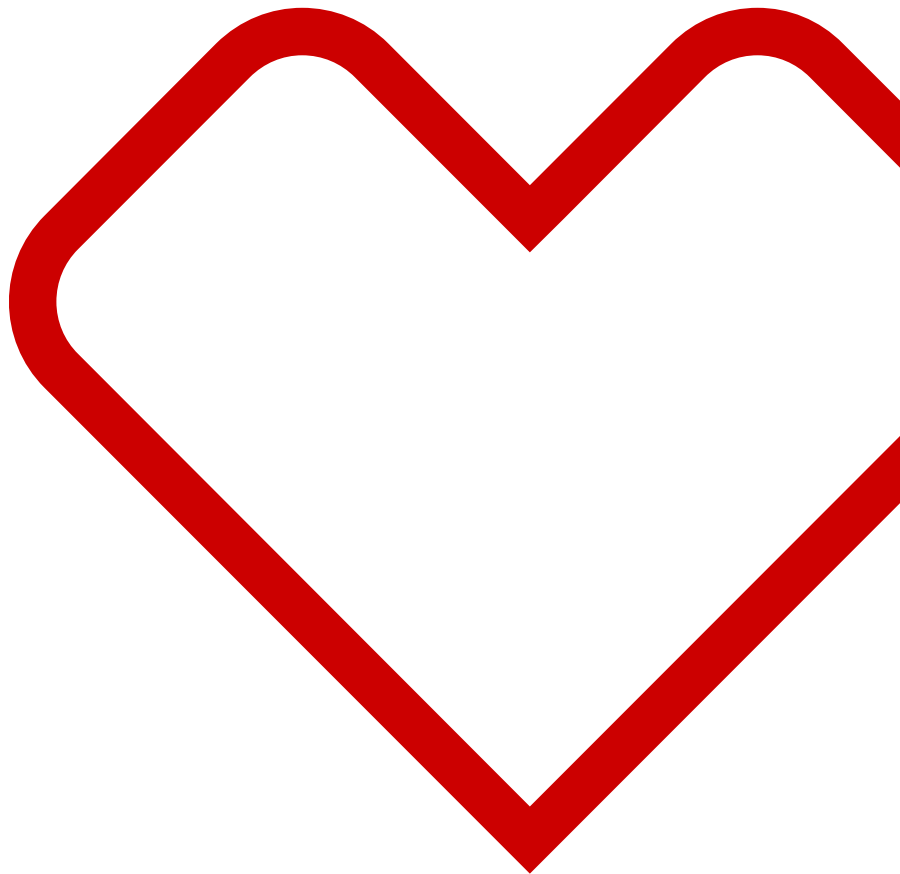


Setting new standards in complex blood specimen collection

How Coram Clinical Trials achieved a 96% success rate



An oncology case study

What we did

At Coram® Clinical Trials, we draw on our national footprint to provide home care to participants in clinical research studies. Our network of 800 employed nurses can provide coverage to 97% of the U.S. population and offer sponsors a team of highly skilled clinicians to execute on complex study requirements.

We supported an oncology clinical trial that required complex blood specimen collection and processing services for more than 400 patients. Our home care nurses completed 24 separate blood draws from each enrolled participant over four cycles of chemotherapy. These valuable samples were a critical source of data related to the study's primary endpoint.



How we did it

Training

One of the hallmarks of Coram Clinical Trials is our approach to training. 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. When we begin a new study, we provide role-based training that is grounded in proven adult learning principles and centered on executing the activities outlined in the protocol. For the complex requirements of this study, training focused on:

- Blood collection procedures for both complete blood count (CBC) and pyruvate kinase (PK) draws
- Intricate lab processing training including centrifugation, serum aliquoting and manual blood smear requirements
- Comprehensive sample shipping instruction including temperature-specific (i.e., ambient and frozen) and labelling requirements for each specimen

To appeal to various learning styles and preferences, we employed a multi-modal approach to training, which included live interactive training, video demonstrations and knowledge checks. The result was a competent and confident team of nurses who clearly understood the requirements of the protocol *and* how to execute effectively.

Communication

Blood processing was not the only complexity with this study. The study also required that Coram home care nurses complete exhaustive documentation at each visit, requiring extensive project management oversight in addition to our standard 24/7 oversight. By working closely with our home care nurses, we increased confidence and mitigated the risk of error, ensuring the preservation of data collected.

Project Management

At Coram Clinical Trials, our standard practice is to assign two project managers to each study to ensure continuity. Due to the complexity of this protocol and the volume of patient visits, we assigned two Senior Consultants and two Consultants, who designed and implemented extensive project tracking systems and paid close attention to accuracy in data entry.

Our team also created a plan for each subject that was approved by the site, the nurse and the pharmacy, in addition to the patient. This helped us set clear expectations and plan for challenges and contingencies.

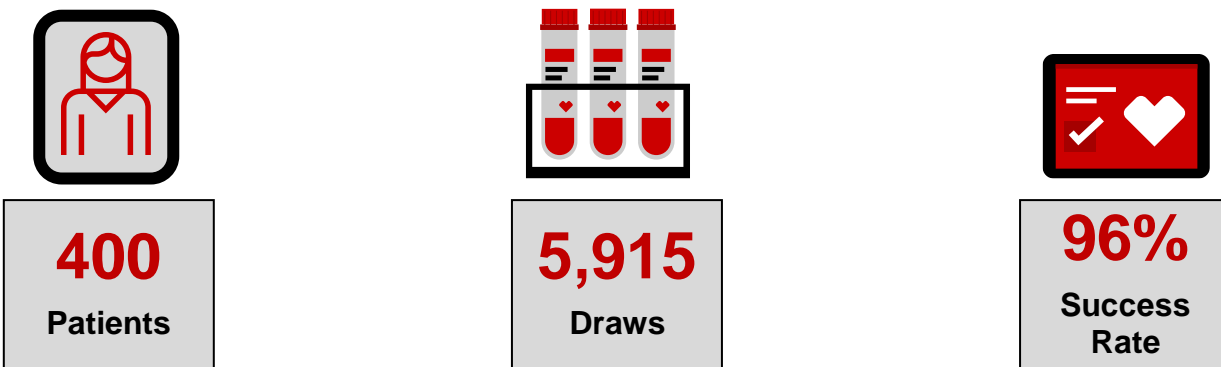
The result of our operational expertise was an efficient trial with minimal errors and deviations.

Integrated services

At Coram Clinical Trials, we have the unique ability to control quality across the clinical supply chain because we own it from start to finish. For this study, we used our central pharmacy as the supply and equipment depot, including shipping supplies. Because our nurses performed centrifugation in the home, we coordinated the shipping of samples to the central laboratory for processing. The integration of services maximized the preservation of custody and minimized the number of potential failure points.

What we achieved

Coram Clinical Trials achieved a 96% success rate across blood draws on 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.
CoramClinicalTrials@CVSHealth.com

*Coram CVS Specialty® Infusion Services