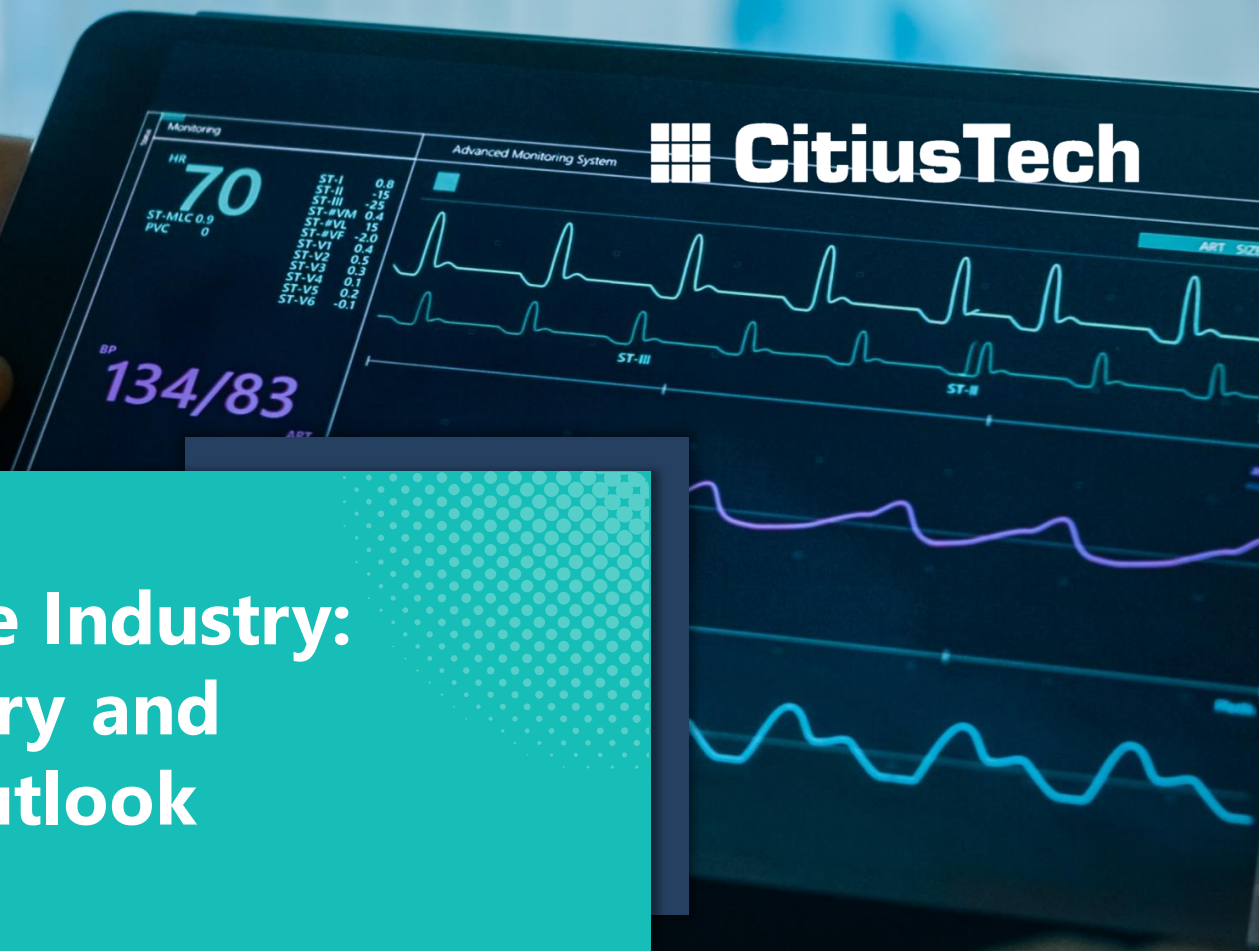


Powering the Future
of Healthcare ▶

 **CitiusTech**



Medical Device Industry: 2021 Regulatory and Technology Outlook

www.citiustech.com

Medical Device Industry: Emerging Trends

In-hospital

- Patient Surveillance
- Connected Equipment
- RTLS
- Smart QR



In-clinic

- Handheld Devices
- Ambulatory Therapies
- Lab-on-a-chip
- Co-ordinated care

On-body

- Smart Devices
- Implants
- Wearables
- Peripherals

In-home

- Digital Assistants
- Activity Monitoring
- Telehealth Consultations
- Home Medical Devices

Trends

- Consumers are increasingly turning to wearables and mHealth apps to drive physical and mental wellness
- Connected medical devices and advancements in software that capture and analyze device data has led to improved delivery of care and new product development
- There is a need to accelerate remote device management and servicing solutions to optimize cost
- Adoption of emerging technologies is essential to drive digital transformation in the medical device industry

