

Volume 10, Issue 1

January 2012 Newsletter



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

Upcoming Medical Meetings CTI will be Attending ...

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

The American Society of Blood and Marrow Transplantation Tandem Meeting San Diego, CA February 1st – 5th

7th Annual Stem Cell Summit New York, NY February 21st

RESCUE STUDIES

Each clinical study presents unique challenges and the one-sizefits all approach to study operations services can sometimes result in the need to enlist the help of rescue services. This is especially true for studies that have non-traditional characteristics (e.g., orphan indications, adaptive study designs, severely ill patient populations, etc). The evaluation of potential clinical research organizations (CROs) offering rescue services requires unique considerations to determine whether the CRO can effectively insert themselves midstream and steer the study back on track.

The first consideration is whether a CRO can get up to speed quickly. Time is of the essence in any study but is especially critical for studies in need of rescue support as they are often already behind schedule. In addition to having resources readily available, the proposed team should be knowledgeable to identify the issues and offer productive and proactive solutions. Flexibility is also key, as a team joining an ongoing study needs to integrate into existing systems and processes as much as possible and change only those aspects which impede the study's progress. A CRO with rescue experience and a relevant therapeutic background would provide an operations team with the wisdom to offer corrective leadership coupled with seamless transition resulting in successful study completion.

CTI offers corrective action plans custom-designed to fit the needs of individual studies. On four recent occasions, CTI was asked to take over the management of stalled and/or troubled studies. Almost immediately (within 1 to 3 months), our team was able to work collaboratively with the sponsor and sites to increase enrollment by 30% to 300% in each case. These successes resulted from a combination of protocol revisions, additions of sites, elimination of poor performing

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 <u>nschatzman@ctifacts.com</u>

Employee Update

Please welcome the newest addition to CTI:

Kathy Wekselman, PhD, RN – Sr. Research Scientist

Congratulations to the following CTI employee recently promoted:

Jessica Ashcraft – Accounting Clerk II

Quick Links...

<u>Our Website</u>

<u>Email</u>

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sites/investigators, streamlining communication flow, and direct hands-on management at the site level. With an accomplished team of experts, including study managers, data managers, CRAs, safety scientists, regulatory specialists, medical monitors, and statisticians, and a strong track record of success, **CTI is well positioned to provide rescue services to bring failing studies back on-track.**

To learn more about the rescue services or any other clinical research activity, please contact CTI.

For more information contact:

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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.