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.

MSC 2011 Innovations in Cell-Based Regenerative Therapies
Cleveland, OH
August 22 – 24

European Society for Organ Transplantation
Glasgow, UK
September 3 – 7

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

Physician Payments Sunshine Act…How It Could Impact You

The Patient Protection and Affordable Health Care Act (H.R. 3590) signed into law 3/23/10 included the Physician Payment Sunshine Act (PPSA). Starting in 2013, the PPSA will require U.S. pharmaceutical, medical device, biological, and medical supply manufacturers to report to Health and Human Services any "payment or transfer of value" to physicians and/or teaching hospitals. The stated intention of this new mandate is to increase transparency for the benefit of patients. However, the burden of required reporting by manufacturers will be significant.

Companies must begin recording any physician payments greater than $10 beginning in 2012. The first reports will be due March 3/31/13. Companies will report data annually to the Department of Health and Human Services, who will then post the information annually on a website.

This new federal legislation follows similar laws passed by several states recently. To an extent, PPSA will preempt state disclosure laws effective 1/1/12. States will be prohibited from collecting the same information required to be reported under the federal law. However, the PPSA does not preempt any state law that requires the disclosure of the type of information not covered by the act. PPSA also does not preempt any more restrictive laws, such as lower limits of payments or gift bans. As such, companies will need to be attentive to both state and federal disclosure laws in each state where they operate.

Employee Update

Please welcome the newest additions to CTI:

Alfredo Garcia Martin – Project Manager Spain

Jeff Smith – Research Associate

Kelly Solinsky – Study Manager

Janette Douglas – Business Development Operations Manager

Quick Links...

Our Website

Email

Join Our Mailing List!

Information to be reported includes physician's information (name, business address, specialty, and National Provider Identifier) and information about the payment, including amount, date, form and nature (e.g. gift, consulting fees, honoraria, education or conference funding, stock or stock option grants, royalties, travel, food, entertainment). Where a payment is related to marketing, education, or research specific to a covered drug or device, the name of that product must be reported. There are exemptions to the reporting requirements including payments less than $10, educational materials for the benefit of patients, and prescription drug and device samples. **Payments related to clinical trials or product development agreements for new products are allowed a publication delay of 4 years or until new product approval, whichever comes first.** Interestingly, companies are not required to report payments made to nurses, physician assistants, and other medical professionals.

Failure to report information will result in fines. For each failure to report, fines of up to $10,000 will be applied, not to exceed $150,000 annually. Fines of up to $100,000 will be applied for each *knowing* failure to report violation, with a maximum of $1 million dollars annually.

While the intent is understood, this legislation will create a significant administrative burden to physicians and pharmaceutical companies.

For help with PPSA or other drug development or clinical research activity, please contact CTI.

For more information contact:

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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.