CTI Clinical Trial and Consulting Services

Volume 9, Issue 1 January 2011 Newsletter

FDA Safety Reporting Requirements: A Paradigm Shift in Safety Surveillance

The Food and Drug Agency (FDA) has issued a final rule and a draft guidance entitled "Safety Reporting Requirements for INDs and BA/BE Studies," which seeks to clarify what safety information for investigational drugs must be reported to the FDA, and the timing requirements for such reports. The final rule requires the rapid submission of certain types of information not previously required on an expedited basis (e.g., adverse events in the aggregate versus individual cases), such as findings from clinical or epidemiological studies that suggest a significant risk or serious, or suspected adverse reactions that occur more frequently than anticipated. The final rule also affects the reporting of information to institutional review boards (IRBs). **The scope of the final rule is extensive, and also addresses topics such as requirements relating to follow-up for reports, study unblinding (i.e., when to unblind and report), and the reporting requirements for bioavailability and bioequivalence studies.**

FDA now expects sponsors to have in place "a systematic approach to safety surveillance during product development that includes a process for evaluating accumulating safety data." Under former Title 21 CFR 50 312.32(a), an adverse reaction associated with the use of the drug that is both serious and unexpected is reported; however, misapplication of the phrase "associated with the use of the drug" seems to permeate the reporting process. The FDA is inundated with safety reports in which the adverse reaction is eventually determined not to be associated with drug exposure. **As such, the FDA, under the new rule, is placing the onus on the sponsor to determine causality of an adverse drug reaction.**

The sponsor will need to evaluate the available evidence and make a judgment about the likelihood that the drug actually caused the adverse reaction. To accomplish this will require not only therapeutic and drug development expertise, but also expertise in epidemiology and safety/pharmacovigilance. The goal is to assess the potential

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Upcoming Medical Meetings CTI will be Attending ...

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

American Academy of Dermatology
New Orleans, LA
February 4-8th

Stem Cell Summit
New York, NY
March 1st

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

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"causal" link between drug exposure and an adverse reaction to determine whether the event is reportable. This can be done in a variety of ways including: meta-analysis, database mining, historical control, etc. As data accumulates, a sponsor will need the necessary infrastructure to support and manage an ongoing safety surveillance program in addition to the expertise to evaluate a causal inference. **Given its therapeutic focus and its analytic and safety expertise, CTI is well positioned to provide our sponsors the necessary skills and systems to develop and manage a safety surveillance program that meet new FDA safety reporting requirements.**

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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.