CitiusTech

Medical Device Industry:
2021 Regulatory and Technology Outlook

The medical device industry will face a series of regulatory challenges in 2021. Staying abreast of emerging technology & regulatory trends can help organizations better navigate the evolving regulatory changes and stay competitive.

- Industry trends and focus areas
- Classification of medical devices
- Key standards and regulations
- Emerging technology use cases

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

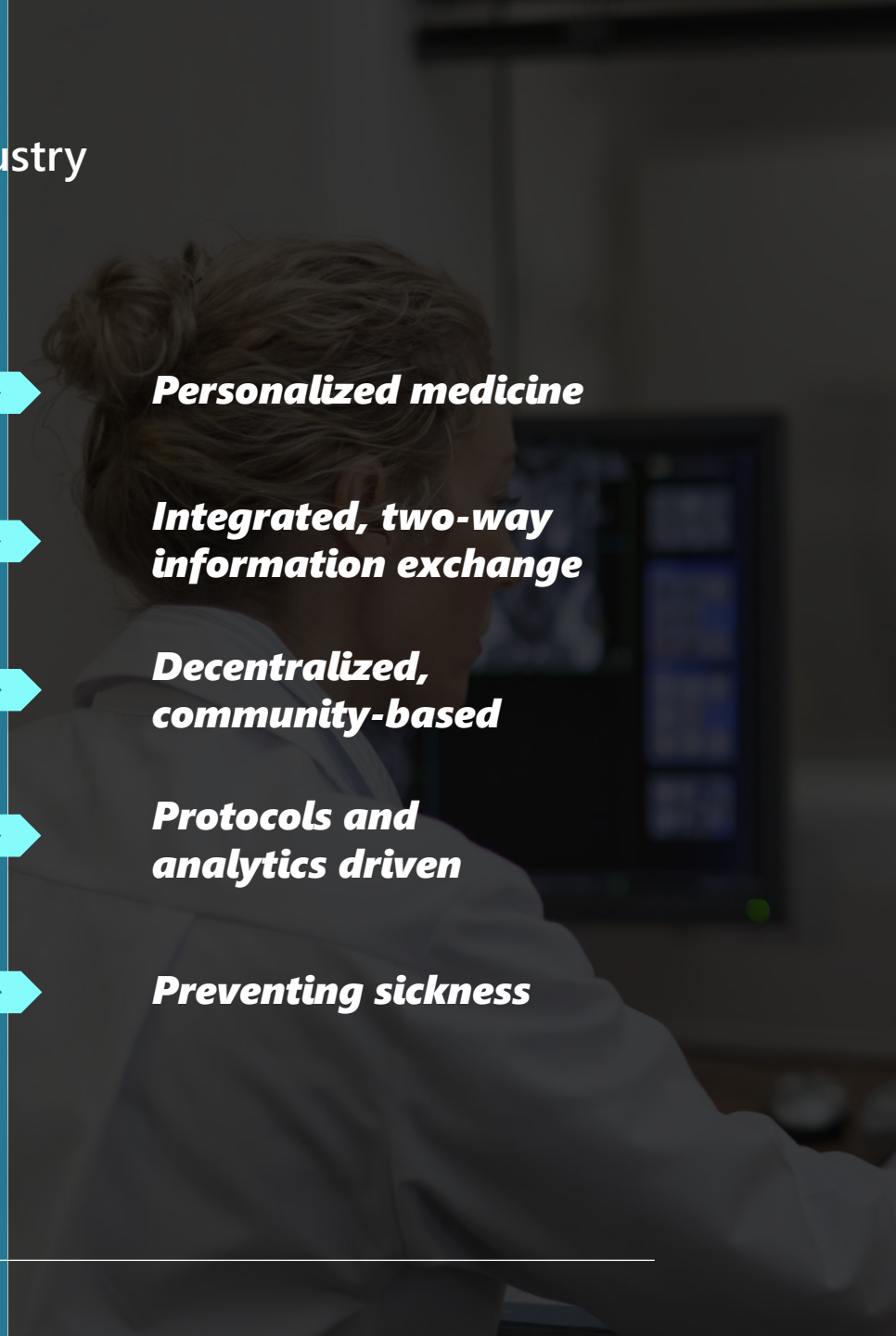
- Digital Assistants
- Activity Monitoring
- Telehealth Consultations
- Home Medical Devices

