SUVODA

CASE STUDY:

Automating the IRT Process for Temperature-Monitored Shipments

How Grünenthal leveraged Suvoda IRT to turn a long and costly manual process into a same-day, automated solution

- Same Day Solution From 29 Days
- Automated Alerts
- Lower Risk of Patient Drug Shortages

GRÜNENTHAL

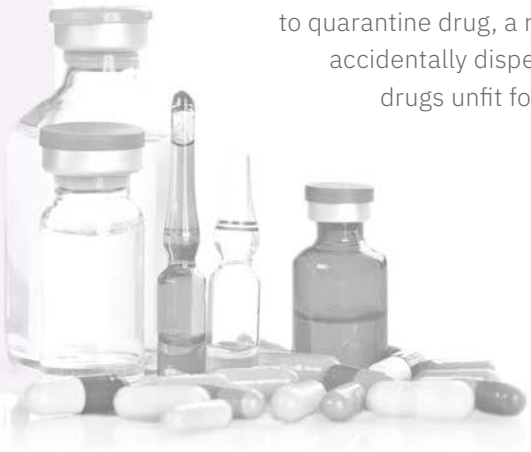
About Suvoda

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.

The Challenge

As a research and development company focused on innovative pain treatments, Grünenthal was very familiar with the frustrating delays that plagued the shipping of temperature-monitored drugs in clinical trials. Historically, the temperature management process was extremely manual, lacking overall visibility and consistency.

Upon analysis of 4,000 of its own temperature-monitored drug shipments, Grünenthal discovered that an average of 29 days elapsed while the study team obtained and evaluated data for each excursion that occurred. During that time, the drugs were quarantined and not dispensable to patients—which could potentially result in a temporary drug shortage or if sites failed to quarantine drug, a risk of accidentally dispensing drugs unfit for use.



The Solution

With too much time being lost in the supply chain, Grünenthal approached Suvoda to collaborate on automating a process that would dramatically reduce the time spent responding to temperature excursions. It was clear that IRT—which governs the raising of drug shipments, handling of depot drug inventory, and registration of shipments upon receipt at site—could be the central, driving force in this first-of-its-kind automation.

Creating a Roadmap for Successful Integration

The future of the clinical supply chain depends on enabling real-time, multi-system integrations with best-in-class partners:

- Suvoda IRT: a modular, SaaS-based IRT that supports complex clinical trials
- Catalent®: depot network used for packaging and distributing clinical supplies
- Berlinger: data loggers for monitoring shipment temperatures

In order for this multi-system integration to be successful, it was crucial to solve these 3 challenges:

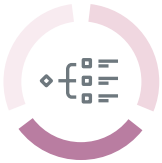
Challenge 1
3 Different Data Models

Solution
Normalize all data and terminology

Challenge 2
3 Different Systems

Solution
Determine data requirements up front and understand technical capabilities of each system

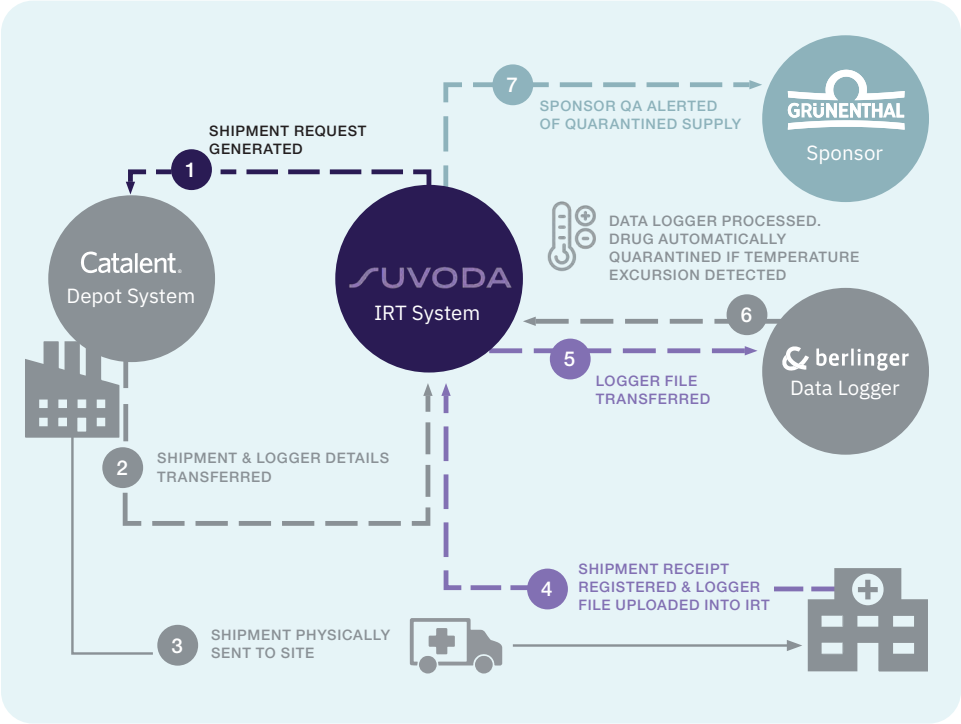
Challenge 3
3 Different Product Roadmaps



