CTI CLINICAL TRIAL & CONSULTING

November Newsletter

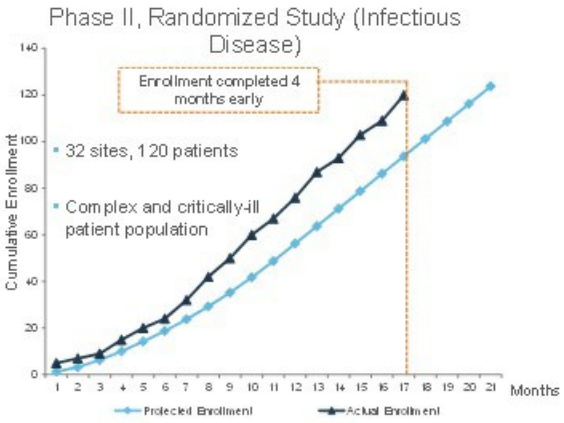
Where Life-Changing Therapies Turn First™

www.ctifacts.com

Volume 12, Issue 11

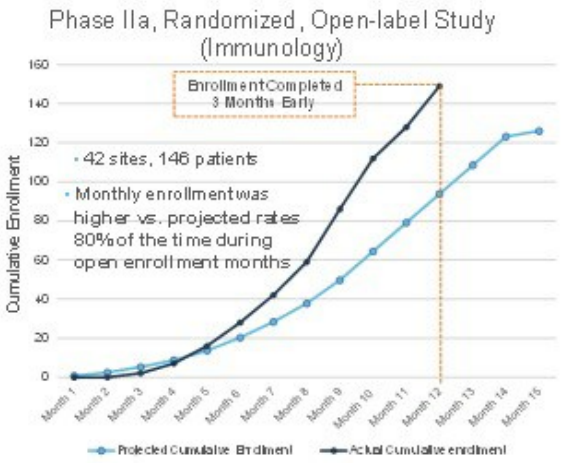
80% of CTI Studies Meet or Exceed Enrollment Expectations

Most clinical trials fail to meet enrollment timelines, with more than 3/4 of trials delayed beyond initial projections. **At CTI approximately 80% of our studies meet or exceed enrollment expectations, despite the challenging patient populations we work in, including rare diseases and gene therapy trials.**



Pre-trial Activities: **Feasibility and site selection are key to all clinical trials.** Poorly designed and under distributed feasibility questionnaires can fail to separate high-performing sites, with access to the appropriate patients, from low performing sites. **At CTI, our feasibility and site-selection process is multi-phased to include not only electronic methods of gathering data but direct outreach from our study managers and medical directors.**

Start-up Activities: Understanding the contracting and regulatory differences, including geography, site type (academic vs. community), and investigational product type (cell/gene therapy vs. biologic vs. chemical entity) is critical to efficient start-up. Proactively addressing the unique contracting and regulatory nuances of each project helps to expedite the process, allowing for maximum enrollment time. **When CTI is given maximum negotiating authority, the average contract completion time is significantly reduced compared to the industry average. CTI has international regulatory and legal experts to aid with start-up activities, and when we manage study start-up, the total start-up time is generally less than half the industry average.**



Ongoing Trial Activities: A high level of site engagement and communication between the operations and site teams are critical to achieving enrollment timelines. **The CTI study management and monitoring teams utilize strategies designed to maintain site engagement and communication continuity throughout the duration of**

CTI Cares Spotlight

MERCY HEALTH

Mercy Health - St. Raphael Santa's Shop

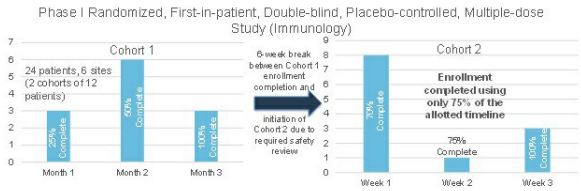
St. Raphael operates a Santa's Shop in December for parents who do not have the ability to provide toys, clothing and food to their children during the holidays.

In 2013, 618 children received toys, clothing and food who would not otherwise have received these items.

CTI is collecting new toys, clothing, books and monetary donations throughout the month.

a clinical trial. In a recent site satisfaction survey, 3 of 4 sites around the world preferred CTI to other CROs due to our history of successful collaboration on trial execution.

Our success is attributed to processes designed specifically around addressing pre-trial, start-up, and ongoing activities that have a known impact on enrollment. In addition, our therapeutic focus allows our team to maintain a comprehensive understanding in the areas we work supporting accurate assessments of site performance, efficient study start-up, and effective trial management, especially in complicated patient populations such as rare disease and gene therapy indications.



To find out more about how CTI can positively impact your program, please contact us.

For more information:
www.ctifacts.com
info@ctifacts.com
513.598.9290

Community Research to Become CTI Clinical Research Center

After 10 years of collaboration, CTI and Community Research (CR) have come together to offer exceptional clinical operations and site services to the pharmaceutical and biotech industries.

Community Research is now CTI Clinical Research Center (CRC)

Upcoming Meetings We Will be Attending

American Society of Hematology (ASH) - 56th Annual Meeting
San Francisco - December 6 - 9

Biotech Showcase 2015
San Francisco, CA - January 12-14

JP Morgan 33rd Annual Healthcare Conference
San Francisco, CA - January 12-15

To schedule a meeting with us at one of these, please click here

New Additions & Promotions at CTI

Lynn Amend joins as Assistant Study Manager

Amanda Coleman joins as Administrative Assistant/ Project Coordinator

Julia Höchst promoted to Senior Clinical Trial Assistant

Renate Hochdorfer promoted to Senior Regulatory Specialist

Karen Huber joins as Patient Recruiter

Megan Kamm joins as Study Manager

Valerie Lander joins as Assistant Director, Clinical Trials

Stephanie Makepeace promoted to Medical Writer

Join our Team!! We're looking for individuals to fill these positions:

Clinical Research Associate
(US, Spain, UK, Germany, France, Belgium, Poland, Australia, Brazil)

Director, Health Outcomes Research (Cincinnati, OH)

Study Manager
(Cincinnati, OH; Philadelphia, PA; Raleigh, NC; San Francisco, CA)

Click here for more information and to apply!