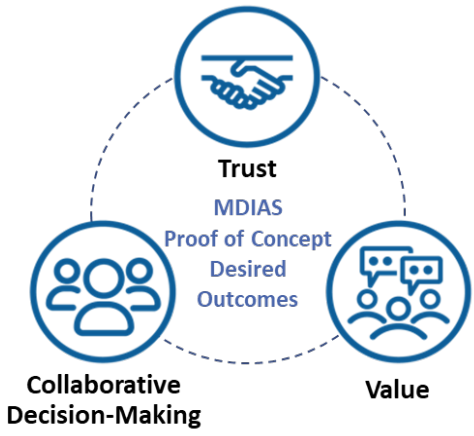
Fact Sheet

MDIAS Proof of Concept (POC) Overview

POC Overview



Since its inception in 2020, the Medical Device Information Analysis and Sharing (MDIAS) initiative – a voluntary partnership between the government and the private sector formed to proactively analyze broad and extensive medical device-related data – has been executing a Proof of Concept (POC). The purpose of the POC is explore how the MDIAS partnership model could operate and whether it could advance device quality and patient safety.

The MDIAS Early Adopters, which include medical device manufacturers, a hospital system, and the Food and Drug Administration (FDA), have been working in collaboration with the MITRE Corporation, the MDIAS Trusted Third Party (TTP), to execute the POC in two phases.

POC Phase 1 – Public Data Studies

In Phase 1, the MDIAS Early Adopters selected and executed two studies using public data from OpenFDA. These studies that ended in September 2021, were chosen to build a singular database comprised of public datasets with high relevance to medical device quality and patient safety.

Study 1: How are Primary Root Causes of Recalls Distributed?

Purpose: To understand trends and outliers in recalls.

Outputs: MDIAS provided interactive data visualizations in the form of dashboards that show trends for the root causes of recalls from 2010 to 2019, and benchmark analysis for each early adopter organization.

Study 2: Are Medical Device Reports (MDRs) Predictive of Recalls?

Purpose: To evaluate if MDRs are predictive of recalls and to what extent.

Outputs: The outputs include an ensemble model which provides a probability of recall per device, along with an evaluation of the model on its accuracy and ability to predict. The predictive ensemble model and refinement resulted in an ability to detect 72% of recall events.

POC Phase 2 – Complaints Study

In Phase 2, MDIAS is selecting and embarking on studies that leverage non-public data from MDIAS Early Adopters. The MDIAS Governing Committee selected four phase 2 studies, the first of which, the Complaints Study, began in late 2023.The Complaints Study examines the relationship between medical device complaints and recalls. The use of non-public data requires formalizing participation in MDIAS through the signing of the Cooperative Agreement, a legal document enabling MDIAS Early Adopters to share data with MITRE (the TTP). The Early Adopter organizations and MITRE (the TTP) are working together to define expectations and dependencies for formalizing participation for partners and data contributors.