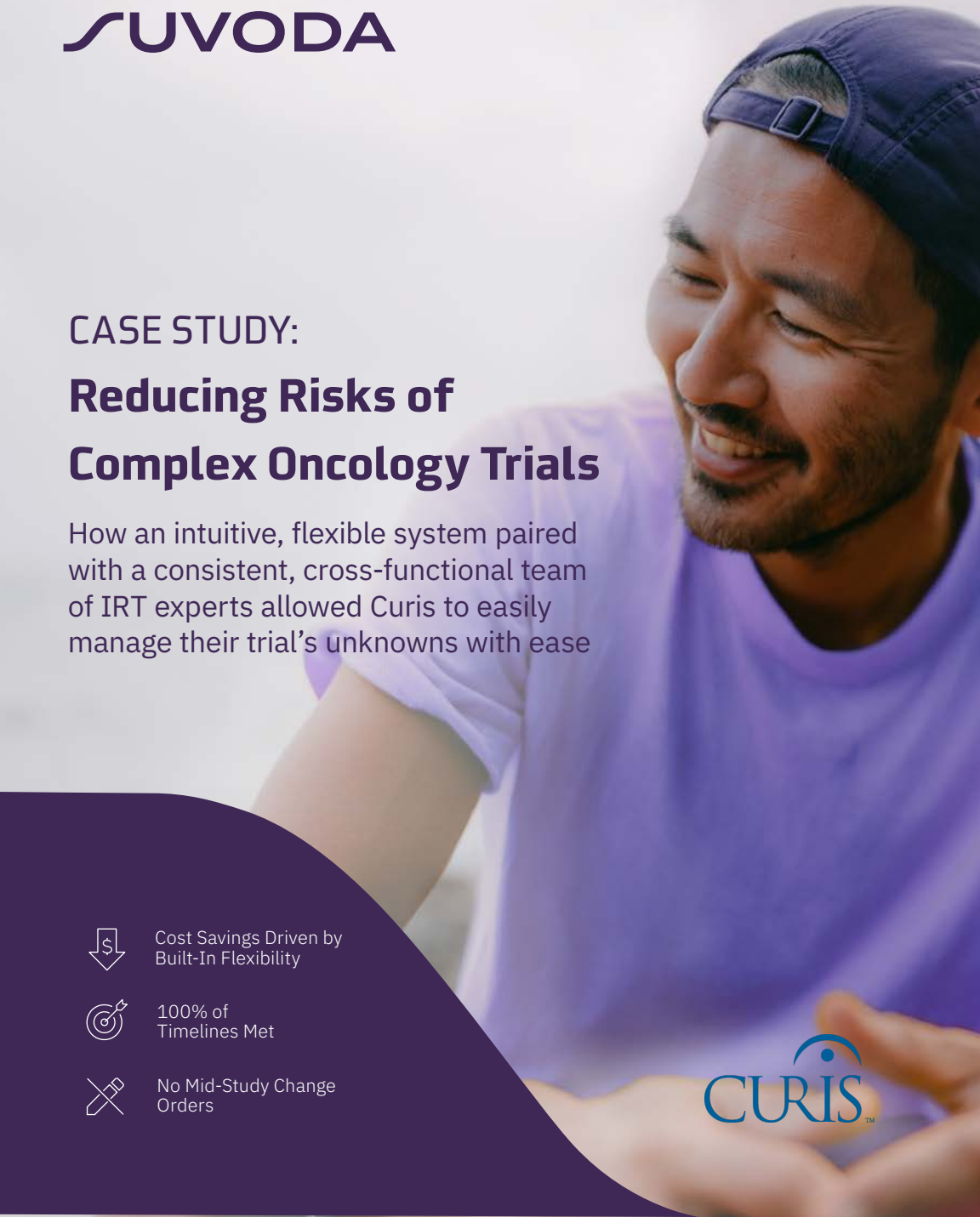
SUVODA

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

CURIS™

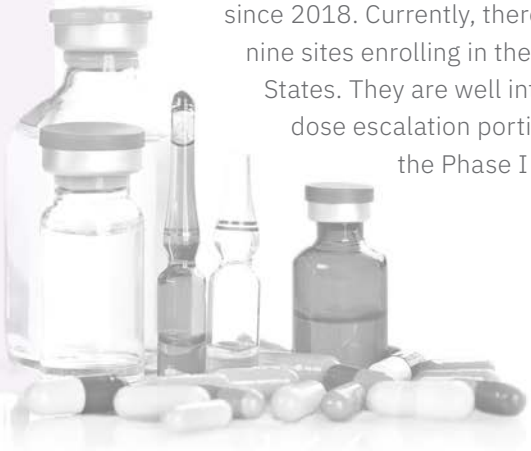
About Suvoda

Suvoda is a global clinical trial technology company that specializes in highly 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 innovative trial design and advanced IRT, eConsent and eCOA solutions. Headquartered outside Philadelphia, Suvoda also maintains offices in Portland, Oregon; Barcelona, Spain; Bucharest, Romania; and Tokyo, Japan. The company consistently boasts customer satisfaction scores of 9 out of 10 and has been selected by trial sponsors and CROs to support more than 900 trials across 65 countries. To learn more, visit suvoda.com.

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 and timelines

No Mid-Study Change Orders

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:

> At Curis, we see Suvoda as a member of our team and not just a vendor.
>
> **— Chris Lieberman**
> Clinical Trial Manager,
> *Curis*

Consistent Point of Contact

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

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.

Contact us

Speak with an IRT expert about your specific business needs.
Email us at salesinfo@suvoda.com or call one of our locations below.

H Philadelphia, Pennsylvania, U.S.: +1.610.572.2920
Portland, Oregon, U.S.: +1.610.572.2920
Barcelona, Spain: +34 935 222513
Bucharest, Romania: +40 31 2265529
Tokyo, Japan: +81 (3) 5786-3871

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Trial wisely