Synteract Beats Tight Timelines for Site Identification in Pediatric Dermatology Study

Highlights

- Feasibility/site identification as part of a full-service contract for a Molluscum Contagiosum study.
- Quickly identified and activated sites, and launched the project to address the Sponsor's tight timelines.
- Developed a structured communications and follow-up plan to beat milestones and ensure FPI was achieved, exceeding Sponsor expectations.

Introduction

We were tasked with identifying 160+ dermatology sites (70 targeted for activation) across the U.S. for two Phase III trials within an eight-week timeframe. This was an increase from the original 60 sites targeted for activation.

Each of the Phase III, multi-center, randomized, double-blind, vehicle-controlled, parallel group studies were designed to compare efficacy and safety of the study drug to treat Molluscum Contagiosum. Synteract needed approximately 340 subjects to randomize, both male and female, six months of age and older.

Challenges

- We were tasked with achieving First Patient In (FPI) within 12.5 weeks. Time for site-level feasibility preparation was reduced to 70% (1.4 weeks versus 2 weeks).
- As per the study protocol, of the 70 US sites identified, no more than 10 percent could be in any one state. Additionally, 70 percent of sites needed to be dermatology sites, with the remaining 30 percent comprised of pediatric and family medicine sites.
- Maintaining balances by region and investigator specialty proved challenging as Molluscum is often more prevalent in areas that are humid and/or where swimming pools are common. There was a lot of interest in Florida, and less in the Midwest, for instance.

Our Solutions

- Synteract saved nearly a month's time in site activation.
- We identified 100+ sites from our investigator database and also used resources to pull in states not represented within the pool. 28 sites were provided by the Sponsor.

- We drew on established relationships with dermatology sites across the U.S. to expedite timelines.
  - Knowledge of these sites was essential to waive pre-trial visits (PTVs) as standard operating procedures (SOPs) state that PTVs can be waived for those sites monitored in the last 12 months.
  - PTVs could be waived in 62 percent of the 100+ Synteract-identified sites and in 61 percent of the 28 Sponsor-identified sites.
- We worked diligently to track progress and maintain the 10 percent maximum per state and 70/30 percent balance in types of sites for each of the two clinical trials.
  - Since the study involved two identical protocols, we tracked them under one, and fielded data (by dermatologist, state, type of site) into the appropriate queue.
  - We created extended metrics to show which queue sites fell into.
  - We also tracked CRAs allocated to each study, so as not to overload them.
  - Teams met each week regarding site selection, and Synteract sent the Sponsor recommendations and a weekly feasibility workbook.
  - At any time, the Sponsor could see site selection status for both protocols.
- We developed processes to expedite site level feasibility and orchestrated several feasibility processes in parallel to save time.
- We trained feasibility managers for site selection launch with discussions on project specifications and expectations.
- We developed an aggressive outreach and escalation process for follow-up and sent reminders to other feasibility managers to maintain timeframes and format.

- As site selection wrapped up, Synteract provided clinical team and functional groups with full details on sites during handover to ensure a smooth transition.

Program Success

- We met all milestones to ensure FPI was achieved.
- Enrollment was closed in record time.
- We launched the project with the Sponsor within 10 days of having the work order signed, addressing its tight timelines.
- We identified 160 sites in four weeks, exceeding Sponsor expectations.

About Synteract

Synteract is an innovative, full-service CRO supporting biopharma companies across all phases of drug development to help bring new medicines to market. Synteract has conducted 4,000 studies on six continents and in more than 60 countries, working with more than 26,000 investigative sites and 750,000 patients. It has contributed to more than 240 product approvals. Synteract offers a notable depth of expertise in oncology, general medicine, dermatology, and neuroscience indications, as well as rare and orphan, pediatric, and immunotherapy studies.

For more information on how we can support your clinical trial, please visit https://www.synteract.com/Therapeutic-Expertise/Dermatology or ContactUs@synteract.com.

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