



FACT SHEET

CONNECT YOUR MEDICAL DEVICE DATA TO THE CLOUD

For hospitals, life sciences, healthcare providers, patient engagement and medical device manufacturers



INCREASED INTEROPERABILITY AND CONNECTIVITY ENABLE DEEPER ANALYTICS FOR BETTER PATIENT ENGAGEMENT AND CARE

Major advances in digital are driving the MedTech and IoMT (Internet of Medical Things) industry.

A growing number of internet-connected medical devices create the ability to generate, collect, analyze, and transmit critical health data to improve care while gaining substantial operational efficiencies. The problem that companies face, however, is that to take advantage of this collected data, you need to have secure, high-performance device connectivity in the cloud that can provide actionable insights and, importantly, a patient-centric approach.



Apexon is a digitally native company that helps MedTech and IoMT companies analyze, operationalize and connect the data in their devices to enable more efficient, innovative, and modern patient and provider experiences.

We work with leaders across the Life Sciences ecosystem, including device makers, biotech companies, providers and contract research organizations (CRO) throughout the product lifecycle to bring their innovations to market faster with greater functionality.

HOW WE DELIVER



UNIQUE TECHNOLOGY
ACCELERATORS FOR
FASTER TIME TO MARKET



CLIENT-FIRST
CULTURE



DEEP EXPERTISE
IN EMERGING
TECHNOLOGIES



DATA ENABLEMENT
AND CLOUD EXPERTISE



DISTRIBUTED AGILE
GLOBAL TEAMS



PROGRESSIVE
DELIVERY



DATA-DRIVEN
USER EXPERIENCE

CHALLENGES & TRENDS

MEDTECH & IOMT

MEDTECH TRENDS



Telemedicine

As remote health takes priority, IoMTs require health data to be transmitted continuously and dependably.



Patient-Centric Care

As patients take more responsibility for their care and utilize technology to track their wellness, providers want to take advantage of the latest advances in health apps, SaMD, and IoMT. In addition, the need to inform patients on treatment, medications and recuperation requires flexible access and utilization of patient data.



Digital Therapeutics (DTx)

The increase in remote access to therapies, and the dominant role of AI and mobile technology have broadened the possibilities of DTx. Provider and device makers need to be able to take advantage of these advancements.



Remote Patient Monitoring

Effective and efficient treatment for chronic diseases requires remote patient monitoring. To achieve that, device makers and providers need the right combination of IT infrastructure, cloud computing, and edge analytics.

TECHNOLOGY IMPLEMENTATION CHALLENGES



Device & Data Connectivity

The real promise of the latest medical devices is the ability to get the data captured by the device into the cloud where it can be analyzed and accessed by providers and patients.



Interoperability

There is a critical need for high levels of system interoperability and real-time data access. Standards like FHIR promise to provide modern and web-based suites of API technology.



Regulatory Requirements

Regulatory compliance and approval have a huge impact on time to market. This requires an experienced technology partner that understands these complex processes and laws.



