



Global Diabetes Device Leader

50 manual steps per PMS report. A year to complete. Now generated in minutes.

50 steps

→ ONE-CLICK GENERATION

~1 year

→ MINUTES PER REPORT

4 types

PSUR · PMSR · HCSR · UK

Unified

SINGLE PLATFORM FOR ALL PMS

About the customer

A top global leader in diabetes management devices that needed an all-in-one post-market surveillance platform to integrate MDR, PMCF, PSUR, and CER reporting. Their vast product lineup created delays at every stage — with report generation and consolidation taking up to a year per cycle, compounded by manual product registration and data silos across multiple source systems.

Industry Diabetes Technology

Pain point 50-step manual PMS reports

Key outcome Reports in minutes, not months

Challenge

The company's PMS reporting process was a **nearly 50-step manual workflow**. Every PMSR, PSUR, HCSR, and UK report was built from scratch — with content creators manually planning, writing, compiling, reviewing, and formatting each report individually. A single PMS report took close to a year to complete.

The problem wasn't the reports themselves. It was everything behind them — disconnected data sources, manual product registration, and a reporting platform that

Data sources

Snowflake + SAP + RIMS

Want more details? Download the full case study.

We'll walk you through Smarteeva with your use cases, your workflows, and your data.

Download case study ↓

required every section to be assembled by hand.

- **50 manual steps per PMS report.** The current system required nearly 50 discrete steps to complete each report — from initial data gathering through section writing, cross-referencing, formatting, review, and submission. Each step was manual. Each step was a bottleneck.
- **Report completion took up to a year.** Content creators had to plan and build each report from scratch. Low productivity and serial workflows extended completion times to almost a year — a timeline that made it nearly impossible to keep up with regulatory deadlines across multiple products.
- **Data scattered across Snowflake, SAP, and RIMS.** Report data lived in three separate systems. Manually collecting data from each source and entering it into reports consumed enormous time and introduced inconsistencies.
- **Manual product registration and workflow management.** The premises-based system was slow, lacked automation, and created data silos. Resources were compiled from disconnected sources with no centralized access.
- **No capability to work on multiple reports simultaneously.** Content creators could only work on one report at a time. With a large product portfolio, this serial approach meant the team was always behind.

"Each PMS report took 50 steps and almost a year. Multiply that by every product in our portfolio and every market we report to. We were perpetually behind."

Approach

Smarteeva's approach was to eliminate the 50-step process entirely — not optimize it. The goal wasn't to make each step faster. It was to automate data gathering, template application, section generation, and review so that a PMS report could be generated in minutes.

- **Connect every data source through API.**
Snowflake, SAP, and RIMS data needed to flow into Smarteeva automatically — not through manual exports. A single integration pipeline would pull analytics, product, and regulatory data continuously.
- **Unify all PMS report types on one platform.**
PSUR, PMSR, HCSR, and UK reports needed shared templates, shared data models, and shared review workflows. No more building each report type in a different tool.
- **Enable parallel work on multiple reports.**
Content creators needed to select and work on multiple reports simultaneously — cutting the serial bottleneck that extended timelines by months.

Solution

Smarteeva implemented a Unified PMSR Solution that automated the entire 50-step process — connecting to Snowflake, SAP, and RIMS via API, and enabling PMS report generation across all report types from a single platform.

- 1 Multi-source data integration via API.**
Smarteeva pulls and analyzes data from Snowflake, SAP, and the RIMS server through API integration. Manual data collection from separate sources is eliminated. Data flows continuously and populates report sections automatically.

- 2 Unified dashboard with auto-assignment.**
A 360-degree view of all reports in one dashboard — with auto-assignment to users or groups. Content creators see every report's status, ownership, and progress in real time.

- 3 Parallel report creation.** Content creators select multiple reports simultaneously, working on several at once instead of sequentially. A year's worth of serial work compressed through parallel workflows.

- 4 One-click section auto-fill.** Executive summary, footnotes, cover page, conclusion — all sections pre-filled with a single click. IMDRF adverse event terminology integrated and standardized across all report types.

- 5 Real-time editing with timestamps.** Users review and adjust information midway through reports via auto-rich text editing. Every change tracked, every version preserved.

- 6 Configurable templates with regulatory logic.** Templates automatically apply the correct regulatory rules for each market and report type. Content creators work from pre-built structures — not blank documents.

- 7 Missing information alerts.** Error-message functionality alerts users to missing data before submission —

ensuring completeness before the report reaches reviewers or regulators.

- 8 **Cross-platform integration.** Generated reports integrate with other software platforms, enabling centralized access management across the regulatory ecosystem.
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Results

The 50-step manual process is gone. **PMS reports that took nearly a year now complete in minutes.** The entire workflow runs on one unified platform.

- **50 steps → one-click generation.** The manual process was automated entirely. Report sections pre-filled from connected data sources with a single click.
 - **Nearly a year → minutes.** Content creators that spent months on a single report now generate, review, and submit PMS reports in minutes.
 - **PSUR, PMSR, HCSR, and UK reports unified.** All four report types on one platform with shared templates, data, and review workflows.
 - **Snowflake + SAP + RIMS connected.** Automated data integration eliminated manual collection from three sources. Report data always current, consistent, and traceable.
 - **Parallel workflows enabled.** The serial bottleneck eliminated. Multiple reports worked simultaneously, keeping pace with portfolio reporting obligations.
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What's next

With unified PMS reporting running, the company is expanding Smarteeva:

- Extending to CER and PMCF report types
- Deploying AI-assisted narrative generation through Smarteeva Orchestra
- Connecting PMS reporting with complaint and adverse event workflows for fully integrated post-market surveillance
- Expanding data integration to additional source systems

Still assembling PMS reports manually?

See how Smarteeva generates PSUR, PMSR, HCSR, and UK reports from connected data — in minutes.

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