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May 2010 Newsletter

CTI Clinical Trial and Consulting Services

CTI Clinical Trial and Consulting Services named "Best Places to Work" in Greater Cincinnati for Second Consecutive Year

New European Union Regulatory Requirements for Medical Devices

On March 21, 2010, Directive 2007/47/EC governing the sale of medical devices became effective in the European Union. Part of this Directive includes the requirement for a comprehensive and detailed evaluation of clinical data supporting the intended purposes and claims made for medical devices.

Such a review is now also required for all medical devices marketed in the European Union, and the reviews will also require periodic updating.

CTI has recently provided Clinical Expert Reviews of relevant medical literature for several medical devices. The process begins with a systematic search of the medical literature, according to a written protocol. The reports that are returned by that semi-automated search are then reviewed by a medical expert for relevance. Information documenting the key data in each report (authors, location, citation, patient population, study design, results) is placed in a user-friendly table, and each report is briefly summarized. The safety information is analyzed with respect to the device instructions for use, and conclusions regarding marketing of the device are spelled out.

We continue to keep our pulse on new Regulatory requirements for drugs and devices. CTI has an efficient process in place for developing and updating this important part of a medical device's European regulatory dossier. The process can also be adapted for other analogous purposes.

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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.

The 16th Annual
ISCT Meeting
Philadelphia, Pennsylvania
May 23-26, 2010

International Liver Transplant Society Meeting
Hong Kong
June 16-19, 2010

CTI will be exhibiting:

46th Annual DIA Meeting
Washington DC
June 13-17, 2010

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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Employee Update

Please welcome the newest addition to CTI:

Dr. Kathleen Rand – Director, Global Safety & Pharmacovigilance

Jaynee Tolle – Project Accountant