unit sales model takes the medical device industry by storm, questions around digital strategy move from "if" to "how." In an outcomes-based market where data has quickly become a product's value driver, manufacturers inevitably come to a fork in the road: invest in-house or partner? The panel will offer perspectives on both routes, from efficiencies realized through partnered drug/device adherence programs to in-house digital R&D programs supporting enhanced patient experience, testing scalable models in international markets.

Global Markets: Where to Invest?

Special Programming

Tuesday, September 24 | 2:15 pm - 3:30 pm

Deciding where to invest regionally requires understanding a variety of factors, depending on the type of investment and new market opportunities you want to establish for your company.

Regional markets all have competitive advantages that you might not know about.

During this program, you will hear a series of 14-minute power presentations outlining the investment incentives available in various regions of the world.

Oh, the places you'll go!

- 2:15 pm –
- 2:30 pm – Costa Rica
- 2:45 pm
- 3:00 pm
- 3:15 pm
- 3:30 pm

Advancing Inclusion and Diversity

Tuesday, September 24 | 3:05 PM - 3:45 PM

CEOs Unplugged

CEOs serving on AdvaMed's inclusion and diversity board committee will discuss how inclusive and diverse corporate cultures link to competitive advantages in talent, innovation and investment. They will also discuss how the industry working together to advance inclusion and diversity will be the best outcome to attract and retain top talent as well as serve the evolving needs of the patients who benefit from our life saving technology.

MDR/IVDR - What Now?

Tuesday, September 24 | 3:45 PM - 5:00 PM

Super Session

Implementation of the MDR/IVDR remains problematic. Relevant and necessary implementing acts remain in limbo, notified body capacity does not appear sufficient to be able to do the necessary reviews in advance of the deadlines and many additional technical questions remain unresolved. This panel will address the fundamental issues in implementing the regulations, as well as attempt to offer perspective on potential mechanisms that could be utilized to reduce the review backlog and ensure products can remain on the market in the EU. The panel will have a wide representation from industry, regulators, consultants, and notified bodies. The session will provide a comprehensive update of the scenarios that are likely to unfold in the coming months and offer insight into how these may be addressed.

How Major New Players Are Challenging the Current Healthcare Ecosystem

Tuesday, September 24 | 4:00 PM - 5:00 PM

Panel Session

Major non-health care players such as Apple, Google, Best Buy, Amazon, Berkshire Hathaway, and JPMorgan Chase are launching key initiatives in various health care segments, driving disruptive change. The insiders of the health care ecosystem are monitoring these new players activities and trying to assess the impact on their product and service innovations. Some of these new players are already changing the way health care is managed and delivered, and they are bringing a fresh perspective to a segment that has historically been inward-focused.

This session will discuss the landscape and impact of these new players, and will discuss:

- *What these players are hoping to achieve, and what strategies are they employing to meet their goals?*
- *As players in the health care ecosystem, should we embrace and welcome their new ideas?*
- *How can MedTech players collaborate with these corporations and form new partnerships to disrupt the dynamics of the ecosystem further?*
- *Will these new entrants leverage the experience of life sciences-focused players?*

The panel will feature speakers from major new entrants in the health care ecosystem.

The Role of Diagnostics in Promoting the Health and Health Care of Women

Tuesday, September 24 | 4:00 PM - 5:00 PM

Panel Session

Diagnostic testing is critical at every stage of a woman's life. From reproductive health to heart health, diagnostic tests give health care providers the ability and confidence to make appropriate health prevention, management and treatment decisions for women. This session will explore how diagnostic tests have enabled researchers to uncover the significant biological and physiological differences between men and women and the progress being made to address the range of conditions and diseases that exclusively, disproportionately or differently affect women.

Innovation, Regulation, and Adaptation: Emerging Legal Issues in Digital Health

Wednesday, September 25 | 8:15 AM - 8:45 AM

MedTech Exec Talk

Digital health—the convergence of digital and healthcare technologies to promote efficient healthcare and personalized medical treatment—is everywhere. Assistive technologies like robotics enable surgeons to perform less-invasive surgeries while reducing the risk of human-error; the same technologies also permit people with disabilities to live more independent lives. Virtual reality and video games supply new forms of patient rehabilitation and education. Artificial intelligence, other computational simulations and modeling aid decisions by clinicians; and the prospect of “precision medicine”—unique care designed for one individual—is on the horizon. Mobile health and telemedicine are making the provision of care more efficient, and are increasing the availability of care to limited mobility patients or those in remote locales.

As these advancements and breakthroughs continue to be adopted, the companies that make them possible will be subject to significant and evolving legal issues. The goal of this session will be to review the most and current pressing of those issues, including, without limitation:

(i) how the existing regulatory framework, from FDA and other governmental actors, will govern digital health technologies,

(ii) the legal risks to digital health companies, and the ways that courts are adapting with traditional defenses and doctrines;

The purpose of the session will be to alert stakeholder companies to the issues they need to address now in order to avoid legal threats later.

Evidence Needs of US and European Payers: Can the Rubber Meet the Road?

