

Maternal RSV Immunization Global Efficacy



Situation

Syneos Health™ is responsible for the management of a large global Phase III RSV Maternal Immunization trial enrolling 8,618 pregnant women over four RSV seasons, across 67 sites, seven countries and two hemispheres, using seven languages.

Syneos Health is providing the following services:

- Clinical Monitoring
- Data Management
- Investigator Meeting
- Project Management
- Randomization Services
- Vendor Management
- Site Contracts, Management and Selection
- Medical Affairs and Monitoring
- Patient Recruitment, Safety and Pharmacovigilance



Challenge

Syneos Health encountered many unique challenges during the course of this trial due to:

- A medically complex study population for its additional ethical and scientific complexities of physiological changes during the pregnancy
- The twofold increase of the cohort to follow up after the delivery of the offsprings
- The seasonality of the disease and the tight immunization window
- The required logistics for blood cord collection and appropriate collection of NP swabs for the efficacy endpoints
- The interactions needed between OB/Gyn and pediatricians to achieve the study activities
- The very large bolus of data to manage and the interim analysis to be conducted with 4,600 patients

Demonstrated Capabilities

- The Syneos Health global footprint has facilitated a smooth and efficient implementation of this global maternal immunization study from the early stage of the study start up to the monitoring and ongoing cleaning of the data (with 75% SDV)
- Early site commitments have ensured sufficient time to work through necessary logistics with their local hospital or local IRB, allowed pre-identification of potential study subjects and education on the upcoming trial
- The successful enrollment and retention was achieved through the partnership, built by Syneos Health and the sponsor with the sites, to establish an operational and logistical plan reproduced across all sites consistently
- Database go-live timelines were met due to a long-standing relationship between the Sponsor and Syneos Health's Data Management team who has applied all lessons learned and efficiencies of previous databases built for vaccine studies
- Due to the seasonal variations in the incidence of disease in each country, the clinical trial management has been robust and flexible
- Timely collection and management of thousands of serology samples and NP swabs

Maternal RSV Immunization Global Efficacy



Solution

In order to manage the global aspect of the study, we took into consideration the cultural habits and the national or regional differences in the way the pregnancies were managed and the patient's pathway.

To ensure appropriate enrollment, we leveraged Syneos Health's strong site knowledge and close relationships with all stakeholders involved, supplemented with country RSV surveillance and support for accurate disease peak, prescreening script and a portal to collect Screening Schedules ahead of time and Screen Failure reasons.

Early trainings were implemented for adequate and timely NP swabs collection.



Impact

Appropriate and accurate vaccination timing was achieved through identification of the regional shifts and national RSV peak identification by the RSV surveillance with official epidemiological data, site historical data and CRAs' involvement.

Continued interest and enthusiasm in the study was accomplished through frequent and transparent communication with clinical sites.

- Streamlined studies activities were secured with strong existing connections between Syneos Health and the sites and PIs and with the coordination with all stakeholders in the study recruitment and follow up.
- The application of innovative technologies, applied in conjunction with our highly disciplined project delivery methodology, the Trusted Process[®], and a commitment to continuous process improvement, results in optimized clinical development, greater operational efficiencies, enhanced quality and greater visibility of trial progress.

For more information please contact us at syneoshealth.com/contact-us.

United States
Tel: +1 919 876 9300

United Kingdom
Tel: +44 1276 481000

About Syneos Health

Syneos Health[™] (Nasdaq:SYNH) is the only fully integrated biopharmaceutical solutions organization. The Company, including a Contract Research Organization (CRO) and Contract Commercial Organization (CCO), is purpose-built to accelerate customer performance to address modern market realities. Learn more about how we are **shortening the distance from lab to life[®]** at syneoshealth.com.