CASE STUDY

Implementing a novel approach for recruiting a seasonal pediatric vaccine mega-trial.

Executing a large, seasonal clinical trial to evaluate the efficacy of a vaccine in infants is no small feat. It requires careful planning to ensure the needs of families, site staff, healthcare systems and sponsors are effectively addressed.

This case study demonstrates how Fortrea developed a novel approach to successfully deliver a large, industry-sponsored Phase III clinical trial to prevent hospitalization of infants due to a seasonal and dangerous illness.

KEY TAKEAWAYS

With a family-focused and site-centric study design and strategy, the Fortrea team implemented a collaborative and coordinated approach that:

- Enhanced the experience of parents, family members and researchers to effectively recruit and retain participants
- Incorporated digital health and innovation to reduce parent and site burden, facilitate timely data collection, ensure quality and achieve study endpoints
- Developed a flexible, scalable resourcing model to align with rapid startup, recruitment and multiple data cuts
- Achieved the first participant in (FPI) milestone nearly eight weeks ahead of the contracted date

Fortrea

Recognizing the challenges

Reducing parent, family and participant burden to promote compliance	Designing and delivering a feasible study that minimizes burden on parents, families and participants, and generates scientific and actionable data needed to support market approval
Engaging investigators in a post-COVID-19 pandemic environment	Identifying the optimal sites and overcoming low interest in participation due to unprecedented site burnout and staff turnover resulting from the COVID-19 pandemic
Working efficiently to prepare for the fast-approaching season	Ensuring all systems are set up and sites are ready to enroll participants at the season's onset to maximize the short enrollment window and achieve FPI milestone
Protecting the study's primary endpoint	Developing patient data collection solutions including tracking if/when babies are hospitalized with lower respiratory tract infection (LRTI) at non-study sites

Designing a thoughtful approach tailored to families and sites

Solicited advice from key stakeholders to design a protocol that minimized burden on participants, families and sites

Researchers are more likely to participate in clinical trials that are less burdensome on participants, their families and site staff. With advice from investigators, potential participants' families, regulatory agencies and Fortrea, the Sponsor designed a clinical trial that requires only one scheduled physical visit, no blood draws, and is fully aligned with standard of care. The study design made participation less demanding on parents and site staff. It also enabled the Fortrea team to create ease in obtaining informed consent, promote protocol compliance, provide enhanced site and parent/family support, streamline data collection and monitor infant safety by harnessing digital health and innovation.

Proactively generated study awareness among key opinion leaders, healthcare providers, site partners and networks

The Fortrea and sponsor teams launched a proactive outreach to investigators prior to protocol finalization, only to discover low study interest due to site fatigue resulting from COVID-19. Fortrea worked closely with the sponsor's medical and clinical teams to generate awareness and spark interest by developing strong messaging to share with key opinion leaders (KOLs) and healthcare providers (HCPs). This included a video featuring the sponsor's medical lead and an electronic flyer distributed via online medical communities, social media platforms and through referrals facilitated by KOLs, site and network partners and the coordinating center of a large healthcare system in one of the countries.

Mobilized and scaled resources to meet the season's early onset and provide support throughout study duration

Seasonal vaccine studies require systems and sites to be activated at the season's onset. As the Fortrea team was preparing for the season to begin in October, they discovered the season was starting two months early in one of the countries. Fortrea applied a "SWAT" approach and ramped up site identification, CRA and start-up resources to rapidly identify and activate sites. A Set-up Manager Role was established to coordinate all activities and communications to ensure digital systems were set up in advance of FPI. The Fortrea team also established a "Vaccine Support Hub" comprised of in-house CRAs to provide enhanced support to traveling CRAs and site staff to resolve EDC queries, system issues and optimize overall study execution.

Implemented digital health technologies and strategies to ensure timely collection of AEs, SAEs and hospitalization data

Digital technologies and strategies Fortrea implemented to facilitate timely and accurate data collection while reducing site and parent burden include eConsent, (where permitted) and eDiaries to collect solicited and unsolicited adverse reactions (ARs). The Fortrea team developed and delivered extensive training at site initiation visits (SIVs) and throughout the study via Webex and provided simplified workflow instructions on the use of the systems. Additional strategies included digital health record interrogation and remote follow-up with sites and participants' families by the Fortrea Medical Communications Call Center to ensure LRTI hospitalization data were effectively captured to achieve endpoints.

Delivering a successful vaccine mega-trial

Fortrea's close collaboration with the Sponsor, investigators and other key stakeholders—coupled with flexible resourcing, digital health and data collection strategies—enhanced the family and researcher experience and achieved study endpoints through timely and accurate data collection.

As a result of these efforts, the study recruited more than 8,000 infants at 210 sites in three countries, achieving FPI nearly eight weeks ahead of the contracted date. The primary endpoint of hospitalization due to LRTI based on clinician decision was met within 11 months of the final approved protocol and within four months of the trial opening.

LEARN MORE about our infectious disease and vaccine expertise at **fortrea.com**

Fortrea