

Improving retention in a rare disease study

How Coram Clinical Trials improved quality of life for families participating in a clinical trial



A case study in pediatrics

Understanding the need

A study sponsor was having retention issues because pediatric patients with a rare disease were traveling long distances to an investigator site for a seven-hour infusion every week, resulting in missed work, school, and other activities. As is common with rare diseases, the families of these subjects were profoundly affected.

By servicing young patients in the comfort of their own homes, they—and their families—were able to maintain their schedules. Weekly travel was eliminated, and quality of life and retention were improved.

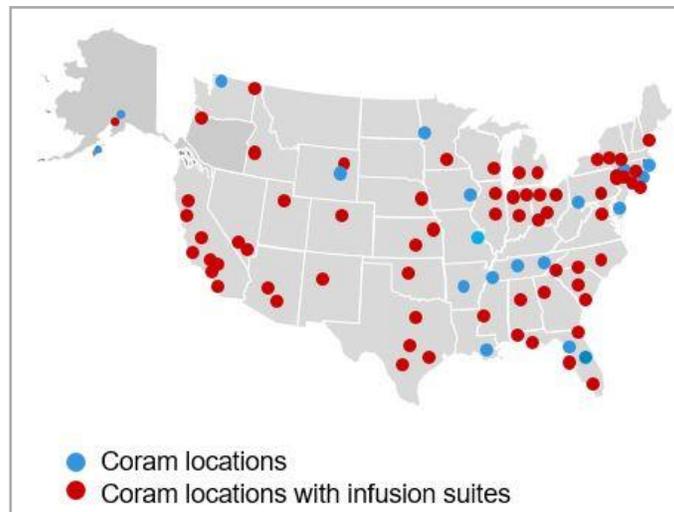
How we did it

Integrated services

One of the hallmarks of Coram Clinical Trials is our integrated services. Because we own the clinical supply chain—including both central and local pharmacies, employed home care nurses, and project management staff—we are able to tailor clinical trial solutions to suit the needs of all stakeholders. We control quality at the same time.

Our integrated services were paramount to our ability to effectively service patients in this study. For example:

- Our local pharmacy option addressed short stability of the study drug and allowed patients to receive drug on the same day it was prepared
- Our local courier ensured timely delivery of the investigational product and helped preserve the chain of custody, minimizing potential points of failure
- Administration was provided during evenings and on weekends to help maintain patient and family routines
- Our home care nurses had the experience required to administer long infusions to pediatric patients



Coram Clinical Trials offers both central and local pharmacy options to accommodate a range of products with varying degrees of stability. Because of the short stability of the investigational product used in this study, we used our local pharmacies for drug preparation and local couriers for delivery to the homes of patients. The map above depicts our extensive pharmacy network, which includes over 90 locations, ~70 of which include an ambulatory infusion suite.

Training

At Coram Clinical Trials, we believe that time invested at the inception of an engagement results in increased stakeholder satisfaction throughout the duration of the study. We provide customized role-based training that is centered on proven adult learning principles. All of our nurses have documented competencies for infusion therapies and injections as well as a wide variety of venous access devices, allowing us to focus our training on the nuances of the protocol and the schedule of study events.

Likewise, we provide training to each site offering home care to study participants. Many sites we work with do not have experience with home care, so we work collaboratively with them to ensure they understand how to access our services, address regulatory requirements, the specific tasks we are delegated to perform, and the standard operating procedures (SOPs) that are relevant to them.

Relationships

Relationships are at the heart of everything we do. In each study, we work with the sponsor to identify ways that home care can be most impactful. We have an extensive repository of SOPs, allowing us to anticipate challenges and mobilize quickly when an issue occurs. At the same time, we have a flexible approach that can be customized to accommodate study requirements and sponsor objectives.

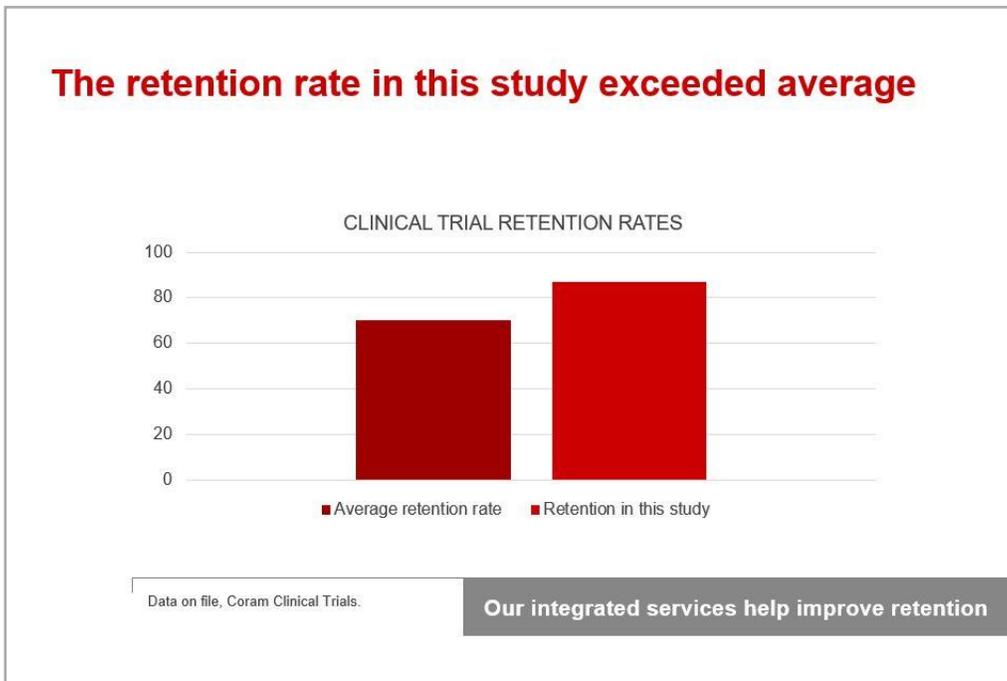
We train two nurses to provide home care services to each patient—a primary and a backup. Because pediatrics involves a complex constellation of stakeholders including the parents and family and because the administration was a long one for this study, we needed to make sure the primary nurse assigned to each patient not only had the right expertise, but that they were a cultural fit, able to seamlessly assimilate into the participant's home environment. To help facilitate that, we scheduled a face-to-face kickoff meeting between the investigator and the nurse to discuss specifics related to the patient, design the communication plan, and set the foundation for a solid working relationship with the patient at the center.

Project Management

At Coram Clinical Trials, our standard practice is to assign a two project managers to each study to ensure continuity of coverage. For this study, our project team created a detailed project plan—including processes and communication requirements for all stakeholders—at the inception of the study to set clear expectations and increase satisfaction. The result of our operational expertise was an efficient trial with minimal errors and deviations.

What we achieved

According to a study by Forte Research, the average patient retention rate across clinical trials is 70%.¹ The chart below depicts the results of this study.



We invite you to learn more about our integrated pharmacy and nursing services for clinical trials and the results we achieve. To schedule an introductory conversation, please contact Coram Clinical Trials.

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1. Source: <https://forteresearch.com/news/infographic/infographic-retention-in-clinical-trials-keeping-patients-on-protocols/>, accessed September 16, 2019