Fact Sheet

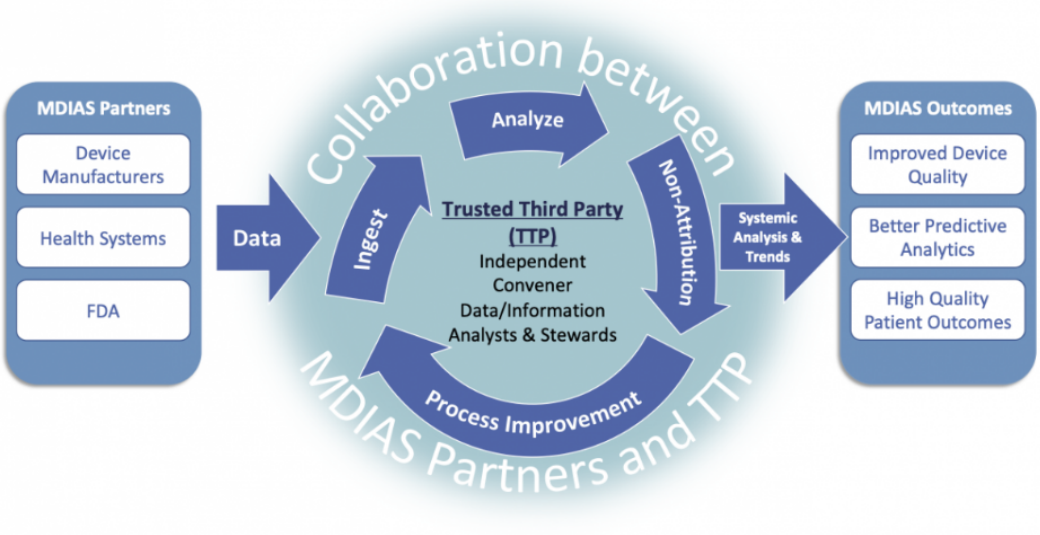
Medical Device Information Analysis and Sharing (MDIAS)

MDIAS Overview

The Medical Device Information Analysis and Sharing (MDIAS) initiative is a voluntary partnership between the government and the private sector formed to proactively analyze broad and extensive medical device-related data to improve healthcare outcomes for patients. The concept stems from the recognition that data from a wide variety of sources can provide greater insights than data from a single source alone. MDIAS enables the medical device community to acquire, integrate, and analyze multiple data sources in a way that provides new insights into systemic quality issues.

How the Partnership Works

The MDIAS community includes a subset of the medical device ecosystem – device manufacturers, hospital systems, and the Food and Drug Administration (FDA) – that contribute time, expertise, and data to the effort. MDIAS Partners share data with the MITRE Corporation, the independent Trusted Third Party (TTP), who is responsible for 1) facilitating the development of MDIAS in collaboration with the medical device community and 2) receiving, storing, processing, and safeguarding data provided by industry partners. In this partnership model, the TTP works collaboratively with MDIAS Partners to conduct systemic analysis on the data and generate results for MDIAS Partners to use for organizational and system-wide performance improvement.



Benefits of MDIAS

- Improve the industry's ability to leverage data to create a knowledge-rich environment that benefits patients, the medical device ecosystem, and regulators.
- Allow manufacturers more flexibility to change, enhance, and adapt processes and products to improve quality while 1) accelerating time to market, and 2) minimizing the use of compliance audits to point out deficiencies.
- Enable pre-market approval and post-market monitoring activities associated with regulation to become more data-driven and quality-centric at FDA over time.