Anti-Viral Treatment for Infants

Background:

A medium-size biotech is developing a novel treatment against Respiratory Syncytial Virus. They started their Phase I First-in-Infant study and, within the same time period, planned for the Phase II study in the same program

Issues:

The patient population in the ongoing Phase I study were **infants and toddlers (from 28 days up to 2 years of age)** which made recruitment of the targeted patients for the study a major challenge. *At the time when Europital activities began, only 20% of targeted patients was recruited.* Any delay in recruitment will have significant impact on the whole development program.

Europital approach:

To boost recruitment in the Phase I study, together with the project team from the Sponsor and the involved CRO, Europital established a Site Engagement Plan that was implemented by our Medical Experts assigned to the project and acting as Medical Representatives of the Sponsor. A series of meetings (i.e. F2F, Teleconferences and videoconferences) had been organized between our Medical Experts and the Principle Investigators (PIs) in the various participating countries in Europe and Asia. These meetings with PIs where used to establish a reliable partnership between PIs and Sponsor and resolve any potential obstacles that might slow down recruitment at site. In the meantime, more detailed clarification were provided about the study and the selection procedures.

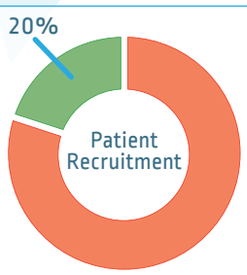
Results:

PIs from all participating sites, both in Europe and Asia, welcomed the Site Engagement initiative and the planned meetings with our Medical staff. The direct interactions between our Physicians and the PIs through the Site Engagement Plan emphasized the Sponsor's commitment towards continuous support to the participating sites and Investigator, and provided needed clarifications and solutions to observed issues at each individual site; this resulted in a greater positive effect on prioritization of the study at the various sites. *During the 6 months following the performed Site Engagement Activities, the remaining 80% of patients required for this Phase I study were recruited and the project met its originally planned timelines.* Additionally, with the continuous interaction of Europital Medical Experts with PIs, these same PIs expressed also their enthusiasm to participate in any planned Phase II study for the same program.

Respiratory Syncytial Virus

Phase I
First-in-Infant study

Infants and toddlers



Challenging Recruitment

MD-to-MD Interaction
Issues Management
Problems Solving
Emphasis of Commitment

Site Engagement Plan

Subsequent 6 Months

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