Accellacare

In-Home Services

Special populations and procedures for maternal and infant studies

Case study

The challenge

A global biopharmaceutical company was conducting a set of post-marketing studies to determine the safety and transference of a drug taken for autoimmune disorders during pregnancy and breastfeeding. This involved the following;

– Placental transfer study - A blood sample from mothers, the umbilical blood, and infants within 24-hours of delivery with additional infant blood samples at four and eight weeks postpartum

– Lactation study - Nine breastmilk samples from lactating mothers across a four week period

There was poor enrolment and retention due to required site visits in the early postpartum period and the burden of frequent sample collections from lactating mothers (approx. every two days).

The solution

Accellacare In-Home Services (formerly Symphony Clinical Research) was introduced to ease the trial burden for mothers postpartum. Visit activities included collecting and processing blood from the umbilical cord with the option for the mother and infant to be at a hospital site setting or at home. Other services included collecting and processing breastmilk samples, arranging shipment of samples, and checking for changes in health, medication or hospitalisations during in-home visits.

The outcome

In-Home Services led to **100% successfully completed visits**, the vast majority of which were within target timelines and without any issues. **There was 0% patient dropout and a 0% nurse turnover rate**. In fact, enrolment increased substantially in the placental transfer study after In-Home Services were introduced (from less than five participants before, to more than 80 subjects enrolled after). This stellar performance led to the FDA requesting the sponsor to participate in a Lactation Workshop in 2016. The sponsor also gave a global presentation on these studies, during which they outlined the benefits of using homecare. Finally, the work on these studies culminated in FDA approval of a label change for the study drugs based on the results of these trials.

Testimonial

Patient

"...The process was relatively seamless. I felt very supported by the staff and doctor at the study... I was setup with a home health nurse who brought all of the supplies I needed for the study. The nurse and I devised our schedule, and with little time or effort, our visits were completed over a two-week period between injections… I am incredibly happy to have had this opportunity"

Principal Investigator

"I am excited to participate in these important studies. Our patients have been eager to join and contribute to our knowledge about [study drug] in pregnancy and breastfeeding. We just enrolled our first patient in the lactation study and have been pleased with the collaborative spirit of the home health agency. They have made the process very smooth for us."

Performance indicator	Study 1	Study 2
Successfully completed visits	**100%**	**100%**
Visits within target timeline	**90%**	**99%**
Visits without issues	**90%**	**98%**
Nurse turnover	**0%**	**0%**
Patient dropout	**0%**	**0%**