

case study -

# Ensuring clinical continuity under regulatory constraints

How SetPoint Medical executed a zero-downtime backend migration with Resolute Software

MongoDB

K8s

Node.js

Terraform

Docker

AWS

## Company

A revolutionary medical device manufacturer

## Customer since

2024

## Overview

SetPoint Medical, a Class III medical device manufacturer, faced a critical infrastructure event when the enterprise provider supporting its backend platform announced it would discontinue the service. SetPoint was running a pivotal clinical trial under strict FDA guidance, which meant it couldn't change its existing system or fast-track rollout of the replacement platform it had built internally.

SetPoint brought in Resolute Software to take over the backend and migrate the system with zero functional changes. Timing was critical. It was essential to avoid any user or API differences, stay fully compliant with regulations, and ensure patients continued receiving therapy without interruption.

## → Challenge

Maintain uninterrupted therapy delivery during active clinical trials while migrating the system, without modifying the system.

## → Solution

Completed an exact copy migration of the system, keeping all functionality the same while taking over operations, security updates, and infrastructure management within strict regulatory requirements.

## → Results

Completed a seamless transition ahead of the shutdown deadline with zero downtime and no user-facing changes. Preserved clinical trial continuity, maintained full regulatory compliance, and avoided disruption to patients' therapy, preventing a potentially unrecoverable setback to the company's approval timeline and commercialization plans.

**"From the point of view of our customers, the system had 100% uptime during this entire process. I've never had any technical concerns – Resolute handled the entire project in an absolutely professional manner."**

**- Bill Calle, Chief Technology Officer, SetPoint Medical**

## Innovation within a highly regulated environment

SetPoint Medical develops implantable neuromodulation therapies for autoimmune diseases, such as Rheumatoid Arthritis. Every component of its system – whether hardware or software – is subject to extensive regulatory review.

The company was operating as a pre-approval startup with finite resources. Most engineering capacity was directed towards building the electromechanical components of the system, while a small team supported the cloud-based backend infrastructure used by clinicians.

The existing backend platform had always been intended as temporary. "We want to own and be in control of all the technology that we utilize," said Bill Calle, Chief Technology Officer, SetPoint Medical. "The backend platform we were using was meant to be an intermediate, no-pressure situation that allowed us to start our pivotal clinical trial and collect data."

That assumption changed abruptly when the provider announced the platform would be shut down permanently in the midst of a 5-year clinical trial.

## Avoid service interruption during active clinical trials

At the time of the end-of-service announcement from the backend provider, SetPoint already had over 240 patients enrolled in a pivotal clinical trial. These patients had undergone surgical placement of the SetPoint device and were dependent on the supporting software infrastructure for managing their therapy and collecting data.

While SetPoint had completed development of its own replacement backend platform, regulatory timing made deployment extremely challenging. In an FDA-regulated environment, even minor software changes would have significantly delayed FDA approval.

"We had a fully functioning, fully tested implementation ready to go," Calle said. "However, this abrupt end to our existing backend provider could have delayed the project by more than six months." Such a delay could have been catastrophic for a startup with limited resources.

As a result, they were locked-in to what existed. "The platform could not be modified, replaced, or altered without creating significant compliance consequences," Calle said. Meanwhile, the deadline was fast-approaching.

## The Cost of Downtime

For SetPoint, downtime was not simply a matter of inconvenience or lost productivity – it was a clinical and ethical crisis.

"If we interrupted therapy for our trial patients, their medical condition would worsen," Calle said.

**"Their joints are deteriorating, and they're subject to other health complications, as well, such as cardiovascular issues.**

**If we hadn't found Resolute Software and been able to transition off the old platform quickly, all our patients were going to go offline, and we would have had to end the clinical trial."**