\$602 Bn

Global medical devices market

\$1.1 Tn

Remote monitoring healthcare market

CAGR >39%

Wearable medical devices market

\$289 Bn

mHealth industry valuation by 2025

Shifting Focus: Medical Device Industry

One size fits all approach



**Personalized
medicine**

*Fragmented, one-way
information flow*



**Integrated, two-way
information exchange**

*Centralized, hospital-
based locations*



**Decentralized,
community-based**

*Individual, expert-based
decision making*



**Protocols and
analytics driven**

Treating sickness



Preventing sickness

Medical Devices: Key Regulations & Standards

The **FDA's** Center for Devices and Radiological Health (CDRH) regulates medical devices in US. All devices are classified into **3 classes** & **16 medical specialties / panels** (defined in 21 CFR 800-898)

Device Regulations

Digital Health Software Pre-certification Program

- Part of FDA's Digital Health Innovation Action Plan
- Identify manufacturers - quality & organizational excellence
- Streamline the FDA approval processes

Draft Regulation for AI/ML based SaMD

- New regulation for adapting evolving AI/ML devices
- New controls: SaMD Pre-Specifications (SPS) & Algorithm Change Plan (ACP)

ISO/TR 80002-2:2017 Medical Device Software - Part 2

- Validation of software for medical device quality systems

New Laws (2020)

Regulatory Standards

- FDA Section 506J - Mitigate medical device shortages during a public health emergency
- USA: FDA Title 21, CFR Part 11, Part 820
- EU: MDR & IVDR (replacing 90/385/EEC; 93/42/EEC; 98/79/EC)

Impact of 21st Century Cures Act

- Medical device & reporting exemptions to select software & accessories respectively
- Quick review of "Breakthrough Devices"
- Updated device clinical trial requirements
- Changes to safety / effectiveness clauses of devices

Standards

Subchapter H - Part 800 (Devices)

- Device classification
- Medical devices – approvals, packaging, and reporting
- Quality systems regulations

