Volume 10, Issue 7 July 2012 Newsletter

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

Interested in a Career with CTI? Contact us about CRA opportunities!

Upcoming Medical Meetings CTI will be Attending ...

16th Investigator-Initiated Trials Conference
San Diego, CA
September 12 – 13

Stem Cells USA & Regenerative Medicine Congress
Boston, MA
September 20 – 21

If you are interested in scheduling a meeting with CTI at one of these events, please contact Nick Schatzman at 513-598-9290

Utilization of Experience and Technology to Optimize Clinical Trial Feasibility Assessments

There are a myriad of contributing factors which can delay drug development in today's pharmaceutical environment. Trial start-up activities can be diverted by regulatory issues, contracting setbacks, and IRB review times. Many of these issues are beyond the control of the Sponsor or the Contract Research Organization (CRO). It is generally accepted industry-wide that clinical trials last approximately 30-45% longer, depending upon the phase of the trial, than originally estimated. **Patient recruitment delays, a controllable variable with proper foresight, are the principal cause of timeline extensions associated with clinical trials**. In a market where a delay in the launch of new drug compound can impact Company revenue by more than $1 million per day, it is critical for Sponsors and CROs to partner together as a means to accurately identify, assess, and select ideal investigators and sites in order to ensure timely patient enrollment and trial close-out.

CTI Clinical Trial and Consulting Services (CTI) is a specialty drug and market development company offering a full range of services that encompass the entire lifecycle of drug development. These services include regulatory pathway design, clinical trial management, data analysis, medical writing, market analysis and development and other consulting services.

Benjamin Franklin has been quoted as saying "*By failing to prepare you are preparing to fail*." **At CTI, our mission is to collaborate with our clients to proactively conduct comprehensive due diligence before, during and after clinical trial site feasibility that will accurately identify potential obstacles which can serve as impediments to start-up activities and to ensure patient enrollment milestones are met or exceeded**. With proper preparation at the feasibility stage, our multi-tiered approach which merges CTI personnel experience

or via email at nschatzman@ctifacts.com

Employee Update

Please welcome the newest additions to CTI:

Nathalie Minasian, PhD - Clinical Project Manager France

Adenike Igoh – Clinical Project Manager United Kingdom

Congratulations to the following CTI employee recently promoted:

Sibylle Lindsey – Sr. Study Manager

Quick Links…

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with technology, our final analysis will include data which is unavailable to other CROs, and will supplement information gathered via site feasibility surveys. Our objective is to accumulate "real-world" data that can be utilized to both identify ideal sites and investigators for clinical trial participation, as well as to accurately extrapolate enrollment timelines.

Distribution of a "standard" feasibility survey cannot, and will not, provide our clients with the information they require to correctly make critical decisions regarding clinical trial execution. Our processes are proven, and are reflected in our results. We are confident that our multi-tiered feasibility assessment approach will continue to provide industry leading results, ultimately saving our clients time and money, and more importantly, ensuring the availability of novel medications to those who need them most- the patients.

Below are some of the tools and approaches which CTI utilizes to prepare and execute comprehensive clinical trial site feasibility analyses:

- **Site selection database with comprehensive enrollment and performance metrics**
- **Proprietary investigator and site contact database**
- **Electronic survey methodologies drafted by experienced clinicians**
- **National and international data systems**
- **One on one telephone calls to investigators, as needed, by CTI Medical Directors**

Improvements in the accuracy of site feasibility are a necessity in today's challenging drug development environment. Preparation and foresight, when combined with existing technologies, are key components in our processes which will allow our clients to maintain timelines and minimize cost.

To learn more about these methods and how CTI may be of assistance, please contact us.

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