Wednesday, September 25 | 8:30 AM - 9:30 AM

Panel Session

Recognition continues to increase that generation of clinical and economic evidence supporting product value can be more challenging for medtech than for pharmaceuticals. Various reasons contribute to this situation, including challenges in conducting device randomized controlled trials (RCTs) due to pragmatic limitations in blinding investigators and subjects; the iterative nature of medtech innovation and associated operator learning curves; operator variation; and organizational changes often required to adopt a new medical technology. Although “real-world evidence” (RWE), such as data from electronic health records (EHRs), billing claims, registries, and patient-reported outcome measures (PROMs) grow in importance, many US and European payers still cite Level I/II evidence as the most valuable for decision making. This panel session will afford attendees to hear directly from seasoned representatives from the payor community, as well as industry health economics professionals, about what type of evidence is viewed as most informative to medtech coverage and reimbursement decision making.

Health Care Fraud: The Government View and the Compliance Perspective

Wednesday, September 25 | 8:30 AM - 9:30 AM

Panel Session

In the last several years, government scrutiny of the health care industry has significantly increased, with 2018 bringing the largest health care enforcement action in the Department of Justice’s history. Medical device and pharmaceutical manufacturers, health care providers, insurers and other players in the industry have been paying close attention and ramping up compliance efforts to ensure they are not the subject of the next big enforcement action. This panel will bring together current and former prosecutors to discuss hot topics at the intersection of government enforcement and industry compliance. Speakers, including the acting chief of the nation’s most active enforcement authority in health care cases, will cover the government’s enforcement priorities in the health care industry — from drug pricing and reimbursement to opioid diversion.

Attendees will also hear the unique insights of former prosecutors who now handle compliance for health care organizations. They will discuss the issues keeping them up at night and how their organizations are responding, including providing practical advice that attendees can apply to their own compliance function.

Beyond Silos: Fusing Digital Across the Enterprise

Wednesday, September 25 | 9:00 AM - 9:30 AM

MedTech Exec Talks

Medical device and diagnostics companies are actively embracing digital initiatives to address evolving provider and consumer demand for convenience and outcomes validation. However, most digital initiatives are consumer/customer or “front office” facing with “back office” functions operating in more traditional forms. This dichotomy of a digital front office and traditional back office presents operational and financial risk as well as consumer/customer disappointment. While clinical differentiation is essential, commercial success will increasingly depend on a manufacturer’s ability to create a cohesive and fused approach to digital transformation.

Recently commission research by Cognizant along with a survey of over 500 business and technology decision makers in the US and UK revealed significant benefits for companies that can seamlessly connect front- and back-office processes. Digital transformation is not about

pilots or commercial launch of discrete apps, but transforming the enterprise to support agile management decision making to consumer/customer demands for visibility, reliability and satisfaction. Cognizant research found:

- Digital transformation maturity is driven by four key areas: process, organization, technology, and data insights

- Less than 40% of companies have aligned internal teams to put the customer at the forefront of their activities

- Back-end process teams (e.g., supply chain, finance) are the least likely to have a decision-making role in digital transformation

However, companies with higher digital maturity are 2.5 times more likely to report double digit revenue growth.

This session will share the findings of the research along with case studies and practical steps companies can take.

Personalized Medicine: Changing the Way We Think About, Identify and Manage Health

Wednesday, September 25 | 9:15 AM - 10:30 AM

Panel Session

Personalized Medicine is the ability to tailor medical treatment to reduce side effects and improve outcomes based on understand the genetic makeup of an individual patient.

Advances in molecular diagnostics and other diagnostic technologies, including data analytics, are the drivers that allow individualizing treatments to become reality. This session will feature leaders from diagnostic companies and drug developers to discuss the advances, challenges and future of personalized medicine.

Digital Transformation of the Medical Technology Market- the Disruptor or Enabler?

Wednesday, September 25 | 9:45 AM - 10:15 AM

MedTech Exec Talk

The three main pillars of digital transformation of Medical Technology industry are Care Delivery Digitization, Connected Device and, Connected Patients. The key questions this presentation would answer:

- What are the future trends of digital transformation in the industry?*
- What is likely to be shift in investments, R&D focus, partnerships and role of various stakeholders in the new digital ecosystem?*
- What is the growth opportunity of the three pillars for the insiders and outsiders of the MedTech Industry?*
- What are the Predictions for the Digital Ecosystem in the MedTech Industry in 2020?*

Medtech, Look to Marketing for the Solution

Wednesday, September 25 | 9:45 AM - 11:00 AM

Panel Session

90% of hospital execs who responded to a recent ZS survey believe that medtech manufacturers can't succeed with product innovation alone. Customers are demanding something different. A more empowered marketing capability can help medtech companies bring more personalized value to patients, providers and healthcare systems—while improving the portfolio's relevance overall. In this panel, we will explore why the industry

needs to evolve marketing's role, how to make it happen, and what benefits leading companies, customers and patients can see as a result.

