Caldera Medical

Drag. Drop. Done. Complaint import from 40 minutes to under 1 — duplicates down 95%.

40 → <1
MINUTES PER BATCH IMPORT

95%
FEWER DUPLICATE COMPLAINTS

~15 days
MEDIAN COMPLAINT CLOSURE

<0.001%
IMDRF/MDR CODE MISMATCHES

About Caldera Medical

Caldera Medical is known for minimally invasive, durable solutions that improve women's quality of life. As complaint volumes grew across multiple intake channels, they needed a system that could handle day-to-day work and high-volume bulk imports without creating downstream cleanup or compliance risk. Smarteeva partnered with them to bring complaint intake, IMDRF coding, investigations, and MDR readiness into one guided workflow — now powered by Agentic AI.

Challenge

Caldera Medical needed a complaint management process that could handle both day-to-day individual complaints and high-volume bulk imports — without creating downstream cleanup work or compliance risk. The system they had wasn't built for either scenario at scale.

Complaints arrived from multiple channels — email, manual entry, and bulk file imports.

Industry	Women's Health / Medical Devices
Pain point	Multi-channel intake, duplicates
Key outcome	95% duplicate reduction
Platform	Salesforce-native

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Each channel had its own problems, and none of them connected into a single governed workflow.

- Multiple intake channels, no unified workflow. Complaints came in through email, manual forms, and bulk file uploads. Each channel operated independently, with different data formats and different levels of completeness. There was no single point where all complaints landed in the same structured workflow.
- High-volume duplicate risk. Bulk imports and multiple users working on related records increased the chance of duplicate complaints — or the same issue being handled differently by different team members. There was no systematic check before records were created.
- Reportability decisions were inconsistent. Teams needed a reliable, guided way to decide whether an event was reportable — and which type of report was required (MDR, vigilance, etc.). Without a standardized decision process, consistency depended on who was making the call.
- Investigation and regulatory reporting disconnect. Investigations, MDRs, and complaint records were not tightly connected in the workflow. The end-to-end process from complaint to regulatory submission was prolonged and error-prone, with manual handoffs at every transition.
- Closure needed to mean something. Changes after complaint closure needed to be restricted to authorized roles and fully traceable — to support inspections and audits. The previous system didn't enforce this governance.

> *"We needed complaint intake that could handle bulk imports in minutes, not hours — and a*

> *system where closing a complaint actually meant it was closed. Governed. Traceable. Audit-ready."*

Approach

Smarteeva implemented an end-to-end complaints application in Salesforce that brings the entire complaint lifecycle into one guided workflow — from intake to closure — with built-in controls for Quality and Regulatory needs and embedded Agentic AI to assist users at each step.

The design centered on three principles specific to Caldera's operation:

- Three intake channels, one workflow. Whether a complaint arrives via email, manual entry, or bulk import — it lands in the same structured workflow with the same data requirements, the same validation, and the same audit trail. No channel gets special treatment. No channel creates lesser records.
- Catch duplicates before they're created. Don't clean up duplicates after the fact — prevent them at the point of import. The system needed to check for duplicates during the upload preview, not after records already exist in the system.
- Guided decisions, automatic next steps. Reportability decisions, investigation creation, and MDR generation should be triggered by the workflow — not initiated manually. When a decision tree determines an event is reportable, the system creates the MDR, populates the fields, and moves the case forward without manual handoffs.

Solution

Smarteeva built seven connected capabilities into one complaint lifecycle — each solving a specific bottleneck that Caldera's previous process couldn't address.

1. **Complaint intake that scales — three channels, one workflow.** Caldera logs complaints three ways, all landing in the same structured workflow. Email-to-Complaints: send an email to a designated address and Salesforce creates the complaint automatically, keeping the original email linked for traceability. Manual entry: a guided form ensures key details (product, patient, event, outcome) are captured consistently. Bulk Import Tool: drag-and-drop a file, review the preview, and import clean records. **Bulk import processing dropped from 30–45 minutes to less than 1 minute per batch** once validation and duplicate checks moved into the import preview step.

