CTI
Clinical Trial and Consulting Services

August Newsletter

Where Life-changing Therapies Turn First™

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We are recruiting for CRAs in the US, Australia, UK, France, Belgium, Sweden, Germany, Poland, Italy and the Netherlands!

If you are interested in scheduling a meeting with CTI, please contact Nick Schatzman at 513-598-9290 or via email at nschatzman@ctifacts.com

Upcoming Medical Meetings CTI will be Attending …

Trial Designs and Endpoints for Liver Disease Secondary to Nonalcoholic Fatty Liver Disease FDA Workshop
Silver Spring, MD
September 5 – 6

European Society for Organ Transplant 2013
Vienna, Austria
September 8 – 11

Newsmakers in the Biotech Industry
New York, NY
September 27

Pediatric Priority Review Voucher

The FDA Safety & Innovation Act (FDASIA) S.3187, signed by President Obama in 2012, addresses the future of rare diseases and orphan drug development in several ways. One exciting provision of the new legislation is Section 908, extending the existing Neglected Tropical Diseases (NTD) Priority Review Voucher program to Rare Pediatric Diseases (RPDs) on a trial basis. Three vouchers will be awarded to this trial program, expanding the incentives for companies to invest in new drugs and treatments for small pediatric patient populations.

The most highlighted aspect of the RPD Priority Review Vouchers, when awarded, will entitle sponsors to a priority review for a product of their choice, where the FDA will strive to provide a decision in 6 months time. There is also the option for the voucher to be sold to another sponsor, adding a tremendous value option for the voucher holder.

In addition to creating the pilot program for pediatric rare diseases, FDASIA also specifies that RPD Priority Review Vouchers can be transferred an unlimited number of times before being used. Additionally a voucher holder is now able to provide only a 90 day notice to the FDA prior to using the voucher, a desired change from the former notice period of one year.

CTI can assist clients with obtaining and using Priority Review Vouchers, along with preparing market applications and other regulatory submissions. Due to our current and historical management of drug development programs for rare diseases and orphan drug products in the pediatric patient population, our clinical development experts are well prepared to provide regulatory strategies for these sensitive programs. Our experts are available to discuss the Pediatric Priority Review Voucher program in greater detail. CTI's goal is to help our sponsors evaluate the potential use of this program and create successful drug development plans for products that can qualify.

Stem Cells and Regenerative Medicine Congress
Cambridge, MA
September 30 – October 1

Employee Update

Congratulations to the following CTI employee recently promoted:

Cyndi Springer – Associate Director, Clinical Operations Study Management

Mike Bahm – Senior Director, Global IT

Please welcome the newest addition to CTI:

Dana Acklin – Senior Study Coordinator

Quick Links…

CTI in the news

Our Website

Email

Join Our Mailing List!

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About CTI

CTI Clinical Trial and Consulting Services is an innovative, international drug and device development organization that delivers a full spectrum of clinical trial and consulting services from bench to commercialization with a focus on immunology and a passion for helping life-changing therapies succeed in chronically and critically ill patient populations. CTI's focused therapeutic approach provides pharmaceutical, biotechnology and startup firms with clinical and disease area expertise from a unique mix of academic, medical and industry specialists; rich intellectual capital in transplantation, immunology, infectious diseases, hematology, cardiology, nephrology, hepatology, regenerative medicine and rare diseases; flexible study designs that accelerate development programs and deliver high approval ratings that are among the best in the industry; and exceptional global project management and gold standard safety and data management systems that strengthen their program's success potential. Established in 1999 and headquartered in Cincinnati, OH; CTI has offices in North America, Europe and South America.