CTI Clinical Trial and Consulting Services

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Orphan Drug Product Development

There are many diseases and conditions which affect such small numbers of individuals in the United States in which adequate drugs have not been developed. Drugs developed to treat these diseases and conditions are commonly referred to as "orphan drugs." The FDA Office of Orphan Products Development (OOPD) defines these populations as less than 200,000 persons in the U.S. or a disease or condition for which there is no reasonable expectation that the cost of developing or making a drug would be recovered.

For those individuals or companies that decide to pursue a drug development program in one of these areas, the challenge is the difficulty in identifying those few individuals affected by these conditions.

Enrollment in clinical trials for studies of drugs granted orphan drug status can be quite difficult and requires persistence, resourcefulness, and frequently a unique or creative approach. Webpages, clinicaltrials.gov, the internet and even the recent introduction of social media websites are some of the newer tools available to identify, direct, and facilitate this process. Meanwhile, maximizing relationships in a therapeutic area and networking with existing contacts and organizations can also bring valuable leads.

CTI has experience navigating these issues with multiple drugs being developed for rare diseases and conditions. While identifying limited patient populations can be difficult, CTI has managed the enrollment issues by employing creative means when necessary to overcome these hurdles. Maintaining focus within specific therapeutic areas has also allowed CTI to continue to remain successful in these challenging programs.

Currently, CTI is involved with more than a dozen orphan drug

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

Employee Update

Please welcome the newest additions to CTI:

Lynda Spiker – Senior Clinical Safety Scientist

Maria Mushaben – Siebel Clinical Administrator

Colleen Colson – Quality Assurance Specialist II

Congratulations to the following CTI employee recently promoted:

Robert McRae – Senior Research Associate

Quick Links...

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programs. CTI has also been involved in more than a dozen previously approved NDAs/BLAs and one current BLA under development in orphan diseases.

CTI would be happy to provide consultation on your orphan drug program.

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.