clinetic

CASE STUDY

The Convergence of Patients, Sites, and a Data Driven Technology Platform in a Challenging Study

Study Objectives

To support the clinical development and launch of a new vaccine, the client sought to better understand the burden of disease for a particular condition in infants. Through this study, the client wanted to understand the burden of disease both in terms of direct healthcare utilization and quality of life (QoL).

CLIENT
Large pharmaceutical organization

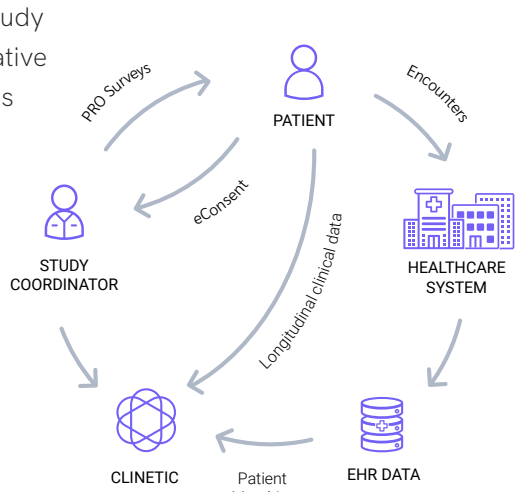
THERAPEUTIC AREA
Infectious Disease, Pediatrics (Infant Respiratory Syncytial Virus)

Challenges

A prospective study design was required as QoL data are not routinely collected in clinical practice. The low prevalence and highly distributed nature of the infant patient population challenged the feasibility of conducting the study through a traditional in-person, in-clinic strategy- it would not have been operationally or cost effective to place research staff at each location given the low patient volume per clinic. Furthermore, participants needed to be enrolled into the study quickly after diagnosis to capture the QoL data as patient reported outcomes (PROs) at specific time intervals.

Our Approach

Clinetic's innovative research platform was used to successfully achieve study enrollment and complete the prospective observational study. A collaborative approach engaging patients and sites through a data-driven technology was deployed to overcome operational barriers.



Several key activities, including patient identification and informed consent, were centralized to drive efficiency. Clinetic software was connected to Electronic Health Record (EHR) data for more than 100 clinics and generated a daily list of identifiable patients based on the prior day's encounters. Both structured and unstructured data elements from the medical record (e.g. chief complaint, symptoms, lab tests ordered) were used to identify potentially eligible patients. A centralized study coordinator confirmed eligibility, conducted outreach, and obtained informed consent electronically.

To minimize the burden of participation, patients completed a series of PRO surveys remotely and were not required to visit a clinic in person. To minimize the burden of data entry, detailed longitudinal information from the patient's medical records were combined with the PRO survey results to create a robust data set for quality review and analysis.

Diversity information (e.g., gender, race, ethnicity, insurance type) for participants was tracked and compared to population-level metrics for the participating clinics to ensure the enrolled cohort was representative.

Results

Collaboration with the research sites enabled the study to take advantage of the powerful existing patient/provider relationships and drive enrollment into the time sensitive study.

Identified 100% of patients who met study criteria across all clinics and care settings

Completed target enrollment in 14 weeks with diversity matching underlying patient population

Retained 97% of enrolled patients for study completion

Generated **results** for dissemination at the **ISPOR conference and in a peer-reviewed journal**

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