CTI CLINICAL TRIAL & CONSULTING

November Newsletter

Where Life-changing Therapies Turn First™

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

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

Upcoming Meetings CTI will be Attending …

American Society of Hematology Annual Meeting
New Orleans, LA – December 7-10

Congratulations to these recently promoted CTI employees:

Michelle Clifford – Study Coordinator

Katie Westerkamp – Project Manager

Kyra Graham – Senior Research Associate

Welcome the newest CTI employees:

CTI's View of Risk-Based Approach to Monitoring

In August 2013, the US Food and Drug Administration (FDA) issued final guidance regarding the utilization of centralized monitoring methodologies, where appropriate, to oversee clinical studies and to effectively monitor clinical investigations. The guidance allows less intensive monitoring, verification of non-critical data, and an acceptance of some error rate associated with those data.

FDA inspections for clinical trials typically focus on key efficacy and safety endpoints, deaths, serious adverse events (SAE), protocol deviations, discontinuations, and drug accountability. One-to-one comparisons are made, and if errors are found, the inspection expands to other data. This latest guidance document is consistent with the FDA's approach to focus on critical data elements.

The final guidance document indicates the following risk evaluation factors should be considered when planning a monitoring approach:

- Complexity of the study design
- Types of study endpoints
- Patient population
- Site experience
- Safety experience of the investigational product

CTI is often involved in first-in-man studies and programs that involve a complex study design and critically ill patient population, in addition to large Phase II or III studies. We carefully evaluate all factors and risks in running each of these studies and we discuss risk based monitoring approaches to these studies with our sponsors. The result is to design a cost-effective, yet results-oriented monitoring approach that meets both regulatory and quality requirements. Our study specific monitoring plan is tailored with the FDA's guidance in mind, and all members of our study management and monitoring teams carefully consider each evaluation factor when finalizing the monitoring approach chosen.

If you'd like to discuss CTI's approach to Risk-Based Monitoring in more detail,

Catherine Van Gilder – Clinical Monitoring Coordinator

Traci Bechtel – Senior Regulatory Specialist

Rachel Gilbert – Biostatistician I

Andrew Schildknecht – Research Associate

Sandra Wöhr – Clinical Trial Associate, Germany

Quick Links…

Website

Email

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please contact:

Kevin Schwarz, Senior Vice President
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About CTI

CTI Clinical Trial and Consulting Services is an innovative, international drug and device development organization that delivers a full spectrum of clinical trial and consulting services from bench to commercialization with a focus on immunology and a passion for helping life-changing therapies succeed in chronically and critically ill patient populations. CTI's focused therapeutic approach provides pharmaceutical, biotechnology and startup firms with clinical and disease area expertise from a unique mix of academic, medical and industry specialists; rich intellectual capital in transplantation, immunology, infectious diseases, hematology, cardiology, nephrology, hepatology, regenerative medicine and rare diseases; flexible study designs that accelerate development programs and deliver high approval ratings that are among the best in the industry; and exceptional global project management and gold standard safety and data management systems that strengthen their program's success potential. Established in 1999 and headquartered in Cincinnati, OH; CTI has offices in North America, Europe and South America.