SUVODA®

CASE STUDY:

Solving Complexity with Integration

How Cara Therapeutics navigated a multi-vendor IRT and EDC approach with ease, agility, and predictability

- Efficient data management
- Quick, comprehensive setup
- Easy mid-study changes

CARA THERAPEUTICS

About Suvoda

Suvoda is a global clinical trial technology company working to transform patients' experience in complex, life-sustaining studies in therapeutic areas like oncology, central nervous system (CNS), and rare diseases. Founded in 2013 by experts in eClinical systems, Suvoda empowers sponsors, CROs, sites, and patients to manage even the most urgent moments in the most urgent trials through advanced software solutions delivered on a single platform. Headquartered outside Philadelphia, Suvoda also maintains offices in Portland, OR, Barcelona, Spain, Bucharest and Iasi, Romania, and Tokyo, Japan. The company's Net Promoter Score (NPS) consistently exceeds the technology industry average, contributing to the company being selected by trial sponsors and CROs to support more than 1,800 trials across more than 95 countries. To learn more, visit suvoda.com. Follow Suvoda on LinkedIn. To learn more, visit suvoda.com. Follow Suvoda on LinkedIn.

Cara Therapeutics ran a Phase II randomized study with a protocol typical of the increasingly complex, data-driven approach that the modern clinical trial landscape demands. Thanks to an integration between two best-in-class vendors in IRT and EDC, Cara easily made mid-study changes and managed clinical data.

Challenges

Time Constraints

The company's fast pace as a clinical-stage biopharmaceutical company meant strict deadlines. Cara's goal was to use Phase I results collected in the first quarter to inform protocol design and begin implementation of their Phase II trial by the end of the second quarter.

Protocol Design Complexity

Their Phase II study for a novel antipruritic drug required a system capable of keeping up with its inherently complex protocol. The study utilized stratified randomization to distribute chronic kidney disease patients across three treatment arms and one placebo.

It capped enrollment of patients in certain strata according to percentages in each treatment arm. Stratification and enrollment were both heavily dependent upon data collected during a seven day run-in period in which patients were screened according to severity of pruritus and severity of chronic kidney disease.

Cara's protocol also allowed patients to be rescreened. They needed a system that would help them keep track of patients to determine if they were unique or rescreened.

Mid-Study Changes

Their protocol required flexibility as it shifted gears mid-study to drop insubstantial treatment arms. It called for an interim assessment of patients once enrollment rates fell to 50 percent due to subject dropout and completion. This was to determine if any treatment arms no longer needed to be assessed due to emergent trends in the data or lack of substantial patient numbers in one or more of these dosage categories. They also needed to change enrollment cap percentages based on stratification of patients on dialysis and those who were not.

Challenge 1
Time Constraints

Solution

Predefined, standard specifications expedite new study configuration

Challenge 2
Protocol Complexity

Solution

Seamless integration with advanced functionality

Challenge 3
Mid-Study Changes

Solution

Multi-system flexibility allows for faster mid-study changes

> This integration created simplicity at every level, removed manual data entry, and brought cohesiveness to all the stakeholders involved in our program.
>
> **— Catherine Munera, Ph.D.,**
> *Cara Therapeutics*

Solution

Cara Therapeutics utilized an integration between Suvoda's IRT and Veeva's Vault Clinical Data Management System (CDMS) for their study to address these challenges. The result was a fast, flexible solution that simplified data capture and management at all stakeholder levels, offered predictability in the midst of dynamic, complex protocols, and mitigated risk in avoiding human error common in data entry across disparate systems.

Speed

Typically, a multi-vendor integration can lengthen the time to study startup. Suvoda and Veeva were able to standardize data points across both their IRT and EDC systems to shorten this initial setup period for Cara and employ the integration for additional studies in their pipeline.

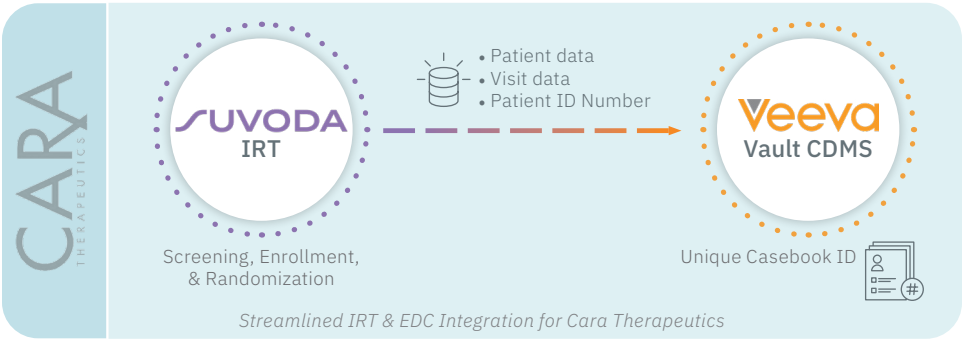
The solution also saved the study team time with data entry. Suvoda and Veeva's integration populates data in real time to both IRT and EDC systems. Cara's site users only had to enter information once if a patient initially failed screening and was later rescreened. This data was saved in both systems for future use to automatically rescreen initially failed patients.

Simplicity

Cara Therapeutics needed a simple solution that allowed them to manage data across IRT and EDC systems. More specifically, they needed coordinated systems to

properly screen, stratify, and randomize patients, to direct and monitor supply for multiple drug dosages, and to properly monitor and limit enrollment. With Suvoda and Veeva's integration in place, Cara did not have to manage and monitor these processes in multiple systems.

By predefining data standards, Suvoda and Veeva's teams were also 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 risk associated with data errors common to working across multiple systems.



