SUVODA®

CASE STUDY:

Increasing Patient eCOA Compliance

Cara Therapeutics increased compliance and reduced burden on study teams with Suvoda

CARA THERAPEUTICS

- A single, detailed start-up process
- Efficient and reusable questionnaire development
- Streamlined operations from Go-Live

Cara Therapeutics is a commercial-stage biopharmaceutical company advancing treatments for patients suffering from chronic pruritus. Their research explores innovative approaches to pruritus treatments across a spectrum of disease categories.

With Suvoda, Cara Therapeutics experienced a dramatic increase in patient eCOA compliance in two pruritus studies, expediting their study submission process with heightened levels of efficiency and visibility.

Challenges

Cara Therapeutics' mission is to bring innovative therapies to market to help patients manage chronic pruritus. During several global studies involving multiple sites and languages, Cara worked with IRT and eCOA partners who failed to deliver in certain areas, including data visibility, timeline transparency, and go-live readiness with questionnaire licenses and translations.

In one study, it took months just for the eCOA provider to send a test transfer of data. On the IRT end, a lack of visibility into this crucial patient data has prevented Cara from monitoring drug supply proactively to avoid unseen issues from impacting studies.

	Study 1	Study 2
Therapeutic area	Chronic kidney disease	Notalgia paresthetica
Phase	Phase Ib	Phase II/III
No. of patients	210*	Part A - 200 Part B - 240
No. of sites	50	160
No. of countries	10	7
No. of assessments	Patient assessments: 5	Patient assessments: 9 Physician assessments: 1
No. of languages	20	9

** Planned. Trial was stopped early.*

Solution

Cara was invited to be an early adopter of the Suvoda Platform, purpose-built to seamlessly integrate IRT and eCOA solutions. These solutions share one database and are managed by a single project team serving as a valuable scientific partner and consultant.

An efficient, streamlined patient data collection and drug deployment process was created, including:

> One of the greatest challenges we've had with eCOA partners is transparency with timelines and achieving those timelines."
>
> **David Vale,**
> *Senior Director, Program Management, Cara Therapeutics, Inc.*

A single, detailed start-up process

Suvoda's unique approach to project management includes a single, highly-experienced project team for both IRT and eCOA. Suvoda experts spent time upfront to fully understand Cara's needs for the trial. Then, clear roles and responsibilities were established and a detailed timeline was agreed on. Suvoda also thoroughly reviewed the clinical protocols, study design, and regulatory guidance together with Cara's study team to ensure the most accurate and robust data capture methods. User acceptance testing (UAT) was handled efficiently and quickly as issues arose.

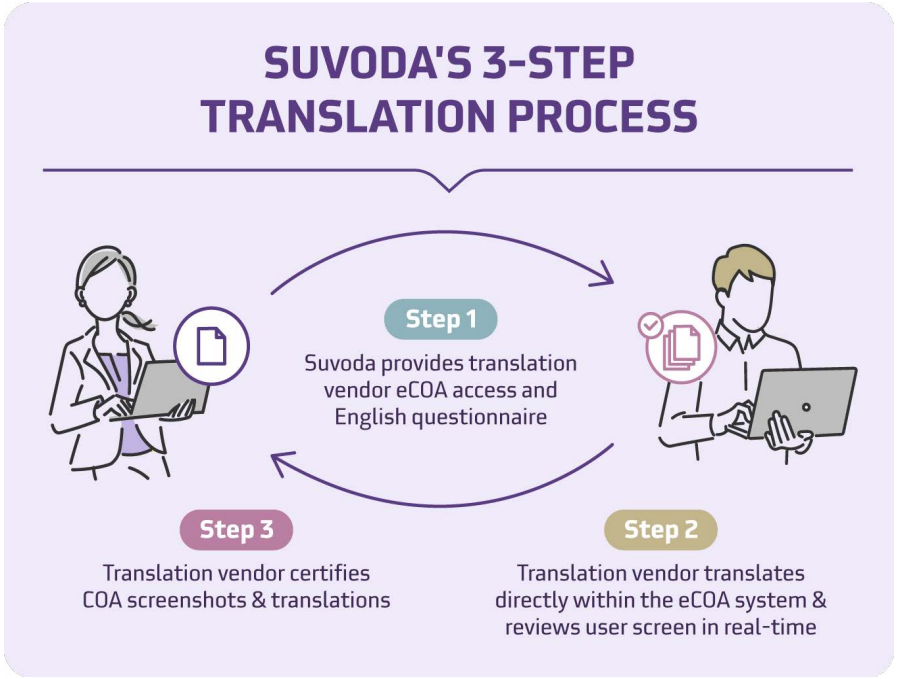
Result:
High-quality, flexible UAT, ensuring usability and consistently meeting study timelines.

> Suvoda brought senior concept knowledge that other vendors didn't have."
>
> **Catherine Munera,**
> *Vice President, Biometrics Cara Therapeutics, Inc.*

Efficient and reusable questionnaire development

An agile questionnaire development workflow simplified the creation, testing, and translations of questionnaires. Suvoda's Questionnaire XD design tool is de-coupled from the main platform, which allowed questionnaire development and translation much earlier than traditional processes. This created a streamlined process where the sponsor could focus on other elements of study start up, while Suvoda was handling questionnaire development, licensing, and translations efficiently. Translated and validated questionnaire items stored in the centralized eCOA repository were then reused for the second study, expediting study start up, once licensing for the second study was secured.

Result:
All languages in both studies were certified before go-live, a first for any Cara study.



