



Clinical Trial and Consulting Services

# February Newsletter



Volume 11, Issue 2

We are recruiting for CRAs in the US, UK, France, Belgium, Sweden, Germany, Poland, Italy and the Netherlands!

Upcoming Medical Meetings CTI will be Attending ...

Bio International  
Chicago, IL  
April 22 - 25

### Employee Update

Congratulations to the following CTI employee recently promoted:

**John Williams** – Assistant Director, Clinical Monitoring

Please welcome the newest addition to CTI:

**Chika Okere** – Research Associate

### Quick Links...

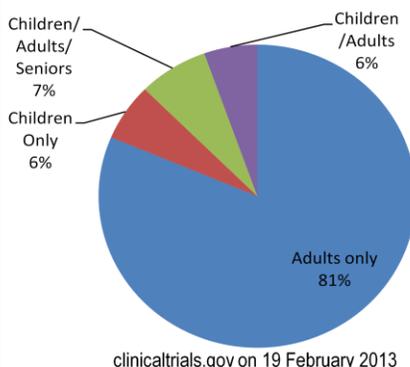
[Our Website](#)

[Email](#)

## Pediatrics: an underserved population in clinical research

In 1968, Dr. Harry Shirkey coined the term ‘therapeutic orphans’ to describe the dilemma resulting in the pediatric drug development process which currently holds a gap in knowledge for this understudied population. Despite recent legislative initiatives, a lack of controlled trials in pediatric populations still exists, setting the stage for off-label use for the majority of drugs prescribed to children.

Demographics of Active Trials



Barriers to conducting controlled clinical trials in this psychologically, physiologically, and hormonally diverse population include:

**Ethical Issues:** Conducting trials in disease areas where treatment is already available, where placebo control is required, and in an emergency setting all pose challenges affecting trial execution.

**Methodological Considerations:** Unique characteristics of the pediatric populations and the general sensitivity of investigational therapies being administered to a vulnerable population require innovative approaches to trial design (adaptive designs, stratification, crossover, etc.).

**Recruitment and Retention Difficulties:** Pediatric trials may require the informed consent of one or both parents, and possibly the assent of the trial participant. The necessity of obtaining multiple consents/assents presents enrollment and retention challenges in an already limited population base.

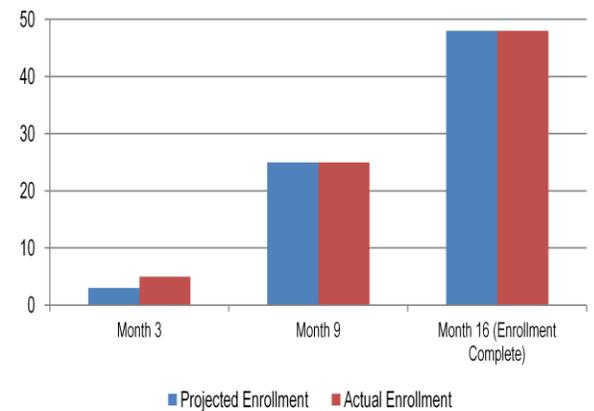
Join Our Mailing List!

## Contact Us

If you are interested in scheduling a meeting with CTI, please contact Nick Schatzman at 513-598-9290 or via email at [nschatzman@ctifacts.com](mailto:nschatzman@ctifacts.com)

Overcoming obstacles in pediatric research requires experienced clinical investigators, trained clinical operations personnel, and child friendly centers. CTI has extensive knowledge of conducting trials in pediatric populations including several active trials. **CTI's established relationships with top pediatric centers offer benefits to effectively working in this challenging population.**

Enrollment in a CTI Managed Pediatric Phase 2 Stem Cell Transplant Trial



Integrating a pediatric plan within the overall drug development process is critical to eliminate the ongoing 'therapeutic orphan' dilemma. **The innovative CTI team has a record of proven success in executing unique trial designs, overcoming recruitment and retention challenges, and leading our Sponsors through the complex regulatory landscape of pediatric research.**

*For more information contact:*

Janette Douglas  
Manager, Business Development Operations  
CTI Clinical Trial and Consulting Services  
10123 Alliance Road  
Cincinnati, OH 45242  
[jdouglas@ctifacts.com](mailto:jdouglas@ctifacts.com)



## About CTI



CTI Clinical Trial and Consulting Services is a repeat winner of "Best Places to Work" in Greater Cincinnati

CTI Clinical Trial and Consulting Services (CTI) is a unique drug and market development company offering a full range of services which encompass the entire lifecycle of drug development. These services include regulatory pathway design, clinical trial management, data analysis, medical writing, CME and training program development, market analysis and development and other consulting services. CTI focuses on the specific disease areas of solid organ transplant, hepatitis, infectious disease, end-stage organ disease and hematology/bone marrow transplant. With its combined expertise of clinical knowledge and market experience, CTI is uniquely positioned to incorporate both clinical and market driven endpoints and interpretations to provide extraordinary results.