Streamlined IRT & EDC Integration for Cara Therapeutics

Flexibility

A primary complaint for study stakeholders using EDC and IRT systems is that mid-study change orders are slow and complicated. Veeva and Suvoda anticipated potential scenarios in their integration to drastically reduce and in many cases eliminate mid-study change timelines.

Thanks to the flexibility of the Suvoda IRT system, changes to enrollment caps, patient re-enrollment, dropping treatment arms, and other unplanned study changes were easily and quickly implemented with few or no change orders involved. A well-implemented and flexible integration offers a degree of predictability that, coupled with responsive support teams, allows sponsors like Cara to move from study to study without worrying what their EDC and IRT systems can and cannot handle.

Confidence & Reliability

Experienced integrations and product teams ensure success
Field-tested, streamlined, and predictable implementation

Speed

Predefined, standard API integration allows a new study configuration to be done quickly and easily

Agility & Simplifying Complexity

Easily manage protocol complexities and mid-study changes

The Takeaway

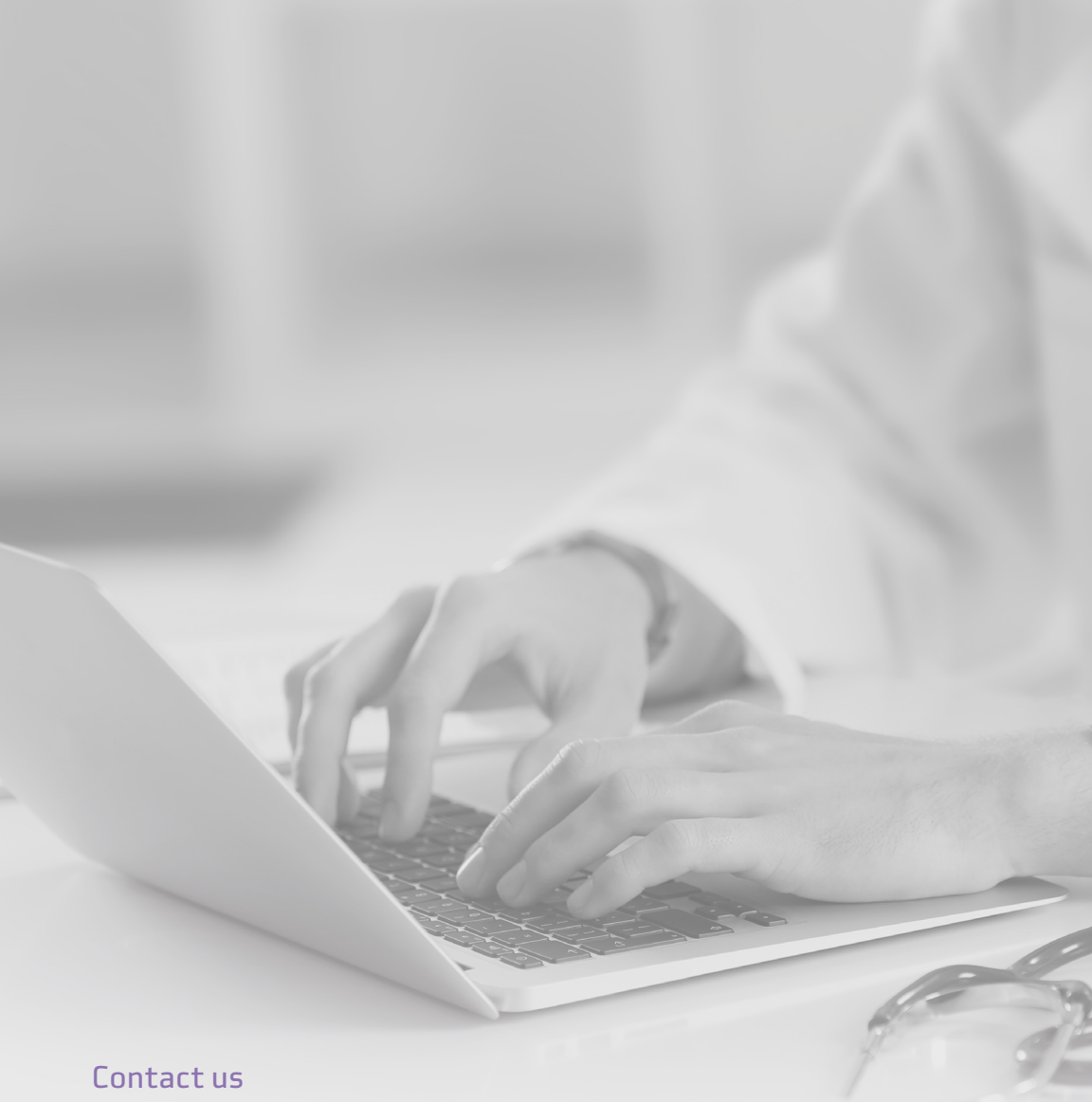
Cara Therapeutics was able to leverage this integration for several other studies after seeing its ability to provide flexibility, simplicity, and speed to this initial trial. They learned that an integrated two-vendor IRT and EDC solution can bring the simplicity of working with a single vendor without sacrificing either functionality or expertise and bring two best-of-breed technologies together.

By providing seamless eClinical solutions to increased complexity in the clinical trials landscape, companies like Veeva and Suvoda are working to help study sponsors focus on delivering meaningful treatments to patients.

About Veeva

Veeva Vault CDMS provides a next-generation EDC. Build complex studies with ease and make mid-study changes without downtime or migrations. The QuickView interface generates a dynamic to-do list that helps you focus on what matters most.

www.veeva.com



Contact us

Speak with an expert about the Suvoda Platform and your specific business needs. Visit us at suvoda.com/contact.

UNITED STATES	EUROPE	ASIA
(H) Philadelphia	Barcelona	Tokyo
Portland	Bucharest	

SUVODA®

Trial wisely