



CASE STUDY : DIRECT-TO-PATIENT

Faced with an incredibly complicated study earlier this year, CSM® took the time to create a solution that was not only effective, but almost revolutionary. The company's innovative approach to this challenging situation has confirmed its standing in the industry.

CHALLENGES

At least five distinct challenges presented with this study, and CSM approached each one in such a way that novel solutions were found, creating successful outcomes.

- 1 The study involved an orphan indication with only two clinical sites participating in the United States. Although the sites were 1500 miles from each other, patients were dispersed around the country.
- 2 Patients participating in the study needed to be dosed three times per day for 14 consecutive days. Strict compliance with the dosing schedule was very important.
- 3 The drug product needed to be reconstituted no more than 48 hours before dosing; it would lose its efficacy after 48 hours. This restriction disallowed patients from picking up a 14-day supply from the clinical site and taking it home.
- 4 The medication is temperature controlled and must be kept at 2- to 8- degrees C.
- 5 The 36 patients are all minors, so they could not be housed at one of the two clinical sites for two weeks, away from their families.

The drug had to be delivered direct to patients, with enough time built into the delivery schedule for actual transit as well as potential transportation problems. The 14-day trial included weekends, meaning weekend delivery schedules had to be considered. The drug also had to be kept at the proper temperature during delivery.

"This was one of the most logistically complex issues we've ever been faced with," says Bob Albanese, Vice President of Operations. "It may even be one of the most logistically complex studies ever for this industry."

But CSM's whole mission is about facing complex issues head-on and finding ways to succeed where others cannot. The company's reputation is built on its ability to work in an agile mindset, embracing high variability. One of the many products offered by CSM is the On-Demand platform, where drugs are packaged and shipped only upon request.

"We don't simply do things the way they've always been done," Albanese adds. "We take the unique thought process that created our platform and apply it to a variety of things. In this case, that platform allowed us to think creatively and find answers that otherwise may have eluded us."

CSM'S SOLUTION

The CSM team designed a patient kit that was reconstituted daily and shipped overnight, even on weekends. Included in the kit was a state-of-the-art temperature monitoring device that updates via cell phone service and GPS to a web-based reporting tool. Using the device allowed CSM to track the location of the package and its temperature as well as when it was opened and for how long.

Some of the main points of CSM's success include:

- New batches were made every day, utilizing CSM's On-Demand process.
- Instead of using freight integrators (whose shipping schedules don't adhere to the trial's regulations) CSM utilized commercial flights and courier services for direct-to-patient delivery.
- CSM used Credo Cube® shippers to keep the contents refrigerated correctly and a SenseAware® powered by FedEx monitoring system that kept CSM apprised in real-time of the status of the package.
- A personalized logistics plan was created for each patient that examined where he or she lived and what couriers and flights would work for him/her. Kits were sent directly seven days a week.
- CSM is a TSA-certified cargo screening facility; everything is inspected before leaving the dock in Fargo and special stickers are applied so TSA knows no further inspection is necessary.
- The cellular-based multi-sensor device used by CSM lets the package "talk" to the team. It sends an alert if it is out of temperature range or if it sits too long without being transported. It also records that it "saw" light and for how long every time the package is opened.
- If the box was not opened three times per day to get the medication, someone at CSM contacted the clinical study site.

Additionally, returns and reconciliation were able to be done right away rather than months later, the standard for most clinical trials. Because a courier delivered the next day's dosage directly the patient's home, he/she was able to pick up the return package at the same time. This verifies that the medication was taken correctly, within acceptable parameters—reconciling within 15 to 16 days of patient enrollment.

"Everyday we find new ways of meeting and exceeding our client's expectations. It's exciting to see how our mindset along with the On-Demand platform is now making the impossible, possible."

Gerald E. Finken, President and CEO



Clinical Supplies Management, Inc.
342 42nd Street S
Fargo, North Dakota 58103
701.235.8002
csmondemand.com