CTI Clinical Trial and Consulting Services

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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.

NewsMakers in the Biotech Industry
New York, NY
October 22nd

Biotech 2010
Philadelphia, PA
October 27th -28th

American Association for the Study of Liver Diseases 2010
Boston, MA
October 29th – November 2nd - Booth 716

Modeling Adverse Events Reports: An Analytic Approach to Safety Surveillance

Post-marketing surveillance (both active and passive approaches) of adverse drug reactions (ADRs), especially ADRs that occur infrequently, play an important role in evaluating the safety of a medicinal product. **Infrequent ADRs may not be detected in pre-licensure studies since sample size and follow-up duration may be too limited to detect a potential problem:** to detect a doubling in an ADR that occurs at a rate of 1/1000 would require a sample size of 50,000 (two-arm, power=80%, alpha=5%).

Planning a drug surveillance program to identify and evaluate a potential safety signal can be problematic and challenging. Careful consideration should be given to the following: What constitutes a safety signal? How would a signal be identified? Utilizing data contained in spontaneous AE reports (collected from patients, health care providers, health authorities, the medical literature and other data sources [e.g., Adverse Event Reporting System]) coupled with data on drug usage (volume, dosage etc) is one way to identify a potential safety signal. **Special statistical techniques (e.g., incidence density estimation, general linear models and extreme value theory) can then be used to analyze the cumulative data with the goal to identify when, in calendar time, the ADR rate is expected to exceed a pre-defined, clinically meaningful threshold.**

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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The methodology proposed above is unique in that a potential signal is derived based on a rate calculation (i.e., ADR per treatment exposure) and not just on the frequency of ADR reports (or specifically, ADR-drug pairs). This allows for a more precise evaluation of the strength of an ADR and, with temporal-trend analysis, can be used to inform the design of a systematic study of a potential signal and for resource allocation.

To learn more about this methodology, and how CTI could potentially help you, please contact:

William Irish, PhD

VP Outcomes Research and Biostatistics

CTI Clinical Trial and Consulting Services

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.