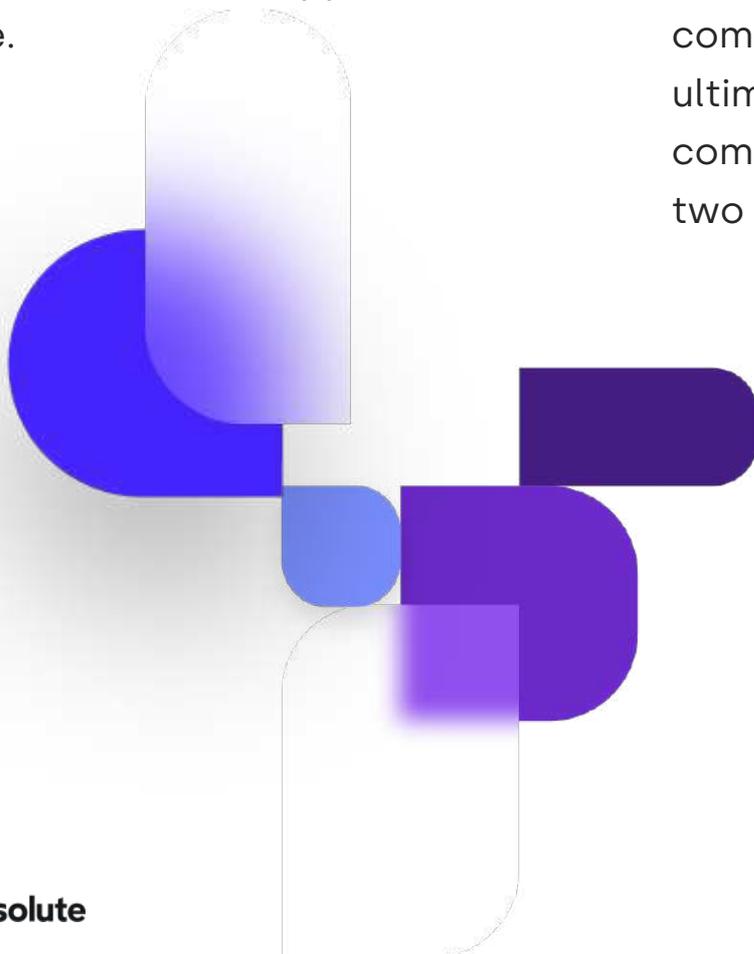
The migration requirement was absolute. "It needed to be the exact solution with zero differences," he said.

# Technical architecture and migration requirements

The existing backend environment functioned strictly as a service layer supporting SetPoint's custom-built clinical applications. It was built on Kubernetes, leveraging Node.js microservices and a MongoDB database layer. The architecture supported event-driven execution, containerized workloads, LDAP-based authentication, and CI/CD components.

Resolute Software was tasked with recreating this environment in a new, single-tenant Kubernetes cluster, without altering a single API, endpoint, or line of application code.

The complexity was not only technical. Legal and intellectual property negotiations delayed the transfer of operational control for months. As a result, the migration window was compressed significantly and, ultimately, Resolute had to complete the migration in under two months.



## A seamless cutover

Despite the compressed timeline, the technical transition was executed seamlessly. Resolute replicated the database images and migrated all of the Docker containers intact.

The Resolute team preserved the MongoDB snapshots and right-sized the infrastructure to support a single-tenant deployment, while maintaining performance and resilience. Importantly, all of this behind-the-scenes work was invisible to end users.

"I have never in my career been involved with such a smooth migration," Calle said.



**"It was absolutely flawless. All of the data and accounts were ported over to the new system, and everything continued to work exactly as designed."**

According to Calle, the success of the migration wasn't accidental, but the result of a coordinated plan between SetPoint and Resolute that included extensive testing. "We made sure that when the switch was flipped, the system would just come to life – and it did."

From a regulatory standpoint, the key outcome was functional equivalence. SetPoint documented the change in an annual FDA report.

"We haven't had to modify one line of our code in order to communicate with the new backend system versus what we were using before," Calle said. "It's indistinguishable."

## Protecting patients through operational stability

Under Resolute's management, SetPoint's environment operated for approximately 18 months, uninterrupted. Resolute handled infrastructure upgrades, security patches, and maintenance coordination without burdening SetPoint's internal team.

After receiving FDA approval, SetPoint transitioned to its internally developed Azure-based backend platform. The shutdown of the migrated environment followed a structured, compliant phase-out plan.

For SetPoint, this backend continuity was inseparable from patient safety and regulatory compliance. The migration was not a technical upgrade but a mission-critical safeguard.

"From the point of view of our customers, the system had 100% uptime during this entire process," Calle said.

**"I've never had any technical concerns – Resolute handled the entire project in an absolutely professional manner."**

# Let's talk about your technology requirements.

Get in touch

## USA

MA 01701, Framingham,  
945 Concord St,

+1-617 386-9697

[sales@resolutesoftware.com](mailto:sales@resolutesoftware.com)

**Clutch** ★★★★★

People First Company Award  
2019 — 2023



Empowering Leadership Award  
2024



**Deloitte.** Company to watch | Tech Fast 50

ISO 9001:2015  
Quality Management  
2025



ISO/IEC 27001:2022  
Information Security Management  
2025



ISO/IEC 20000-1:2018  
IT - Service Management  
2025



EcoVadis Commitment  
2025

