L&T Technology Services

Next-Gen Healthcare through SaMD

Software-driven solutions for Healthcare

OVERVIEW

A Clinical Evaluation Report (CER) documents the conclusions of a clinical evaluation of your medical device. It consists of analyzed clinical data collected either duringAs per the International Medical Device Regulators Forum (IMDRF) document (IMDRF/SaMD WG/N10 FINAL:2013), Software as a Medical Device (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device. a clinical investigation of your device, or collated from the results of studies on substantially equivalent devices.A favorable CER demonstrates that your device achieves its intended purpose without exposing users and patients to additional risks.

THE BENEFITS

- SaMD can facilitate rapid data collection and analysis – far outpacing the capabilities of human operators working in clinical management
- Smart devices can monitor real-time data and triggers patterns for investigation
- Regulatory compliance can boost device efficacy and increase adaptation and usage

THE CHALLENGE

While SaMD has the potential to offer tremendous benefits to the healthcare system, we need to overcome challenges around:

- Tailoring regulatory framework for AI/ML-based SaMD
- Integrating modern product development methodology with patient safety and regulatory compliance
- Frequent software updates that can hamper the effectiveness of the software-driven product

OUR APPROACH

Across software lifecycle

Adaptive maintenance, Perfective maintenance, Corrective maintenance, Preventive maintenance

KEY DIFFERENTIATORS

- Experience in Grounds Design and Development of medical applications with end-to-end documentation support
- Enabling regulatory compliance with code reverse-engineering designs generating traceability
- Expertise in MLaMD (Machine learning as Medical device) and FHIR
- A consulting approach to provide market fit and innovative solutions
- End to end cross-channel experience for Product extension (Web, Mobile Apps)
- Expertise in interoperability and connectivity – Standards- based HL7, FHIR, DICOM, MLaMD (Machine learning as Medical device BLE, RFID, NFC, Cellular, WiFi. and many more.

OUR SUCCESS STORIES

Blood Glucose Monitoring

Designed and developed an application on iOS and Android platforms to read and record insulin dose information and blood glucose of a patient by connecting over BLE

NEXT-GEN Smart inhaler

Designed and developed a software on iOS for patient adherence, medication management, dosage alerts, and physician data sharing

SaMD Regulation Documentary Support

Supported in the labeling of the devices with adequate regulatory documentation and approval

Reduced time to market by 60%

Sleep Diagnostic Application

Developed a complete robust suite for clinical applications in neurology for EEG, Long-term Epilepsy Monitoring(LTM), and Sleep Monitoring

The solution enables the integration of HL7 capabilities for the exchange, integration, sharing, and retrieval of electronic health information for better ease of use

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ENGINEERING **THE CHANGE**