

BACKGROUND -

Sponsor is conducting a Phase III study in India to evaluate the effectiveness of their drug on the ambulation of pediatric patients with DMD. The study is 72 weeks in duration followed by an additional 72-week OLE. Once patients are randomized to the study, it will be key to ensure that they are able to complete all study visits over the extended duration of the study.

CHALLENGES -

The remote locations of the patients in relation to the site facilities results in difficulty ensuring that patients will complete their study visits.

Adding to the logistical challenges are the advanced disease state of the patients and the related need for two caregivers to accompany the patient at each visit.

SCOUT'S APPROACH

Upon review of the study design, patient population and necessary logistics support, we suggested a scope of Scout Clinical services to include:

- 1. Specific forms of transport available to local remote areas in India bus, specialized non-emergency medical transport, train, flights, and car service
- 2. Hotels to accommodate up to four people in a room with wheelchair access
- 3. An expense management system simple and effective for individuals who may not have an active bank account, or where debit cards may not be accepted.

SCOPE -

Provide logistics services and expense management services to 45 patients and families located in remote areas of India participating in a Phase III study and its Open Label Extension.

SPECIALIZED SOLUTIONS -

Two days prior to Diwali, a study site randomized a patient and scheduled their first study visit for the day immediately following the conclusion of the festival. The patient would be accompanied by two caregivers. Although the patient lived only 250km from the treatment site, the train and bus schedules were affected by the Diwali festival activities and were not fully functional or reliable. Our India-based team worked during the days of Diwali, while the site was closed, to organize private car transport and the necessary hotel bookings for the patient and caregivers. Upon the sites' return to the office, all of the arrangements had been finalized and the patient's travel was already in progress. The patient was safely delivered to the site and completed the study visit on time.

The site, patient and caregivers, CRO and Sponsor all expressed their gratitude to the Scout Clinical global team for our dedication to service, our perseverance in difficult circumstances and for our knowledge and experience in the site and patient local region.

Scout quickly and competently provided customized ground transportation, hotel accommodation with wheelchair access, and an easy to use expense management account, thereby ensuring no patients dropped out of the study due to financial or logistical barriers.