Evolving Commercial Models in the New Healthcare Ecosystem

Wednesday, September 25 | 10:00 AM - 10:20 PM

With the industry changing rapidly, it isn't about the device, prescription or IT system. It's about the health care ecosystem focusing on improving patient outcomes while reducing costs. The health care industry is now a seller-beware world of super-informed, highly-connected and data-driven buyers. From precision medicine, connected platforms and apps to artificial intelligence, data and media, the future of healthcare is transforming, and commercial strategies must evolve to keep up. Join us for an in-depth look at top trends and key commercial strategies for managing these new types of buyers. We will be looking at the three drivers of change impacting commercial models: innovative technologies, changing job market and new buyer expectations. Audience takeaways include: practical insights that can be applied within your own organization, frameworks and tools to uncover potential opportunities and gaps in your commercial model and highlights from the latest research on commercial strategy and industry trends.

Global Regulatory Convergence – Emerging Trends and Future Opportunities

Wednesday, September 25 | 10:45 AM - 12:00 PM

Panel Session

The complexity of the global medical device regulatory landscape continues to increase. This session will discuss emerging trends in the regulatory landscape, taking an in depth look at global harmonization & convergence initiatives and the opportunities and challenges that lay ahead. Focus will include activities within the International Medical Devices Regulatory Forum (IMDRF), with a deep dive look at initiatives designed as building blocks for the development of a Medical Device Single Review Program (MDSRP) to ultimately enable a single regulatory pre-market review to satisfy multiple regulatory jurisdictions.

Lessons from a Legend

Wednesday, September 25 | 11:30 AM - 12:15 PM

Super Session

The recipient of this year's Lifetime Achievement Award had a long and distinguished career and made a significant impact on our industry and health care in general. Join her and several of her proteges for an hour long fireside chat about the making of a truly legendary career and the lessons learned from it.

New Diagnostic Technologies are Transforming Testing

Wednesday, September 25 | 10:45 AM - 12:00 PM

Panel Session

Emerging and innovative new technologies in diagnostics are advancing at a tremendous pace – transforming how providers and patients manage health. The session, led by IQVIA, an organization with deep experience in helping healthcare companies innovate to drive human health forward, will examine and showcase new diagnostic technologies that are creating opportunities for clinical laboratories and physicians make faster, more accurate diagnosis.

The Changing Payer/Provider Landscape: Opportunities for Medtech

Wednesday, September 25 | 11:15 AM - 11:45 AM

MedTech Exec Talk

Transitioning to value-based care models pose transformational and financial challenges for the medtech industry. One of the biggest shifts companies have to address is the development of relationships and creation of partnerships among the providers, health plans and life sciences companies. The session will address issues such as program structure, financial considerations, reporting and patient engagement in the context of developing these partnerships. Additionally, the session will discuss how, when done well, collaboration between these three parties can lead to a patient experience that is a competitive and strategic differentiator.

Participants in this session will hear presenters discuss:

- *The value based care “triangle” and inter-connections of payers, providers and life sciences companies*
- *Examples of value created from medical device and diagnostics partnerships*
- *Best practices in implementing value-based care processes*

What Do Hospital Administrators Really Want?

Wednesday, September 25 | 11:15 AM - 12:15 PM

Panel Session

Hospital mergers and acquisitions, group purchasing organizations (GPOs), integrated delivery networks (IDNs), accountable care organizations (ACOs), and Value-Added Committees (VACs) have high expectations that their hospital administrators (HA) skill sets are growing in sophistication. The impact on traditional medical device/diagnostic sales and marketing strategies is profound and keeping up with HA learning curves and expectations can be difficult. What are the most recent trends in HA decision-making processes and how can we integrate those into our own sales and marketing programs? How can medical device companies appeal to the economic buyer and:

- *Charge a price premium?*
- *Create meaningful value propositions for disruptive medtech products?*
- *Integrate advances in technology and analytics and leapfrog the competition?*
- *Identify buyer segments that will respond to a strong clinical value proposition?*
- *Arm a clinical champion with the tools needed to grow HA interest?*

This panel will consist of a moderator and three market leaders in medical devices responding to the finding of qualitative research with hospital administrators.

Everyone Knows Health Care Is DOJ's Favorite Target; What Does That Mean for MedTech Executives?

Wednesday, September 25 | 12:00 PM - 12:30 PM

MedTech Exec Talks

Unfortunately, it's become abundantly clear that health care has become DOJ's favorite target. Recent policy pronouncements and enforcement trends indicate an important shift to the ways in which companies, their management, and their board members need to handle investigations and compliance. This panel will explore very recent DOJ enforcement rulings, trends and policy pronouncements with the goal of providing valuable take-away

lessons/information that addresses best practices for companies, executives and board member intent on avoiding, if not surviving, a DOJ investigation.

CDRH Town Hall

Wednesday, September 25 | 2:15 PM - 4:00 PM

Super Session

Join us for an exclusive peek into FDA's Center for Devices and Radiological Health (CDRH) during our Wednesday afternoon CDRH Town Hall. This is a rare opportunity to interact directly with Dr. Jeffrey Shuren and other senior office leaders from CDRH. After Dr. Shuren provides an update on CDRH priorities, panelists will answer specific questions from the audience. Take advantage of this session and get answers to all of your burning questions directly from CDRH.