Supporting Complex Protocols with an Integrated EDC and IRT Solution

Cara Therapeutics achieves greater agility with Veeva Vault CDMS and Suvoda IRT

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 EDC and IRT, 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.
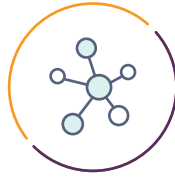
Challenge 1
Time Constraints

Solution
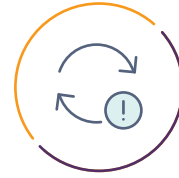Predefined, standard specifications expedite new study configuration

Challenge 2
Protocol Complexity

Solution
Seamless integration with advanced functionality

Challenge 3
Mid-Study Changes

Solution
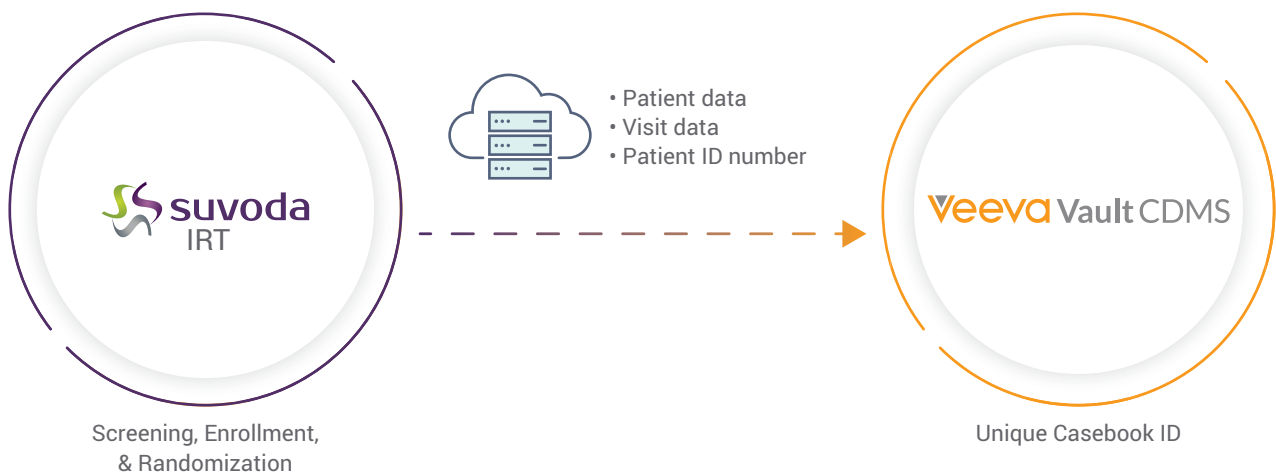Multi-system flexibility allows for faster mid-study changes

Solution

Cara Therapeutics utilized an integration between Veeva's Vault Clinical Data Management System (CDMS) and Suvoda's IRT 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.

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 managed and monitored all these processes with a cohesive integrated solution.

By predefining data standards, Veeva and Suvoda'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.

suvoda IRT

- Patient data
- Visit data
- Patient ID number

Veeva Vault CDMS

Screening, Enrollment, & Randomization

Unique Casebook ID

Streamlined IRT & EDC Integration for Cara Therapeutics

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*

Speed

Typically, a multi-vendor integration can lengthen the time to study startup. Veeva and Suvoda were able to standardize data points across both their EDC and IRT 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. Cara's site users only had to enter information once in Suvoda IRT and the integration populated patient and visit data in near real-time to Vault EDC. Additionally, this data was saved in both systems and was reused rather than re-entered if a patient initially failed screening and was later rescreened.

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 change scenarios in their integration to eliminate the need for most change orders and drastically reduce mid-study change timelines.

Thanks to the flexibility between Veeva's EDC and Suvoda's 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 field-tested, streamlined, and predictable implementation

Speed

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

Agility & Simplified Complexity

A powerful integration between IRT and EDC allows teams to easily manage protocol complexities and mid-study changes

The Takeaway

Veeva and Suvoda's integrated IRT and EDC solution provides the functionality and advances of two best-of-breed technologies without sacrificing the desired simplicity of working with a single vendor. After experiencing the simplicity, speed, and flexibility of this integrated solution, Cara Therapeutics leveraged the two systems for several subsequent studies.

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

About Veeva Systems

Veeva is the global leader in cloud software for the life sciences industry. Committed to innovation, product excellence, and customer success, Veeva serves more than 1,100 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. As a Public Benefit Corporation, Veeva is committed to balancing the interests of all stakeholders, including customers, employees, shareholders, and the industries it serves. For more information, visit veeva.com/eu.

About Suvoda

Suvoda is an industry leading SaaS company, focused on solving complex patient randomization and clinical supply chain challenges. Founded in 2012 by experts in eClinical technologies and pioneers in IRT software, Suvoda has led the way in standardizing IRT for innovative trial designs that require multi-system integrations. Headquartered in Conshohocken, PA, Suvoda has offices and staff around the world offering exceptional customer services and advisory services to biopharmaceutical companies of all sizes.