

CASE STUDY:

Reducing Risks of Complex Oncology Trials

How an intuitive, flexible system paired with a consistent, cross-functional team of IRT experts allowed Curis to easily manage their trial's unknowns with ease





Cost Savings Driven by Built-In Flexibility



100% of Timelines Met



No Mid-Study Change Orders



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.

Being immersed in drug development for almost two decades now, Curis understands at a fundamental level what is needed to achieve a well-run trial. As a small biotech company, they operate with a few key principles:

- Resources are to be carefully managed, as the time horizon for trial completion is typically very long
- Technology and outsource partners are extensions of themselves and as such, should share similar attitudes towards precision, service, and milestone completion
- The environment will always be changing but the need to manage it will be constant

The "4948" trial that targets non-Hodgkin's lymphoma has been enrolling patients since 2018. Currently, there are nine sites enrolling in the United States. They are well into the dose escalation portion of the Phase I trial.

The Challenge

In selecting their IRT vendor, Curis identified key challenges that needed to be carefully managed in running trial 4948.



Dose Escalation: As Curis moves forward in the dose escalation phase, tracking and implementing investigator feedback is essential to their success. This will most likely mean adding amendments to the trial as new information is gathered.

Keeping Sites Engaged: Sites are extremely busy tending to their patients and competition for investigators' time and attention is significant. To increase investigator engagement, Curis knew it needed an easy and intuitive IRT interface, as well as effective communication between teams.

Unpredictable Protocol Changes: Based on emerging data, Curis adjusted the dosing regimen mid-study. A change like this could pose a major challenge in a traditional IRT system, requiring system updates and additional costs.

Meeting Timelines: Since trials are long and budgets are tight, it's important for Curis and their valued partners to consistently adhere to timelines in order to build confidence inside and outside the organization.

The Solution

Domain Expertise

Suvoda supports Curis with a proven and experienced team of subject matter experts (SMEs) that provide cross-functional support from study design through system archival. Implementing cost-effective and reliable trials, especially when sites span multiple countries, requires a finely-tuned knowledge in some key areas including:

Providing an intuitive user interface for investigators
 Proper management of data for integrity and quality
 The ability to anticipate changes in trial design without interrupting flow or slowing progress
 Providing operational and logistical support when needed, especially as it relates to managing drug inventory, reporting and tracking
 System training for the Curis team and users at investigator sites
 Ability to proactively manage study changes to adhere to Curis's budget

No Mid-Study Change Orders

and timelines

Curis wanted to avoid requesting change orders to minimize additional costs and also reduce the potential of slowing down study progress or halting enrollment. Suvoda's IRT software is built to withstand as much change as possible by using a configurable design and making sure that the features themselves are designed to handle flexibility. This design philosophy allows Curis to make real-time changes through the user interface, in conjunction with Suvoda's guidance.

Efficient Collaboration

Beyond valuing speed, quality and cost, Curis deeply cares about having an excellent relationship with their partners. The interaction must be relatively easy as the workload is heavy. Viewing partners as extensions of themselves, Curis has identified effective collaboration as a top priority in vendor selection. Suvoda understands this need and is guided by a few key principles:

Consistent Point of Contact

Knowing who to go to as issues arise should be simple and straightforward.

At Curis, we see Suvoda as a member of our team and not just a vendor.

Chris Lieberman
 Clinical Trial Manager,
 Curis

100% accountability

Curis wants partners who focus on the solution and can collaborate to get to the desired endpoint.

A peer relationship

Curis believes in parity with its partners. Organizations should be viewed as having different but equal strengths, and value comes when the vendor and the client work shoulder to shoulder with respect and mutuality.

Overall easy to work with

In a technical world driven by science and analytics, "easy" might sound soft, but Curis knows from previous experience, how important "easy" is. Thorough communication and a clear alignment on goals up front and throughout a trial can help to foster excellent performance.

By discussing Curis's protocol in great detail upfront, we were able to provide design recommendations that would account for all potential future protocol changes. So when dosing regimen changed after the system went live, no system changes were needed - just some guidance from Suvoda about how to make the updates within the user interface.

 Abigail Williams, Services Delivery Manager, Suvoda

The Results

Biotech companies, with little margin for error, need to be able to manage constant flux in their environment.

Carefully selecting the right technology partner is a big part of solving this challenge, setting the table for future success. Curis selected Suvoda's IRT solution because, in addition to the technology company's ability to manage change with relative ease, their IRT technology was exceptionally intuitive, allowing the team to become self-reliant and avoid seeking constant support.

The winning combination of Suvoda and Curis has enabled Curis's potentially life-saving clinical trials to progress as they envision a future of new effective therapeutics.





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