Product Standard

- IEC 60601-1/2, IEC 61010-1: Medical Elec. Equipment Safety

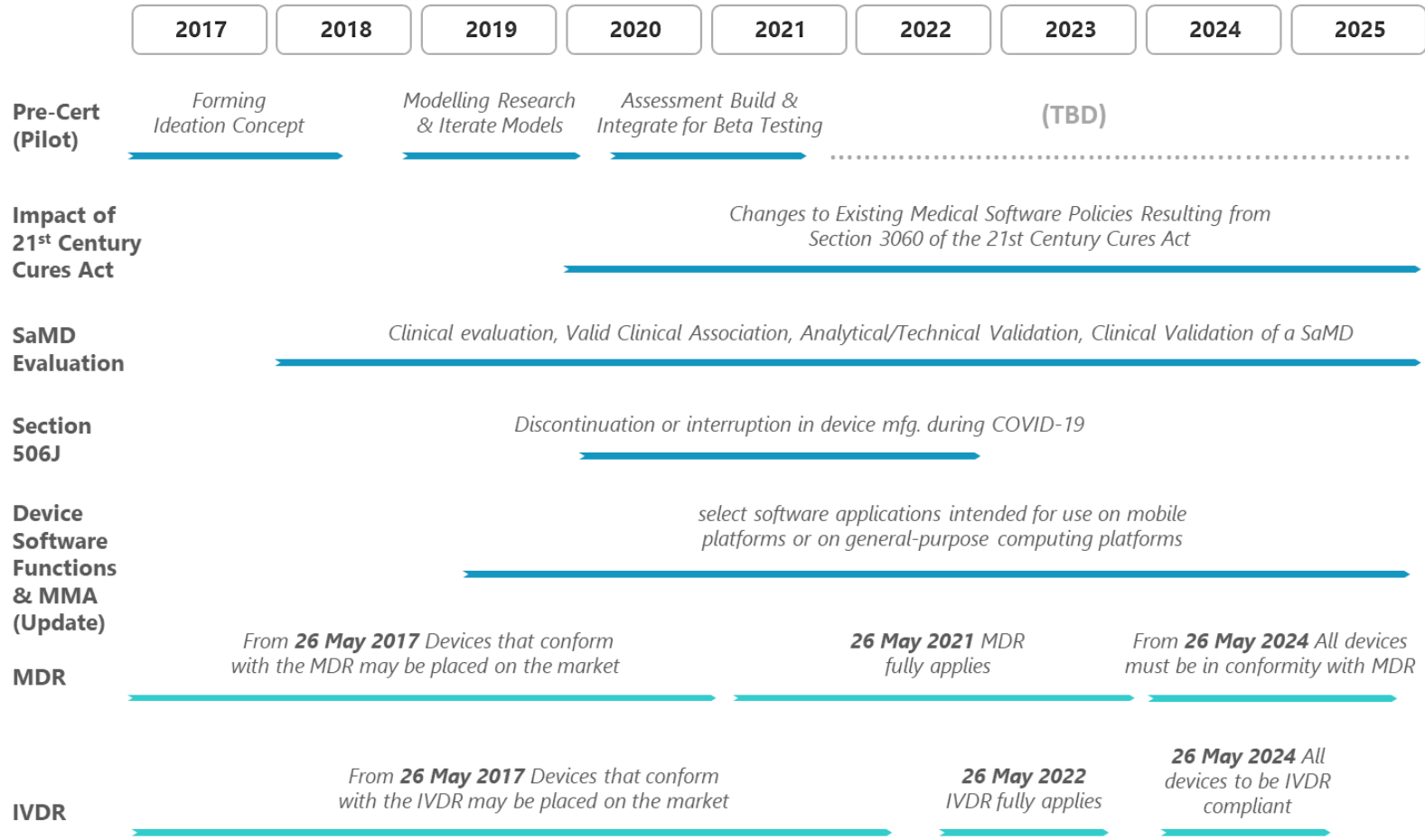
Quality & Risk Management

- ISO 13485 based QS regulation
- ISO 14971 risk management
- ISO 31000:2018 principles & generic guidelines on risk mgmt.

Process Standards

- IEC 62304: Medical Device Software Lifecycle

Timeline: Medical Device Regulations



Emerging Technology: Use Cases (1/2)



Smart Devices & Wearables

- Smart IoT enabled devices & wearables with decision support alerts for enhancing clinical workflows
 - AI-based SaMD development for disease diagnosis, care management and therapeutics
-



Patient & Provider Engagement

- Mobile medical apps including chatbots for teleconsultation, patient education and surveys
 - Apps for care coordination, wellness management and personalized care
-



Legacy Device Digitization

- Digital enablement through robust connectivity with data platform and cybersecurity
 - Software modernization, cloud migration with microservices, containerization, etc.
-



Remote Monitoring

- 24x7 access to patient vitals using remote monitoring devices can drive clinical interventions
 - Track trends in device utilization, connectivity, battery level, performance, etc.
-



Intelligent Automation

- Automated status tracking of documents and compilation of records necessary for regulatory submissions
- Adverse event reporting and recalls management using RPA bots

Emerging Technology: Use Cases (2/2)



Proactive Device Maintenance

- Predictive analytics for proactive device maintenance and service scheduling
 - Streaming device data analytics to drive remote device configuration and updates
-



Smart Surgery

- Simulators for surgery planning and smart wearables for health monitoring post surgery
 - Telesurgery using remote surgery robots
-



Digital Twin

- Digital simulations of device twin to provide risk free virtual environment for device testing
 - Digital implant prototypes for accurate design, optimal size to fit patient, saving time & cost
-



Medical Imaging

- VR and AR medical Imaging apps for pain management, virtual environment for physical therapy
- Image analysis for lung cancer risk quantification by processing raw CT / MR images from modalities

Emerging Digital Therapeutics: Use Cases (1/2)

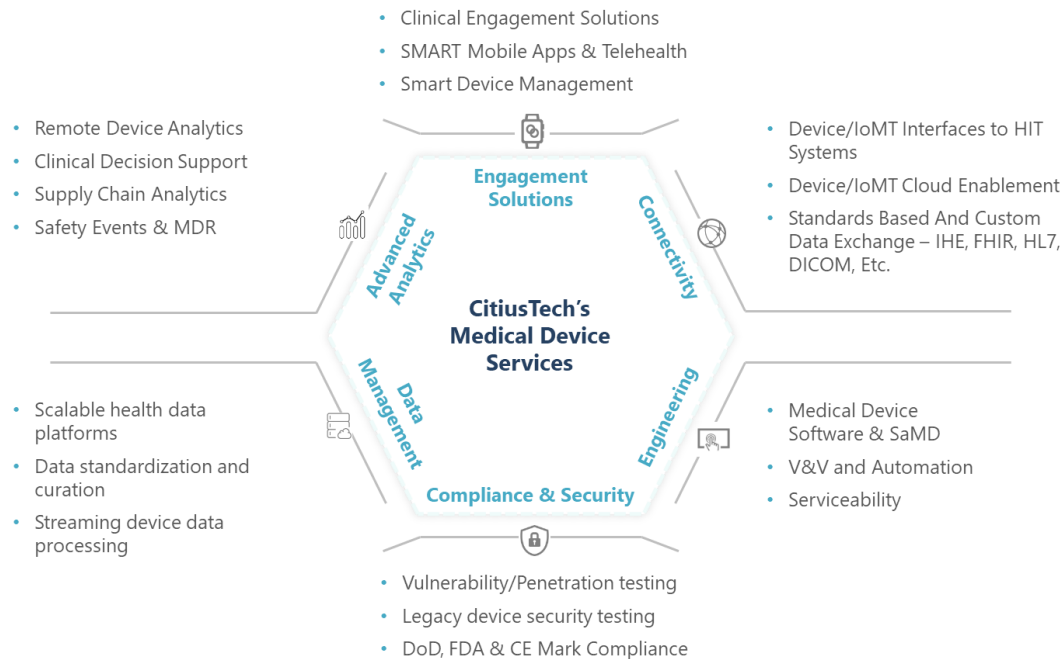
Therapeutic Area	Healthcare decision	Use case
Pulmonology	Diagnose	Perform analysis of cerebrospinal fluid spectroscopy data to diagnose tuberculosis meningitis or viral meningitis in children
Pulmonology	Drive Clinical Management	Use the microphone of a smart device to detect interrupted breathing during sleep and sound a tone to rouse the sleeper
Pulmonology	Inform Clinical Management	Collect output from a ventilator about a patient's carbon dioxide level and transmit the information to a central patient data repository for further consideration
Oncology	Diagnose	Calculate the fractal dimension of a lesion and surrounding skin and build a structural map that reveals the different growth patterns to provide diagnosis or identify if the lesion is malignant or benign
Infectious Disease	Diagnose	Combine data from immunoassays to screen for mutable pathogens / pandemic outbreak that can be highly communicable through direct contact or other means
Dermatology	Diagnose	Diagnose if a skin lesion is malignant or benign by taking pictures and monitoring the growth over time