Trends

- The COVID19 pandemic has accelerated the need for *remote device management* and servicing solutions
- 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*
- Adoption of emerging technologies is essential to *drive digital transformation* in the medical device industry

$602 Bn	$1.1 Tn	CAGR >39%	$289 Bn
Global medical devices market	Remote monitoring healthcare market	Wearable medical devices market	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 Electrical 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

US EU

2017	2018	2019	2020	2021	2022	2023	2024	2025

Pre-Cert (Pilot)

Forming Ideation Concept — *Modelling Research & Iterate Models* — *Assessment Build & Integrate for Beta Testing* — (TBD)

Impact of 21st Century Cures Act

Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act

SaMD Evaluation

Clinical Evaluation, Valid Clinical Association, Analytical / Technical Validation, Clinical Validation of a SaMD

Section 506J

Discontinuation or Interruption in Device Mfg. During COVID-19

Device Software Functions & MMA (Update)

Select Software Applications Intended for Use on Mobile Platforms / On General-purpose Computing Platforms

MDR

*From **26 May 2017** Devices that Conform with the MDR may Be Placed on the Market*

***26 May 2021** MDR Fully Applies*

*From **26 May 2024** All Devices must be in Conformity with MDR*

IVDR

*From **26 May 2017** Devices that Conform with the IVDR may be Placed on the Market*

***26 May 2022** IVDR Fully Applies*

***26 May 2024** All Devices to be IVDR Compliant*

Emerging Technology: Use Cases (1/2)

Smart Devices

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

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

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.

Emerging Technology: Use Cases (2/2)

Medical Imaging

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

Proactive Device Maintenance

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

Patient & Provider Engagement

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

Smart Surgery

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

CitiusTech Offerings: Medical Devices

Engagement Solutions

- Clinical Engagement Solutions
- SMART Mobile Apps and Telehealth
- Smart Device Management

Compliance & Security

- Vulnerability / Penetration Testing
- Legacy Device Security Testing
- DoD, FDA, and CE Mark Compliance

Connectivity

- IoMT Interfaces for HIT Systems
- IoMT Cloud Enablement
- Standards Based Custom Data Exchange

Data Management

- Scalable Health Data Platforms
- Data Standardization and Curation
- Streaming Device Data Processing

Engineering

- Medical Device Software & SaMD
- V&V and Automation
- Serviceability

Advanced Analytics

- Remote Device Analytics
- Clinical Decision Support
- Supply Chain Analytics
- Safety Events and MDR

CitiusTech's medical device solutions cover the end-to-end development, testing, clinical integration, security, and support activities across the product lifecycle

About CitiusTech

CitiusTech enables healthcare organizations to drive clinical value chain excellence, across integration & interop, data management (EDW, Big Data), performance management (BI / analytics), data science (predictive analytics, AI, ML) and digital engagement (cloud, mobile, IoT).

CitiusTech Medical Device Solutions

CitiusTech has a dedicated Medical Device Practice that works with some of the world's leading healthcare technology companies to solve key industry challenges such as interoperability, patient monitoring, and analytics.

The Medical Device practice has deep clinical data expertise. It has executed multiple projects dealing with massive amounts of clinical and operational data generated by connected devices across expansive ecosystems and deploying AI / Machine Learning models to enhance clinical performance.

400+	**Top 5**	**500+**
Medical device experts	Medical device companies as clients	HL7, FHIR certified professionals

$205+ Mn
in revenue

4,000+
healthcare IT professionals

40 Mn+
lives touched

69+
NPS - highest in the industry!

110+
healthcare customers