Straive™

Case Study

# Transforming MedTech Surveillance: Achieving 99% Accuracy in Adverse Event


## Challenge

A MedTech organization faced significant challenges in post-market surveillance for medical devices. Manual risk identification processes were time-consuming and error-prone, with inefficiencies in synthesizing insights from FDA databases and fragmented data silos.

## Approach

We implemented an end-to-end (E2E) Risk Analytics Platform that automated data collection from FDA databases using intelligent web harvesting. We combined the expertise of life sciences and biomedical instrumentation specialists with AI to create and design a comprehensive knowledge architecture. Advanced analytics were applied to identify adverse events accurately.

## Impact

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| **9M** | Processed over 9 million records from 20+ data sources |
| **200,000+** | Standardized data for 200,000+ Class II and III medical devices |
| **70,000+** | Disambiguated data from 70,000+ manufacturers |
| **99%** | Identified 4.3 million adverse events with 99% accuracy |

### About Straive

Straive is a market-leading content technology enterprise that provides data services, subject matter expertise (SME), and technology solutions to multiple domains, such as research content, eLearning/EdTech, and data/information providers. With a client base scoping 30 countries worldwide, Straive's multi-geographical resource pool is strategically located in seven countries - the Philippines, India, the United States, Nicaragua, Vietnam, the United Kingdom, and Singapore, where the company is headquartered.

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