

Volume 8, Issue 12

**December 2010 Newsletter** 



CTI Clinical Trial and Consulting Services named "Best Places to Work" in Greater Cincinnati for Second Consecutive Year

Upcoming Medical Meetings CTI will be Attending ...

CTI will have a significant presence at upcoming medical meetings over the next few months.

J.P. Morgan's 29<sup>th</sup> Annual Healthcare Conference San Francisco, CA January 10 – 13<sup>th</sup>

American Society of Transplant Surgeons 2011 Hollywood, FL January 13-16<sup>th</sup>

## **Clinical Study Reports**

As a full service Contract Research Organization, CTI provides services for all aspects of trial management, including development of Clinical Study Reports (CSRs) upon completion of a clinical trial. Following an impressive end of the year push to meet aggressive milestones, our Medical Writing team has successfully completed a series of CSRs for our sponsors to meet, or exceed, their 2010 business commitments.

In our standard process, CSR development does not begin at the end of the study. CTI's medical writers work throughout the study, developing a CSR shell document and populating fields long before database locks. Writing sections of the CSR prior to the end of the study enables our team to expedite timelines at study closure.

Depending on the phase of the study and the nature of the patient population, CSRs can be from 1,000-10,000 pages in length. The development and QA of these large and technically demanding documents can become a burden on even the largest companies.

It is common for sponsors who are familiar with CTI's expertise to contract with our Medical Writing team to develop stand alone CSRs, where CTI did not manage the trial.

Requests for CSR development fall into a variety of categories:

- Sponsors who recently acquired products with incomplete trials
- Large pharmaceutical companies who need functional resources on a temporary basis
- Small to midsized biotech companies who utilize CTI's experience, templates and regulatory compliant SOPs
- Independent Quality Assurance(QA) audits of internally or externally developed CSRs

As we move into 2011, we look forward to collaborating on many new

If you are interested in scheduling a meeting with CTI at one of these events, please contact Nick Schatzman at 513-598-9290 or via email at nschatzman@ctifacts.com

## Quick Links...

Our Website

**Email** 

Join Our Mailing List!

programs, and hope you consider our team in your next clinical study report.

From all of us at CTI, Happy Holidays; we look forward to working with you in 2011.

To learn more about CSRs and CTI's capabilities in this area, please contact:

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CTI Clinical Trial and Consulting Services

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.