Emerging Digital Therapeutics: Use Cases (2/2)

Therapeutic Area	Healthcare decision	Use case
Cardiology	Inform Clinical Management	Use data from individuals for predicting risk score for developing stroke or heart disease for creating prevention or interventional strategies
Nephrology	Drive Clinical Management	Calculate bolus insulin dose based on carbohydrate intake, premeal blood glucose, & anticipated physical activity reported to adjust carbohydrate ratio and basal insulin
Audiology	Treatment	Provide sound therapy to treat, mitigate or reduce effects of tinnitus for which minor therapeutic intervention is useful
Audiology	Inform Clinical Management	Use hearing sensitivity, speech in noise, and answers to a questionnaire about common listening situations to self-assess for hearing loss
Cardiology, Nephrology	Diagnose	Integrate and analyze multiple tests to provide recommendations for diagnosis in certain clinical indications, e.g., kidney function, cardiac risk, iron & anemia assessment
Cardiology, Pulmonology	Drive Clinical Management	Receive data from wearable health sensors for patients with multiple chronic conditions, transmit data to monitoring server, and identify higher-level information such as tachycardia and respiratory infections and communicates this information to caregivers

CitiusTech Offerings: Medical Devices

CitiusTech Medical Device offerings cover the end-to-end development, testing, clinical integration, security and support aspects of the product lifecycle



Recent Experience

- *Infusion Pumps Integration using IHE*
- *Product Identification IoT Platform*
- *ML Dose Optimization SaMD with 510(K) submissions for SaMD*
- *Embedded Development for CRRT Device*
- *Surgeon iPad application for Medical Device Data System*
- *DoD & FDA compliance on cybersecurity for CT Scan devices*

250+

Medical device Professionals

20+

Medical device engagements

25+

Types of Medical Devices Connected

ISO 13485:2016

Certified for Medical Device QMS

IEC 62366:2015

Usability engineering of medical devices

IEC 62304:2019

Medical Device Software Lifecycle Processes

About CitiusTech

CitiusTech (www.citiustech.com) is a leading provider of healthcare technology services, solutions and platforms to over 130 organizations across the payer, provider, medical technology and life sciences markets. With over 5,000 technology professionals worldwide, CitiusTech powers healthcare digital transformation through next-generation technologies, solutions and accelerators. Key focus areas include healthcare interoperability & data management, quality & performance analytics, value-based care, omni-channel member experience, connected health, virtual care coordination & delivery, personalized medicine and population health management.

CitiusTech has two subsidiaries, FluidEdge Consulting (www.fluidedgeconsulting.com) and SDLC Partners (www.sdlcpartners.com), with deep expertise in healthcare consulting and payer technologies, respectively. CitiusTech's cutting-edge technology expertise, deep healthcare domain expertise and a strong focus on digital transformation enables healthcare organizations to reinvent themselves to deliver better outcomes, accelerate growth, drive efficiencies, and ultimately make a meaningful impact to patients.

130+
healthcare clients

\$300M+
worldwide revenue

5,000+
healthcare IT professionals

40M+
lives touched

80+
NPS - highest in the industry!



Powering the future of healthcare ▶



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