

Making a complex pediatric clinical trial possible

New medications require complex clinical trials. The trial for an inhaled pediatric therapy was especially challenging. The 36 young patients, located across the U.S., were required to take doses at three specific times each day for 14 consecutive days.

The challenge was that the medication had to be prepared in a laboratory, shipped fresh daily, used within 48 hours, and maintained at 2 to 8°C at all times.

While some companies might shy away from a trial this complex, the team at **Clinical Supplies Management, Inc. (CSM)** relished the opportunity to demonstrate their expertise. They considered the trial's challenges — children, product life, temperature, multiple doses at exact times, and geography — and determined they could make it work with SenseAware®, a FedEx innovation.



12:32 p.m. Is it the right temperature?

- A patient kit with three freshly constituted doses of test medication ships overnight from CSM to the patient's residence.
- The SenseAware device verifies the drug remains between 2 and 8°C during transit.



8:03 a.m. Where is it?

- When the patient kit passes through the geofence around the child's home, SenseAware emails the trial coordinator that the shipment will soon be delivered.
- If the package is delayed, CSM can quickly verify location in real-time.



9:45 a.m. Did it arrive safely?

- The trial coordinator views the patient kit's journey.
- Data shows the temperature held steady and no exposure to light was detected from laboratory to the patient's home — verifying safe delivery.
- The coordinator calls the caregivers to remind them to refrigerate the patient kit.



2:00 p.m., 9:30 p.m., 9:30 a.m. 3 doses confirmed

- The coordinator uses the light exposure notifications from SenseAware to verify the kit was opened at the proper times for all three doses.
- Continuous temperature monitoring validates the product's temperature from shipment to final dose.



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To learn more about SenseAware, call a SenseAware Advisor at **901.434.3030** or go to **senseaware.com**.