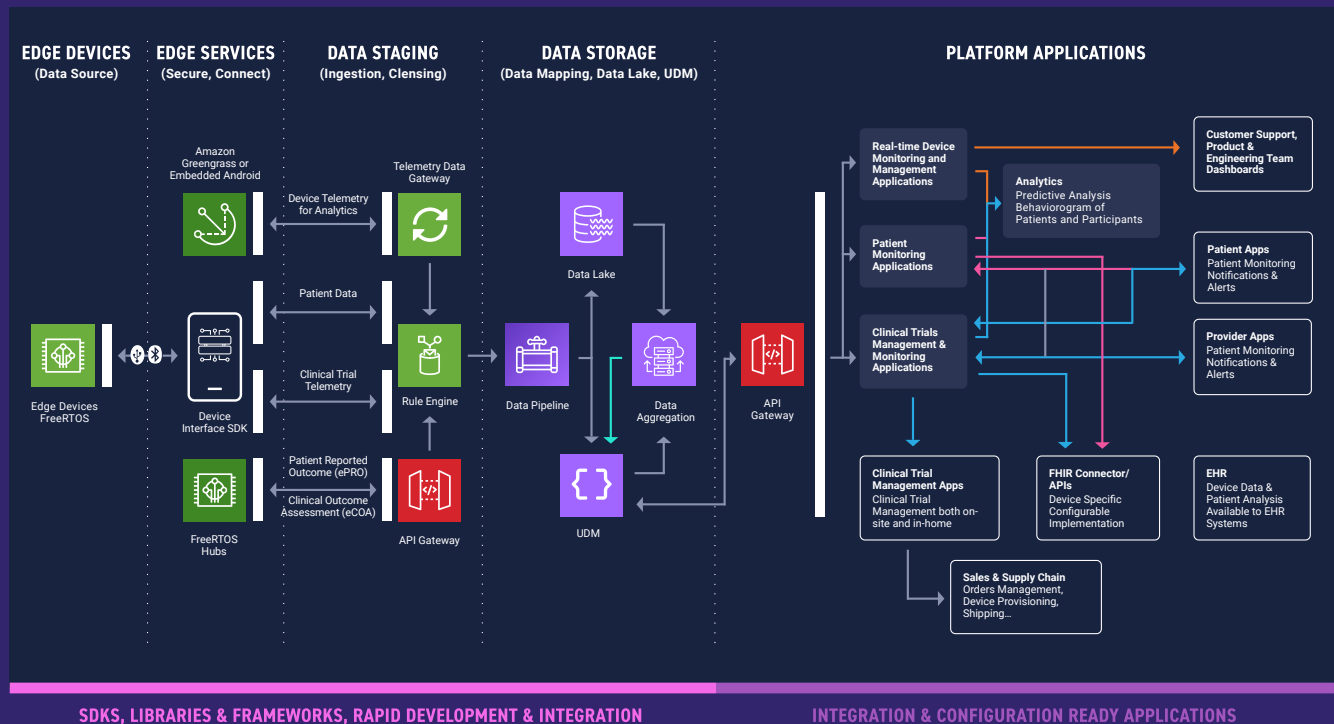
Data Security

As continuous patient monitoring increases, both invasive and non-invasive connected devices are at risk of data breaches, putting both providers and patients at risk.

IOMT FRAMEWORK

Digital healthcare's evolution has not happened overnight. The use of MedTech to provide care and wellness solutions has been growing steadily for a decade, but the effectiveness of providers and healthcare professionals increasingly relies on connected IoMT solutions to help diagnose, monitor or treat patients and their specific needs.

Apexon's IoMT Framework addresses this as an ecosystem in the following ways:



TECHNOLOGY IMPLEMENTATION CHALLENGES

MEDICAL DEVICE FIRMWARE

Design, development and testing

MEDICAL DEVICE SOFTWARE & MOBILE MEDICAL APPLICATION

Companion application development, re-engineering

VERIFICATION & VALIDATION

Human subject validation, design verification, system verification and tools validation

TEST AUTOMATION

Automation framework development and automation scripting

CLOUD ENABLEMENT

Cloud engineering, re-engineering and migration

CONNECTIVITY AND INTEROPERABILITY

Ingestible and medical imaging, tracking and analytics, BLE connectivity, workflow management, Lab-as-a-Service, HL7

PRODUCT LIFE CYCLE MANAGEMENT

PLM strategy, roadmap, evaluation and implementation

REGULATORY COMPLIANCE

Documentation, DHF creating and remediation, CAPA, FDA compliance and pre-compliance testing

PATIENT & PHYSICIAN APPS & PORTALS

Interfacing with sensors, personal care and wearable devices and apps

DIGITAL TWIN

Define parameters and duration to make making robust twin for better prediction, play

