Precision Under Pressure:

How a Small Biotech Partnered with Us to Navigate
Trial Complexity with Confidence and Control

Endpoint®

▶ Introduction

A small biotech company engaged Endpoint after encountering persistent limitations with their previous RTSM provider. As their clinical strategy evolved, the constraints of a rigid, legacy platform became increasingly misaligned with the realities of early-phase development.

They selected Elosity, Endpoint's fifth-generation Randomization and Trial Supply Management (RTSM) solution, to support a more adaptive approach to trial execution. The decision was driven not by a single feature, but by the need for a system architected to accommodate change as a routine element of clinical development, rather than an operational exception.

The Challenge

The engagement began with a Phase I, randomized, open-label, dose-escalation study designed to assess the safety, tolerability, and preliminary effectiveness of a novel therapeutic for the treatment of urethral strictures (USX).

During study testing, the protocol direction shifted, prompting a request for a substantial redesign of the trial structure. The change introduced new configuration requirements that, within many traditional RTSM platforms, would necessitate custom development, extended validation cycles, or downstream compromises to timelines and operational continuity.

At this stage of development, the sponsor needed to preserve momentum while ensuring that any changes were implemented within a controlled, compliant framework.

The Endpoint Solution

Elosity was purpose-built to address exactly this type of clinical and operational complexity.

As Endpoint's fifth-generation RTSM solution, Elosity is designed around configurable study constructs that allow protocol evolution without introducing technical debt or system fragility.

1 **Configuration-driven flexibility**

The study redesign was implemented using Elosity's native configuration capabilities, eliminating the need for custom code or platform-level modifications.

2 **Clinical and technical expertise applied in concert:**

Endpoint's services team leveraged deep therapeutic, operational, and platform expertise to execute the redesign with precision and accuracy.

3 **Preservation of operational continuity:**

Changes were introduced within an established governance framework, allowing the study to progress without disruption to planned milestones.

4 **Sponsor confidence maintained:**

The updated study configuration was delivered efficiently for review, reinforcing trust in both the solution and the delivery model supporting it.

"Seamless executions, no disruptions"

The Results

The engagement demonstrated the practical advantages of deploying Elosity in early-phase clinical development:

▶ **Elasticity without compromise:**

Study requirements evolved without destabilizing the system or introducing rework.

▶ **Operational control:**

Changes were managed within a validated, scalable framework that preserved data integrity and supply oversight.

▶ **Integrated delivery model:**

Product, services, and delivery teams operated as a cohesive unit, ensuring alignment between platform capability and study execution.

The result was not simply a successful study re-design, but a more resilient operational foundation for ongoing development.

Why It Matters

Clinical development is inherently iterative, particularly in early-phase programs where insights emerge rapidly and protocols must adapt accordingly. Success depends on technology that is intentionally designed for this reality.

This case underscores what differentiates Elosity as an RTSM solution. It is not a system that merely reacts to change, but one that is architected to absorb it through configurable design, disciplined execution, and deep clinical understanding. By aligning flexible

Explore how Endpoint's fifth-generation RTSM solution, Elosity, enables clinical teams to manage change with control, confidence, and operational rigor.

▶ **Get in touch**

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