2. **Duplicate-smart importing.** During upload, the tool checks for duplicates inside the file (matching product, serial/lot, event date, and reporter) and checks against existing complaints in Salesforce. When a match is found, users must choose one clear action: Retain both, Replace, or Cancel — so duplicates don't slip in silently. **Duplicate complaints from bulk imports reduced by 60–70% in the first 3 months, and by 95% within 6 months after go-live.**

3. **Strong complaint records with built-in traceability.** Structured record layout with clear sections for product, dates, and

patient details reduces variation across users. Patient age is auto-calculated from date of birth (days/months/years), removing manual math. Evidence — notes and files — stays attached to the complaint record, not buried in someone's inbox. Every change is logged: what changed, who changed it, when, and old vs. new values. Audit evidence preparation reduced from 24–48 hours to 30–45 minutes.

4 IMDRF code management that stays in sync with MDRs. A dedicated IMDRF Codes tab on each complaint with clear sections (Device Problem, Type of Investigation, Investigation Findings). Search-and-link to add codes. Drag-and-drop to remove. The critical differentiator: any change on the complaint automatically updates the related MDR codes — add on complaint, appears on MDR; remove on complaint, removed from MDR. One source of truth. IMDRF/MDR code mismatches during internal QC dropped from 9% to less than 0.001%.

5 Consistent reportability decisions via guided decision tree. Caldera uses a guided MDR decision tree that asks the same key questions every time — event details, patient outcome, device issue, recurrence, and risk factors. Once the decision completes, the system moves the case forward automatically: creates an investigation record, updates complaint status, and if reportable, creates the MDR record with key fields pre-populated from the complaint and product registration. No manual handoffs. No retyping. Median complaint closure improved from 45–60 days to approximately 15 days.

6 Controlled approvals, closure, and reopening with governance. Complaints

can be submitted for approval with role-based actions restricted to authorized managers. The system blocks approval or closure if required work (like related MDR steps) isn't complete. Once closed, records are locked to prevent downstream edits and protect the final record. If new information arrives, only authorized roles can reopen — creating the right follow-up work (new investigation or follow-up MDR) while preserving the full history.

7 **Real-time visibility through reporting and dashboards.** Caldera's quality team filters, groups, and summarizes complaint data in Salesforce reports and dashboards, then drills into records for quick review. This supports faster audits — **evidence compilation time reduced from 24–48 hours to 30–45 minutes.**

Results

The numbers tell the full story. This isn't a system that made things slightly faster — it changed how Caldera's quality team operates day to day.

- **Bulk import: 40 minutes → under 1 minute.** Batch imports that previously took 30–45 minutes of manual validation and cleanup now complete in under a minute — with duplicate checks and data validation built into the preview step.
- **Duplicates reduced by 95%.** Duplicate complaints from bulk imports dropped by 60–70% in the first 3 months and by 95% within 6 months after go-live. The system catches duplicates before records are created, not after.

- Complaint closure: 45–60 days → ~15 days. Guided reportability decisions and automatic next steps (investigation creation, MDR generation, status updates) eliminated the manual handoffs that previously stretched the complaint lifecycle across weeks.
- IMDRF/MDR code mismatches: 9% → less than 0.001%. Bidirectional IMDRF code sync between complaints and MDRs eliminated the manual reconciliation that previously introduced coding errors at a 9% rate.
- Audit evidence prep: 24–48 hours → 30–45 minutes. Real-time dashboards and structured complaint records with complete audit trails mean evidence compilation for inspections takes minutes, not days.

What's next

With the complaint management foundation running and delivering measurable results, Caldera Medical is expanding Smarteeva's capabilities across their post-market surveillance operation:

- Deploying Smarteeva Orchestra to build custom AI agents for automated complaint triage and severity classification at the point of intake
- Expanding AI-assisted investigation — using similar complaint matching and AI-generated investigation summaries to accelerate root-cause analysis
- Extending automated adverse event detection from complaint narratives to flag potential reportable events at intake
- Building product-level trend dashboards that connect complaint patterns with device

registration and field action data

Drowning in bulk imports and duplicate complaints?

See how Smarteeva handles multi-channel intake with built-in duplicate detection. 30 minutes. Your data. Live product.

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