> Suvoda's approach to implementing questionnaires across multiple studies and countries was a major win. [The translations] worked perfectly, despite having some uncommon languages, such as Xhosa and Setswana, for our South African sites. Our clinical scientist is not worried about the licensing for an upcoming study because Suvoda is handling it."
>
> **Catherine Munera,**
> *Vice President, Biometrics Cara Therapeutics, Inc.*

Streamlined operations from Go-Live

A unified eCOA and IRT platform simplified data collection for sites and study teams, and the platform's single database delivered immediate and seamless visibility to sponsors. The single access helped sites and study teams proactively track patient compliance and course-correct quickly. Unlike previous studies using other vendors, working with Suvoda meant no costly and resource-intensive post-production changes.

Result:
Cara Therapeutics didn't miss a single deadline because the Suvoda process ensures steps are well-defined and clearly communicated to all team members.

> Suvoda worked with us as a single project team, which meant better communication as everything was done with the same goal in mind. Together, we could implement complex IRT and eCOA designs quickly and accurately to achieve great results."
>
> **Catherine Munera,**
> *Vice President, Biometrics Cara Therapeutics, Inc.*

Results

As a result of Suvoda's purpose-built infrastructure, Cara Therapeutics' time from draft protocol to go-live was faster, more efficient, less burdensome on the study team, sites, and patients, and easier to implement than previous eCOA studies.

> "Visibility to and transparency around timelines is one of the biggest challenges in eCOA implementations. Working with Suvoda, we knew from the beginning when each step in the process would be complete. And then they actually delivered."
>
> **David Vale,**
> *Senior Director, Program Management, Cara Therapeutics, Inc.*

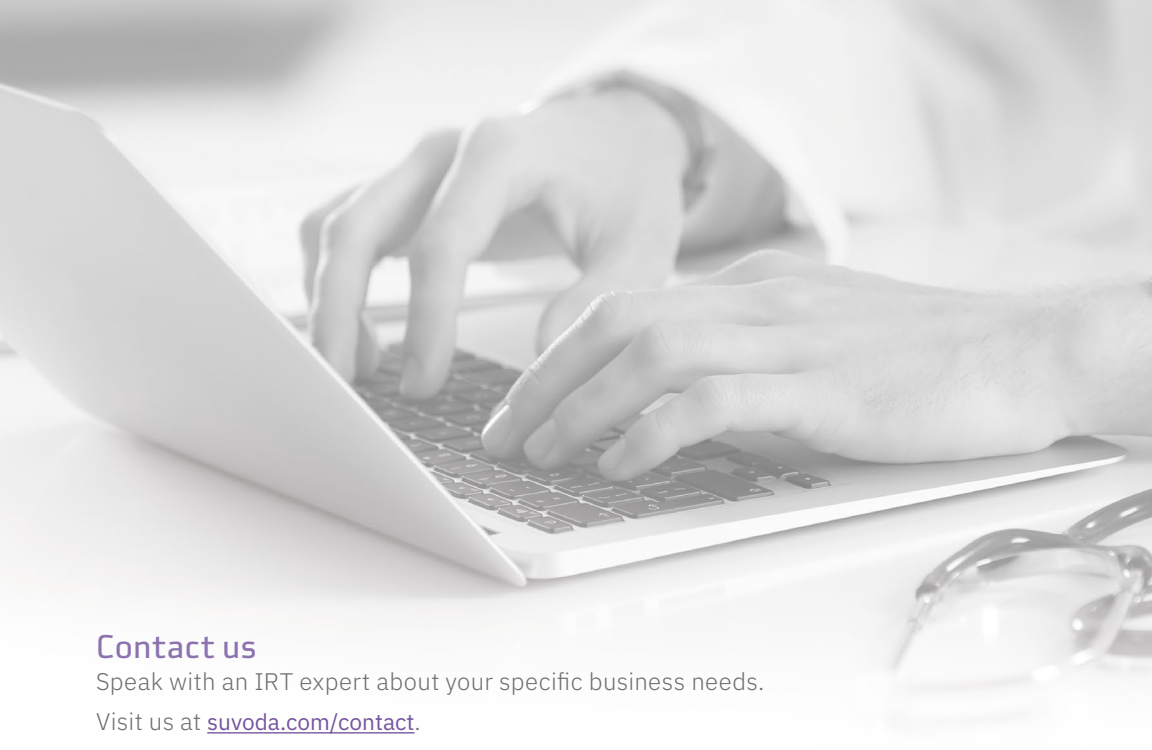
A collaborative effort for successful studies

As an early adopter, Cara Therapeutics has seen its feedback on the platform influence improvements, including the creation of eCOA templates, making documents more user-friendly for non-technical staff, and creating patient training videos for eCOA.

> "At Cara Therapeutics, our goal is to always improve and to find better approaches to issues. Suvoda thinks the same way, looking creatively at how to approach challenges. We also appreciate seeing some of our suggestions lead to internal discussions at Suvoda."
>
> **Catherine Munera,**
> *Vice President, Biometrics Cara Therapeutics, Inc.*

About Suvoda

Suvoda is a global clinical trial technology company specializing in complex, life-sustaining studies in therapeutic areas like oncology, central nervous system (CNS), and rare disease. Founded in 2013 by experts in eClinical technologies, Suvoda empowers clinical trial professionals to manage 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 1,400 trials across 85 countries. To learn more, visit suvoda.com. Follow Suvoda on LinkedIn and X.



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