



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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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.

### Upcoming Medical Meetings CTI will be Attending ...

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

The 16<sup>th</sup> Annual  
ISCT Meeting  
Philadelphia, Pennsylvania  
May 23-26, 2010

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

### CTI will be exhibiting:

46<sup>th</sup> 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

### Employee Update

*Please welcome the newest addition to CTI:*

*Dr. Kathleen Rand – Director,  
Global Safety & Pharmacovigilance*

*Jayne Tolle – Project Accountant*