

CASE STUDY

WCG Randomized 1,600+ Participants for RSV Vaccine Trial

A top 5 sponsor turned to WCG to recruit expecting mothers for its Phase III RSV vaccine trial. WCG support covered multiple countries and contributed almost one third of overall randomizations in the supported countries, bringing the study in ahead of schedule despite delays due to COVID-19 impacts on RSV seasonality. The sponsor met study timeline past enrollment by continuing to work with WCG's retention support.

CHALLENGE

Given the seasonality of RSV, the study had a limited enrollment window. Further complicating enrollment, the vaccine needed to be administered to mothers during pregnancy. After birth, infants were expected to attend office visits to determine their immunogenicity since the

mother received the vaccine during pregnancy, adding to the caregiver and/or mother's already-busy schedule. Shortly after recruitment began the global COVID-19 precautions reduced the spread of RSV. While positive for those not infected, this further pushed out initial study timelines and WCG was forced to adapt quickly.

METRICS

- ▶ WCG contributed 1,600+ consents
- ▶ WCG contributed one third of all randomizations in supported countries
- ▶ WCG contributed 1,600+ randomized participants
- ▶ WCG supported over 50+ sites globally, providing end-to-end progress for each participant through My Patient®

SOLUTION

WCG developed an end-to-end recruitment strategy that provided the necessary resources for screening, enrolling, and retaining participants. WCG also provided study champion support by working with the sponsor to identify Key Opinion Leaders (KOLs) and experts within the specific therapeutic area to provide guidance to other study sites/PIs.

RESULTS



Providing Dedicated and Customized Support

WCG's consultative approach resulted in a strong collaboration with 50+ sites determine which study activities needed the most support and when. WCG aligned to the fluctuating seasonality of RSV in northern and southern hemispheres to meet recruitment windows. Additionally, WCG collaborated with the PI to only provide support in areas that were needed and comfortable to the participant. As participating mothers gave birth, WCG pivoted to retention support, ensuring infants attended upcoming office visits.



Meeting Tight, Shifting Deadlines

Amidst the COVID-19 pandemic, RSV's seasonal patterns underwent a transformation. WCG successfully pivoted recruitment timelines and strategies to align with this shift. Originally, the strategy involved directing recruitment efforts towards a specific timeframe coinciding with RSV activity, followed by a focus on retention. However, owing to the prolonged effects of COVID-19, WCG found it necessary to sustain emphasis on recruitment for an extended period. Despite these challenges, the program stayed on course, meeting every deadline, and adhering to the allocated budget.



Leveraging Trust to Improve Recruitment

In the process of interacting with potential participants, WCG pinpointed a noteworthy hurdle within the study population: a hesitancy to change healthcare networks, a potential requirement for study participation. Addressing this challenge, WCG realigned its recruitment strategies within the existing network, expanding chart review and cultivating referral connections with other physicians in the healthcare network. The crucial factor in achieving the initial office visit was capitalizing on the trust participants already had with their own physicians.