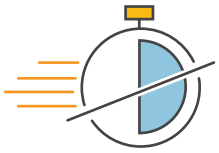
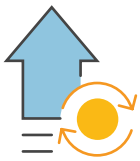
From Early Adopter to Optimized Trials: Cara Therapeutics and Veeva Vault CDMS

Clinical-stage biopharmaceutical company focused on the treatment of pruritus finds greater speed and flexibility in clinical trials with modern EDC

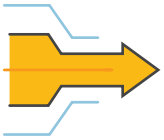
Success Highlights



>50 % faster build times than original EDC provider



Greater CRF consistency and standardized trial data when working with CROs



Rapid post-production changes with **zero migrations**

Life as an Early Adopter

Cara Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing a novel class of peripherally acting kappa opioid agonist therapeutics with a primary focus for the treatment of pruritus and pain. The company's fast paced environment meant it needed technology and processes that would support tight deadlines, complex protocol designs, and frequent mid-study changes. When Veeva approached Cara about Vault EDC, Cara had a phase I and a phase II study that would fit an early adopter program. With those first two studies, Veeva cut Cara's standard build times by half.

> *The builds were fast and effective. We've had CROs with other systems take 10-12 weeks for each study build, even when the studies use the same system, the same page, and the same format. But the Veeva team made all the updates based on the original protocol in just six weeks. Veeva has been building the database for all our studies over the past three years and the average build time is at least 50% faster than before.*
>
> – ***Evelyn Dorsey,*** *director of data management, Cara Therapeutics*

As an early adopter, many of Cara's requests and product ideas helped inform Veeva's product roadmap and produce an EDC that offers a powerful reporting tool for operational insights and supports sponsor/CRO collaboration.

Improving CRO Collaboration and Gaining Control of their Data

As a small clinical-stage biopharmaceutical organization, Cara Therapeutics outsources its studies to CROs, often using different vendors for different studies. Outsourcing trials created delays in accessing data because the company was dependent on CROs to handle periodic exports of the data. Working with multiple CROs also introduced variability into the CRFs and datasets, creating more work downstream for the programming team because each CRO used its own EDC and standards. Cara wanted the benefit of using CROs that specialized in specific clinical areas, while also maintaining control over CRFs. By providing CROs with Veeva's cloud-based EDC, Cara was able to standardize, achieve greater consistency in the CRFs, and align data collection from multiple CROs.

> *Veeva Vault EDC gives us control over our casebooks and consistency in our data when working with different CROs. We've used the system with more than five different CROs, and they have all been impressed with the speed of building studies and making mid-study changes.*
>
> – ***Evelyn Dorsey,*** *director of data management, Cara Therapeutics*

Cara has constant, direct access to its trial data in real time. With higher visibility into study status, it also sees the operational reports showing the status of data collection and cleaning without having to ask the CRO for a separate report. Flexible reporting within a cloud-based EDC is also valuable when working with multiple CROs. Sponsors see operational data in a consistent way across studies, while each CRO can see the study metrics and reports according to its own preferences.

> *We have six or seven different CROs working with us, and they have three or four team members within the data management group working on each of our studies. Flexible reporting is really valuable to us, as we are able to share our custom reports from other studies as a baseline. Each team member with access to the EDC can customize their view of that report however they like it, without the need to request such reports from the programming team, which also means cost savings for Cara.*
>
> – ***Evelyn Dorsey,*** *director of data management, Cara Therapeutics*

Seamless IRT and EDC Integration that Supports Complex Trials and Mid-study Changes

Cara Therapeutics ran a Phase II randomized study with a complex protocol design for an adaptive trial with data-driven mid-study changes. The study for a novel antipruritic drug required a system that could keep up with stratified randomization to allocate chronic kidney disease patients across three treatment arms and one placebo. They also needed a flexible protocol that allowed dropping treatment arms for futility or safety reasons, and controlling enrollment cap percentages.

Cara Therapeutics utilized a productized integration between Veeva's Clinical Data Management System and Suvoda's IRT to address the challenges of working with multiple systems during a complex trial. Multi-vendor solutions often lengthen and complicate time to study startup due to siloed integrations causing duplicative efforts. By predefining data standards, Veeva and Suvoda's teams were able to help Cara avoid errors in data entry and eliminate the time it takes to reconcile disparities or duplicate data points. As a result, Cara's team of stakeholders were able to mitigate the risks associated with data errors common when working across multiple systems.

The integration also helped the Cara team save time in data entry. The data populates in near real-time in both the EDC and IRT systems, with Cara's site personnel only needing to enter the information once. In addition, flexibility between Veeva and Suvoda's systems also allowed Cara to manage changes to enrollment caps, patient re-enrollment, dropping treatment arms, and other unplanned study changes with few or no change orders.

The result was a fast, flexible solution that simplified data capture and management, offered predictability during complex protocols, and mitigated risk for human error.

Optimizing for Tomorrow's Trials

Cara Therapeutics continues to expand and move their clinical trial pipeline of pruritus therapies into more complex Phase II and Phase III studies. With Veeva Vault CDMS, Cara is able to adapt and manage these trials faster, more consistently, and with greater visibility.

Learn more how your organization can streamline your clinical trials with Veeva Vault CDMS at veeva.com/products/clinical-data-management.

> *This solution [between Vault EDC and Suvoda IRT] created simplicity at every level and for all stakeholders, the site, data management, the operational team, and for the drug supply team.*
>
> – ***Catherine Munera,*** *Ph.D., Head of Biometrics, Cara Therapeutics*