ThermoFisher SCIENTIFIC

CASE STUDY

Delivering Clinical Trial Medications Direct-to-Patient

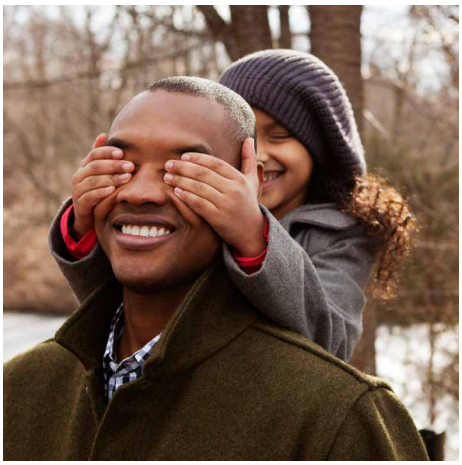
In a perfect world patients enrolled in clinical trials would live a short distance from the investigator site where they receive their treatment. Unfortunately that is not always the case. In recent years the Direct-to-Patient model, which brings medical procedures to a patient's home, has emerged as a solution for Sponsors to increase patient recruitment and retention in clinical trials.

The challenge

A pharmaceutical manufacturer was working with Thermo Fisher Scientific in support of multiple clinical trials and protocols. Patients enrolled in these trials were occasionally unable to maintain an appointment at their respective investigator site. The circumstances were many and varied. Examples included:

- A hurricane had impacted all travel to one of the locations dispensing the medication.
- A patient had moved to another state in southwest United States. Although approved to receive the medication from a west coast facility, they could not travel the distance.
- In a compassionate use scenario the patient was located in Florida but the medication was in New England.

The Sponsor recognized that providing Direct-to-Patient service on an exception basis would meet a critical need. Because the patients participating in these trials were able to self-medicate, it was strictly the residential delivery that needed to be addressed.



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The solution

The Total Transportation Management, in conjunction with Patheon speciality logistics offering, includes courier transportation services. The Fisher Clinical Services℠ Distribution Project Managers, their specialty logistics colleagues and the sponsor's clinical trial drug supply management team joined forces to outline the requirements and possible solutions.

The Investigational Medicinal Product (IMP) involved in the Sponsor's trials required a variety of temperature controls managed through to patient delivery. To meet these needs, the specialty logistics team recommended re-usable shippers which have a 96-hour hold time, and can be validated to three different temperature settings: -20°C, 4°C and 20°C.

The sponsor established a QA-approved Standard Operating Procedure for these exception deliveries. In practice, the process was outlined as follows:

1. Patient contacts the Clinical Investigator Site advising that they are unable to maintain the scheduled appointment at the investigator site.
2. Clinical Investigator Site contacts the sponsor to obtain required approvals.
3. Sponsor notifies Fisher Clinical Services Project Manager who obtains the patient-specific details from the Clinical Investigator Site.
4. Fisher Clinical Services Project Manager contacts the specialty logistics team and provides the timeline, the pickup & delivery address and contact information, product involved and required temperature.

5. Specialty logistics Program Manager arranges for the transportation, validated re-usable shipper and temperature logger. They coordinate communications with the Clinical Investigator Site and patient, establishing a 1-hour delivery appointment, and maintain personal contact throughout the process in the event of delays or exceptions.

6. At the investigator site, the Clinical Investigator Site staff ensures the medicine is properly packed in the re-usable shipper and activates the temperature logger.

7. Upon arrival at the patient's residence, the driver stops the data logger. The temperature information is reported to Fisher Clinical Services via the specialty logistics Program Manager, and the re-usable shipper is returned by the courier.

8. The Fisher Clinical Services Project Manager shares the delivery data with the Clinical Investigator Site. The patient then follows the instructions from the Clinical Investigator Site and is now able to take the medication.

Conclusion

The close collaboration of sponsor, Clinical Investigator Site, Thermo Fisher Scientific and the specialty logistics team was evidence that all have the same priority: We're serving a patient. From the patient's perspective it removes a costly and time-consuming transportation burden, and provides an uninterrupted flow of medication that is critical to their treatment. For the sponsor, it clearly demonstrates the patient comes first, maximizing patient engagement while ensuring they remain enrolled in the trial.

We have since further optimized our processes for emergency Direct-to-Patient needs and implemented a standard approach for regular study set-ups. Moreover, the Direct-to-Patient service offering has been expanded globally to meet all customer needs. For more details on our Clinical Site-to-Patient, Pharmacy-to-Patient, and Depot-to-Patient services, please contact your sales representative.

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