Solution
Coordinate development and validation to ensure a long-term solution

Configuring the Automated Process

At a very high level, the movement of data was always centered around IRT, which acted as the nucleus for all drug shipment logistics from beginning to end. Suvoda IRT raised the shipments, but also needed input from Catalent on the shipment data loggers and Berlinger on excursion data.



Suvoda built a smart, predictive system that was flexible enough to handle a number of edge case scenarios such as a damaged logger, or a logger that was mistakenly excluded. With these scenarios in mind, logic was built into the system to ensure a seamless user experience and to support automation, regardless of what happened in real life.

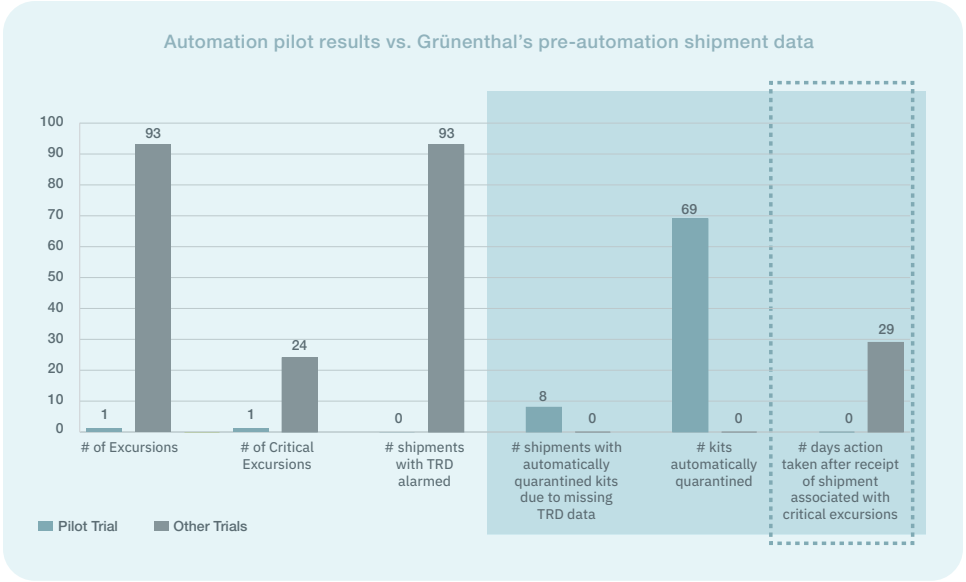
Automatic notifications generated by the IRT system kept the Grünenthal Clinical Supplies staff informed, which allowed them to streamline their excursion review process.

The Results

After conducting a 50-site pilot study utilizing this innovative integration, Grünenthal saw a significant improvement in the visibility of their temperature management process. It became a powerful demonstration of how dramatically automation can improve trials with temperature-controlled shipments. Its principal findings:

- A 29-day manual process became a same-day solution, helping to prevent drug shortages
- 89% reduction in shipments with automatically quarantined kits
- Process automation can ensure that World Health Organization guidelines for ambient temperature are consistently observed.

> Ten years ago, our industry was focused on the need for detailed drug accountability, and the role of IRT systems became more integral to the supply chain as a result. Now, leveraging IRT systems with more automation will have a similar impact on the drug development landscape.
>
> **— Henk Dieteren**
> Former Senior Clinical Supply Manager, *Grünenthal*



The Future of Clinical Trials

Grünenthal and Suvoda, supported by a multi-partner innovative integration, demonstrated the ability of IRT to automate a critical aspect of a clinical trial: the accurate tracking and recording of drug status for high-value, high-cost, temperature-monitored drugs. The clinical trial process offers many more opportunities for automation, each holding more potential to accelerate successful outcomes for clinical trials.

For Suvoda, this successful pilot demonstrates how the company's focus on providing speed, agility, and insight into the most complex clinical trials can drive innovation for its customers. By continuing to collaborate with other patient-centric pharmaceutical and biotechnology companies equally passionate about innovating the supply chain, and by providing the best integration and project management services in the industry, Suvoda believes IRT-based automation will continue to uncover new ways of getting treatments to patients faster and more efficiently.

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

SUVODA

Trial wisely