CASE STUDY

Optimizing Staff in Phase 1 Clinical Trials

About WCCT Global

WCCT Global is a full service strategic development partner. Since 1998, WCCT has conducted well over 500 Phase 1 clinical trials at its corporate-owned Phase 1 unit in Cypress, CA, with experience in conducting large volume studies requiring over 200 patients. WCCT is the industry leader in Japanese bridging and has recognized expertise in multiple therapeutic areas, including Ophthalmology, Gastroenterology, Vaccines, and Influenza.

Summary

Optimizing staff for Phase 1 clinical trials can be difficult, especially when there are stringent protocol requirements and a high number of patients. Larger cohorts can result in greater efficiencies but increase the risk of deviations and errors due to burdened staff and congestion. Smaller cohorts can create more risk-free environments but result in fewer efficiencies for Sponsors and thus higher costs.

The highest-performing Phase 1 units will be able to strike a balance between these needs and conduct studies in which there are efficiencies at the staffing level, risks and deviations are mitigated, and value is passed to the Sponsor without sacrificing quality.

In a recent study, WCCT was tasked with designing a study which would accelerate timelines for the sponsor, optimize the use of staff, and keep costs down as much as possible, all while keeping the risk of deviations to a minimum. WCCT was able to create and implement such a study design at their Phase 1 unit in Cypress, CA.

Study Summary

Start Screen	7/1/2013
End Screen	7/16/2013
Total Screening Duration	15
Subjects Screened	173
FSD	7/19/2013
LSLD	7/24/2013
Subjects Randomized	96
Enrollment Duration (FSD to LSLD)	5

Study Title: *A Randomized, Double-blind, Placebo-controlled, Single Ascending Dose Study to Assess the Delivery Performance of the *** Device with *** and *** Modification Using Placebo Buffer under Ambulatory and Sedentary Conditions.*

Study Differentiators:

- High enrollment needs
- Comprehensive assessment of administration sites
- Large emphasis on device performance endpoints (complex timing, delivery, adhesion, various positioning, etc.)
- Extensive standardized photography pre, during, and post device delivery

COHORT NUMBER	SUBJECTS RANDOMIZED	DATE OF RANDOMIZATION
1	16	7/19/2013
2	16	7/20/2013
3	16	7/21/2013
4	16	7/22/2013
5	16	7/23/2013
6	16	7/24/2013

Challenges

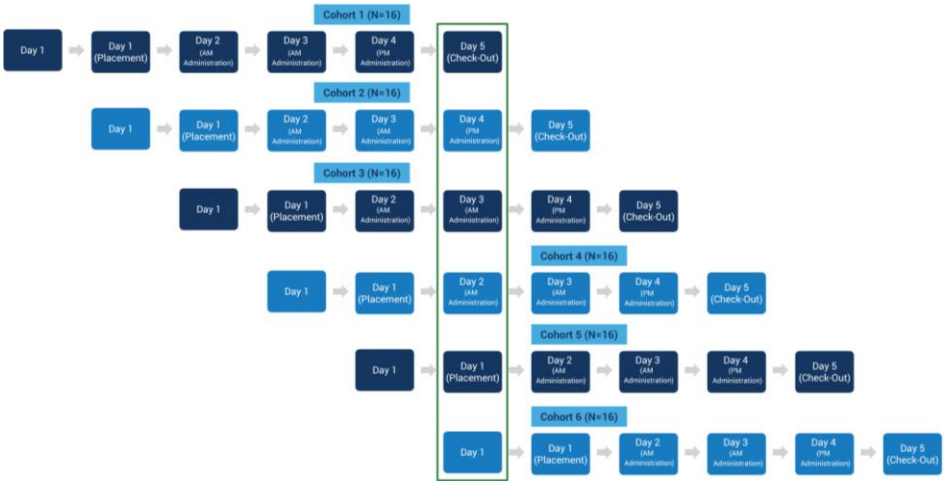
All of the aforementioned signals needed to be observed by WCCT staff, in a complex logistical situation, due to:

1. Doses occurring in a small window stagger between subjects
2. Protocol requirement to do smaller cohorts in order to minimize the repercussions of potential device failure and due to the method in which the devices were randomized
3. Protocol requirements for subjects to walk and lie down with strict timing designations during the infusion

WCCT implemented a study design which would accelerate Sponsor timelines and optimize the use of staff in order to keep costs down.

Solution

WCCT created and implemented a study design in which cohorts were enrolled simultaneously with a one-day succession of one another. What this allowed for was a single team that was used over the course of six days with procedures for each cohort that would take place alongside or on the same day as different procedures or checkpoints for a separate cohort. WCCT staff was utilized to the maximum potential each day, reducing overall costs to the Sponsor.



As seen in the above diagram, Day 5 was the day on which staff were used to their maximum potential, with every cohort in the study having some sort of procedure or timepoint on that day.

This study design allowed for continuous efficiency and quality, because the same individuals with the same experience and expertise were assigned to the same task versus having different teams assigned to tasks. Designing a study in that way would potentially create study cohort teams which were the least experienced.

Results

The study was completed on time with no major AEs or deviations reported. All 96 subjects enrolled completed the study. WCCT was able to keep costs down by utilizing a smaller, effective team of staff over the course of the entire study and required no change orders to accommodate for unforeseen costs.