Volume 9, Issue 5 May 2011 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.

DIA 2011
Chicago, IL
June 19 – 23
Visit us at Booth 601

ILTS 2011
Valencia, Spain
June 22 – 25

Bio International 2011
Washington, D.C.
June 27 – 30

If you are interested in scheduling a meeting with

FDA Issues New IND Safety Reporting Requirements

In September 2010, FDA issued two important new documents with regard to safety reporting requirements for clinical studies being conducted under an IND. These documents include a guidance document available from the FDA website (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM227351.pdf) and a Final Rule published in the Federal Register (http://www.federalregister.gov/articles/2010/09/29/2010-24296/investigational-new-drug-safety-reporting-requirements-for-human-drug-and-biological-products-and#p-17). The new requirements went into effect on March 28, 2011 but FDA will not enforce the changes until September 28, 2011.

Under prior guidelines, FDA provided little guidance on what constituted an adverse event "associated with the use of the drug". As a result, sponsors and investigators took a conservative approach to the reporting of safety data, often based on the principal that it was difficult to rule out any possibility of a relationship between an adverse event and a study drug. This resulted in over-reporting of adverse events with high levels of "background noise" in the safety database that obscure important safety signals. It also made for a burdensome amount of work for investigators, IRBs, sponsors and the agency.

The former term "associated with use of the drug" has been replaced with the term "serious adverse drug reaction" which is defined as "any adverse event for which there is a reasonable possibility that the drug caused the adverse event." "Reasonable possibility" is not "any possibility," but rather is the existence of evidence supporting a causal relationship between drug and adverse event.

FDA has further clarified reporting requirements with regard to events that are protocol-defined study endpoints as well as for those events that are commonly observed in the study population. Adverse events that have been reported for the class of drug, but are not yet listed as having been reported for the specific drug under study, must be reported. Serious adverse reactions that occur in higher than expected frequencies must be reported as well. This will require sponsors to monitor and report aggregate data to detect trends in the safety data and to report these to investigators and IRBs. In addition, sponsors must

CTI at one of these events, please contact Nick Schatzman at 513-598-9290 or via email at nschatzman@ctifacts.com

Employee Update

Please welcome the newest addition to CTI:

Michael Sommer – Manager Business Development Europe

Congratulations to the following CTI employee recently promoted:

Tara Hutchins – Senior Clinical Data Associate

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report relevant findings from animal and *in vitro* studies and findings from other clinical or epidemiological studies that suggest a possible risk to study subjects. Finally, safety data from bioavailability and bioequivalence studies must now be reported.
The major emphasis in the new requirements is submission of only information that will "meaningfully contribute to the developing safety profile of the drug," including those related to the drug. This is based on what is known about the study drug or on a strong temporal relationship between drug and event, as well as medically important events, such as those uncommon in the population under study that are of sufficient importance to be considered a possible safety signal. It is hoped that this will help reduce the number of irrelevant individual case reports filed, improve detection of trends in the safety database, and lead to improved safety signal detection.

CTI offers a full range of global pharmacovigilance services and would be happy to discuss this with you in more detail.

For more information contact:

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