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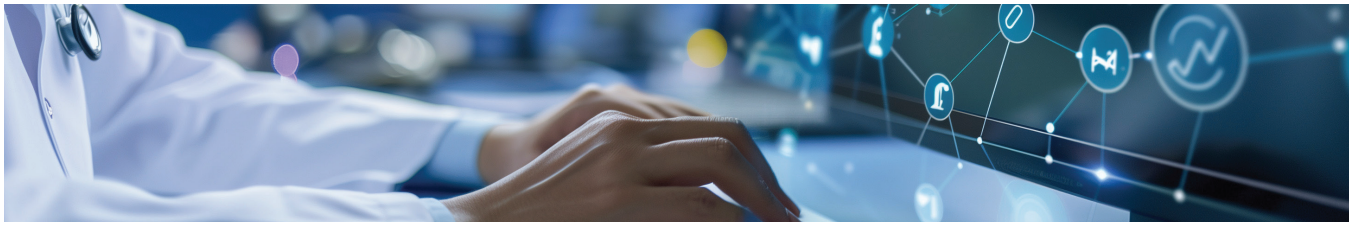
# Improving Speed and Accuracy in the Analysis of Clinical Data with C3 Generative AI



A leading multinational medical device company serves over 40 million patients annually, delivering life-saving innovations across hundreds of products. To ensure product safety and regulatory compliance, the company invests nearly half of its R&D budget in meticulous surveillance of post-market data with the goal to reduce patient harm. Not only is managing these highly sensitive, extensive, and ever-growing datasets challenging, but reasoning on and extracting insights from them is becomingly increasingly difficult.

The surveillance of customer feedback and the associated regulatory documentation (especially related to customer complaints management) was a highly manual and time-consuming process. Quality engineers (QEs) needed weeks to review customer complaints, identify relevant hazards and harms, and then map them to specific product issues. The process involved tallying occurrences and generating periodic safety update reports (PSURs) for regulatory agencies. Recognizing the inefficiency and scalability challenges, the company sought an AI-native solution — C3 Generative AI — to support QEs and reduce the time needed for complaint classification and mapping.

Previously, mapping complaints to technical product hazards and harms was a manual process that relied on the expertise of highly trained QEs and subject matter experts. This process was difficult to scale because new QEs needed extensive training to interpret data and handle complex scenarios. To increase the speed and scale of documentation while maintaining high safety and regulatory standards, the company looked to AI — aiming to not only improve speed, but also consistency and accuracy.

To achieve this, the company partnered with C3 AI on a 16-week C3 Generative AI pilot project. The pilot application automated complaint mapping for post-market surveillance, cutting manual effort by 75%. Freed from repetitive tasks, teams could focus on higher-value activities — while the scalable framework set the stage for broader implementation across regulatory documentation and additional business lines.

In addition to achieving high-accuracy and zero-hallucination output, C3 Generative AI has gained strong adoption among QEs. Users particularly value its simple, intuitive interfaces and streamlined workflows. C3 Generative AI also delivers clear, transparent rationale explanations and ensures outputs are precisely formatted to align with company standards.

With C3 Generative AI, the medical device company reduced time to produce complaint mappings by 75%, unlocking approximately $1.7 million efficiency gain in their post market surveillance process.

## Project Objectives

- Enable a more streamlined, automatic and consistent process for complain mapping analysis documentation.
- Provide an easy-to-use workflow-driven interface to help quality engineers be more efficient.
- Configure the C3 Generative AI for Clinical Documentation application for scaling to additional use cases across the company.

## Results

**75%**

reduction in time to map complaints in post market surveillance phase from weeks to hours

**80-90%**

accuracy of C3 Generative AI generated complaint mapping documents

**16**

weeks to complete the pilot

# Challenges

The company allocated nearly 50% of its R&D budget to documentation, covering everything from product research and risk assessments to manufacturing procedures and post-market surveillance. Among these, complaint mapping was one of the most critical and complex tasks, essential for ensuring product quality, driving improvements, and meeting global regulatory standards.

Despite significant investment, the documentation process remained slow and fragmented. Quality engineers (QEs) spent years mastering company-specific terminology and regulatory requirements, while struggling to locate disjointed information across various sources such as Instructions for Use, historical risk documents, compliance guidelines, and customer complaints.

The process often required weeks of work, multiple SME reviews, and still had inconsistencies in documentation quality. This inefficiency increased the risk of variability in output, jeopardizing product quality and raising the potential for patient harm.