CUSTOMER SEGMENTS

- Medical Device Manufacturers
- Healthcare Providers (HCP)
- MedTech Startups
- Life Sciences
- Clinical Research Organizations (CRO)

MEDICAL DEVICES

CONNECTED DEVICE = PATIENT CARE



FIRMWARE



CONNECTIVITY



CLOUD



AUTOMATION



DATA



REGULATORY
COMPLIANCE



PRODUCT LIFE CYCLE
MANAGEMENT



CONSUMER HEALTH
WEARABLES



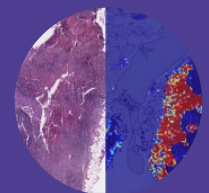
CLINICAL-GRADE
MEDICAL DEVICES



INGESTIBLE
SENSORS



IMPLANTABLE
MEDICAL DEVICES



IN-CLINIC /
IN-HOSPITAL DEVICES

CERTIFICATIONS/ STANDARDS

FDA

SaMD categories I, II, III, IV
Medical Devices V&V:
- 21 CFR 820, 30
- 21 CFR Part 11
MDDS Class I, II, III

Interoperability

HL7 v2 / v3
- CDA
- FHIR
EDI v12

Care Delivery

HL7 v2 / v3
SNOMED CT
LIONIC
ICD
CPT

DEVICES TO CARE COMPONENTS



Edge IOs

Data logging
and controlling



Processing & Communication Gateways

Data acquisition,
controlling,
wireless interfaces,
wireless protocols



Patient & Provider Engagement & Integrations

Business use
cases, data
visualization



Cloud Solution Layer

Presentation and
cloud architecture



Data Engineering

Presentation,
data engineering
analytics

DELIVERING RESULTS FOR OUR MEDTECH AND IOMT CLIENTS



Improved Medical Device Platform

Enhanced mobile and web platform for type-1 diabetes patients and created scalable solution for BLE health data, encryption, and personalization driven by algorithms for CGM medical device.

Multinational
Healthcare Company

FDA-Compliant SaMD

Led development and supported FDA compliance requirements from concept to launch for this companion mobile app for SaMD.



Ingestible Digital Medicine

Led ideation, development, and V&V of this FDA-approved MDDS class-II ingestible digital medicine including high-performance BLE connectivity and support for HIPAA and CFR compliance.



Wearable Breast Pump Technology Solution

Developed companion mobile app and automated firmware testing, while meeting FDA compliance requirements. Resulted in faster time to market and lower development costs.



Body sensor and the IoT ecosystem

Developed the front-end user experience on the patient portal for their main IoT product, and we are also building the Android-based app that communicates with and controls the IoT based products. In addition, we are involved in developing the companion app, web app, CI/CD over cloud, the secure AWS workspace and patient monitoring on the web app. This latter project includes patient engagement analytics, end-to-end quality assurance for deliverables and a potential headwind into the firmware side of the business.

PARTNER ECOSYSTEM



As an Advanced Consulting Partner, Apexon leverages our in-house access to AWS Certified experts to help companies optimize their cloud strategies and accelerate the time to market.

With access to AWS Centers of Excellence in Digital Engineering, DevSecOps, Data Analytics and IoT, we can offer key deliverables and actionable insights through cloud solutions.



Our partnership helps organizations move to the cloud at speed increasing application availability, technical flexibility and security improvements.



Apexon is a pure-play digital engineering services firm focused on helping companies accelerate their digital initiatives from strategy and planning through execution. We leverage deep technical expertise, Agile methodologies and data-driven intelligence to modernize systems of engagement and simplify human/tech interaction.

We deliver custom solutions that meet customers' technology needs wherever they are in their digital lifecycle. Backed by Goldman Sachs and Everstone Capital, Apexon works with both large enterprises and emerging innovators — putting digital to work to enable new products and business models, engage with customers in new ways, and create sustainable competitive differentiation.

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FEELING SOCIAL?

