smarteeva

PRODUCT DATA SHEET

Smarteeva
Decision Tree

AI-driven reportability decisions for medical devices. Guided workflows determine whether a complaint requires regulatory reporting based on product type, incident location, and regional regulations. Every step recorded for audit.

AI	80+	Every	ML
DRIVEN DECISIONS	COUNTRY REGULATIONS	STEP RECORDED	ENHANCED ACCURACY

KEY FEATURES

Reportability Decisions, Standardized and Recorded

Smarteeva's Decision Tree guides quality teams through reportability assessment based on product type and incident country. The system records every step, produces a standardized audit trail, and learns from historical decisions to improve accuracy over time.

01

Region-Specific Logic

Decision trees adapt to the regulatory framework of each country. FDA, EU MDR, Health Canada, TGA, and 80+ other jurisdictions supported.

02

Step-by-Step Recording

Every question answered and every path taken is logged. Re-execute with new data at any time without losing the original assessment.

03

Machine Learning Enhancement

ML models learn from historical decisions, improving the speed and consistency of reportability assessments as data accumulates.

04

Self-Service via Smart Guy

Extend decision tree functionality to web portals, mobile apps, and connected devices. Customers and field teams can initiate assessments directly.

BENEFITS

Consistency Across Every Assessment

Reportability decisions vary from person to person and shift to shift. Decision trees standardize the process so the outcome depends on the data, not who is reviewing it.

✓ **Standardized Process**
Same decision logic applied to every complaint, regardless of who reviews it.

✓ **Regulatory Compliance**
Meet FDA, EU MDR, and global reporting requirements with documented, auditable decision paths.

✓ **Reduced Errors**
Guided steps prevent skipped assessments and inconsistent coding.

✓ **Faster Decisions**
What takes 15 minutes manually takes under 2 minutes with a decision tree.

✓ **Audit Trail**
Complete record of every reportability decision, retrievable at any time.

✓ **Continuous Improvement**
ML models flag patterns where decision trees can be refined based on actual outcomes.

FROM ASSESSMENT TO S

From Assessment to Submission in One Flow

When a decision tree determines a complaint is reportable, the system automatically routes it to the adverse event module. No manual handoff. No re-entry of data. The complaint record, decision path, and all supporting data carry through.

Auto-Routing
Reportable events flow directly to adverse event processing

Multi-Country
One complaint assessed against multiple jurisdictions simultaneously

Predictive Insights
ML surfaces complaints likely to be reportable before manual review

35%
of FDA MDRs filed through Smarteeva

70%
Faster complaint resolution

96%
First-pass extraction accuracy

50K+
Users across 80+ countries

USE CASES

How Teams Use This

Incoming Complaint Triage

Every new complaint runs through the decision tree to determine reporting obligations before manual review begins.

Multi-Market Assessment

A single complaint assessed against FDA, EU MDR, Health Canada, and TGA requirements in one pass.

Customer Self-Service

Device users complete a guided complaint form that feeds directly into the reportability decision tree.

Audit Response

Pull the complete decision path for any complaint, showing every question, answer, and outcome with timestamps.

Why Companies Choose Smarteeva

⚙

Built on Salesforce

100% native. Enterprise security. Integrates with your CRM.

⚡

AI That's Auditable

Every AI decision has a traceable audit trail.

🔗

Connected by Design

All modules share one data model.

🌎

Any Size, Any Market

10-person startup to global top 100.

See Smarteeva In Your Workflow

30 minutes. Your use cases, your data, your regulatory markets. A live walkthrough configured for your team.

Book a Demo →

smarteeva.com | sales@smarteeva.com | support@smarteeva.com