## About the Company

- $15+ billion annual revenue in 2023
- 40+ million patients each year
- $1+ billion R&D investment

## Project Highlights

- 16 weeks from kick-off to production-ready application.
- Reduced time to map complaints by 75% from weeks to minutes.
- Achieved up to 90% accuracy in responses.
- Built in robust security features that comply with company's policies and governance frameworks.
- Configured the application with an intuitive and seamless user interface to meet customer requirements.
- Set up the system to be ready to scale to other regulatory use cases and across business lines.

# Deploying C3 Generative AI for Clinical Documentation

Over 16 weeks, C3 AI configured C3 Generative AI for Clinical Documentation, focusing first on complaint mapping for the endoscopy and urology division.

A joint team of developers, data scientists, and quality engineering subject matter experts identified the corpus of documents required for complaint analysis and mapping, the desired output, various input formats, user interfaces, and the most efficient workflows. The team designed the approach that incorporated various innovative techniques, such as advanced document processing and chunking to handle non-standard formats and deep learning to inject domain-specific, contextual information. These techniques enabled minimal pre-processing work from quality engineers and reliable information retrieval and content mapping capabilities that mimic human logics with zero hallucination.

C3 AI also configured complaint mapping output formats and enabled access controls to tailor to the strict requirements of the company in format compliance and security.

This allowed QEs to further shorten the time to review each complaint. The application achieved 80–90% accuracy for complaint mapping analysis and reduced intra-engineer

variability, significantly shortening the documentation time and freeing up QE time for other higher value tasks.

In the next development phase, C3 AI will deploy additional applications for other documentation tasks across the regulatory documentation value chain and across departments or divisions. This will help the company reduce 500,000+ hours (~10% of total time) and a significant portion of the nine-figure spend on R&D documentation.

## Solution Architecture

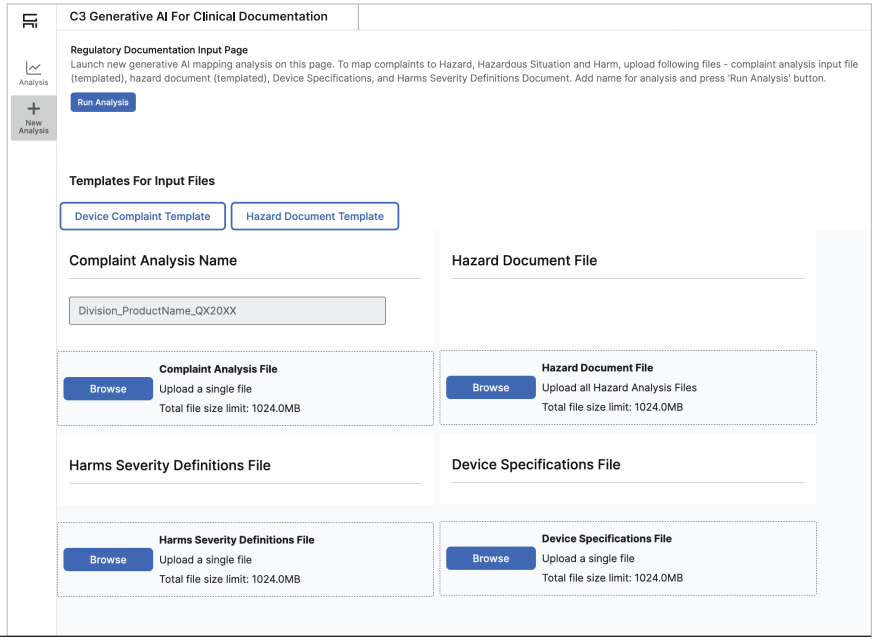
# C3 Generative AI

**Enterprise Data Sources**

- Raw Complaints Data
- Failure Mode and Effects Analysis
- Hazard Analysis
- Instructions for Use
- Master Effects and Severity List
- As-Reported Codes
- Product Specifications

**External Data Sources**

- Published Literature
- Case Reports
- Regulatory Policy




# Benefits

By using C3 Generative AI for Clinical Documentation, the leading medical device company can:

## Reduce

75% of the time to map complaints with hazards from weeks to hours.

## Improve

Quality engineer adoption of the application with an intuitive user interface, easy workflows, and AI rationales for effective reviews.

## Achieve

Up to 90% accuracy for the automatically mapped hazard analysis by C3 Generative AI for Clinical Documentation.

## Ensure

The automatically generated complaint mappings comply with the company's policies and governance frameworks via security and compliance features.

# Proven Results in Weeks

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