CTI Clinical Trial and Consulting Services

Volume 10, Issue 6 June 2012 Newsletter

CTI Clinical Trial and Consulting Services is a repeat winner of "Best Places to Work" in Greater Cincinnati

Upcoming Medical Meetings CTI will be Attending ...

International Congress of the Transplantation Society
Berlin, Germany
July 15 – 19

Expanded Access and Rare Disease Meeting
Philadelphia, PA
July 19 – 20

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

Regenerative Medicine

Regenerative Medicine is an exciting and popular topic for everyone from the scientific, biotechnology and pharmaceutical communities, down to the lay press and everyday person. The straightforward concept of using healthy cells or organs grown in the laboratory to repair or replace damaged, disease or decaying organs has an almost overwhelming appeal. Yet, as simple as the concept may seem, the safe, effective and efficient development of a unique product that is commercially viable is a tortuous road fraught with peril.

An initial challenge for companies in regenerative medicine is the precise characterization of their unique cellular product or manufacturing process. For example, the various types of "stem cells" can be confusing and overlapping, but each one has potential advantages and unique risks. Embryonic stem cells (ES) are controversial; induced pluripotent stem cells (iPS) have unique safety concerns; hematopoietic stem cells (HCT) are already widely used; mesenchymal stem cells (MSC) have profound immunoregulatory potential and adipose-derived stem cells (ADSC) are easily obtained. Furthermore, properly describing and validating the safety, consistency and reliability of the source (bone marrow, blood, cord blood, fat, or skin) for regulatory agencies is difficult. Is the unique product a biologic or simply a manufacturing process? Is it a minimally manipulated product and, therefore, eligible for a shorter approval process? The regulatory path for these products can be quite unique. **CTI has worked in the development of the entire spectrum of cell types, stem cell sources and manufacturing processes and our team has scientific, laboratory and regulatory experience with these products**.

Although a well-defined product or process and a clear developmental plan is an excellent start, successfully designing,

Employee Update

Congratulations to the following CTI employees recently promoted:

Colleen Colson – Manager, Quality Assurance

Carrie Bishop – Sr. Study Manager

Patrick Massa – Medical Affairs Associate

Quick Links…

Our Website

Email

Join Our Mailing List!

enrolling and completing the necessary clinical trials in the regenerative medicine field is challenging. Frequently the target patient population runs the entire gamut from asymptomatic, early-stage disease to critically ill, late-stage patients with organ failure. Designing the right trial is imperative to give the product a chance to "regenerate" healthy tissue while quickly demonstrating meaningful clinical benefit. Operational experience can sometimes overcome unique hurdles such as the ultra-orphan disease trial that requires innovative ways to find subjects. Well-trained and knowledgeable monitors are mandatory to success in cell-based therapies. **CTI's clinical trial design and management experience in the transplant arena and with very ill patients uniquely positions us to succeed in these challenging populations.**

Finally, the ultimate commercial success of a safe, effective and beneficial regenerative medicine product requires regulatory approval by the FDA and EMA. CTI interacts with the FDA and EMA on a regular basis. Whether the goal is a BLA submission or a 510(k) registration, each step of the approval process for biologics can be particularly challenging. The FDA's growing experience with cell-based products allows for more interactive dialogue to create novel solutions for problems. However, optimally utilizing their expertise requires outside advice and experts in the biologics arena who have experience with all phases and all types of meetings, whether pre-IND, end-of-phase I or II, type B or type C meetings. These experts must also have significant scientific understanding of the cell therapy field and have specific experience in regulatory pathway negotiations. **CTI combines our team of scientists, medical directors and regulatory experts to effectively and successfully address regulatory hurdles in the regenerative medicine arena.** By collaborating with you, our experienced team can help you navigate the perilous road to success.

To learn more about these methods and how we may be of assistance, please contact us.

John R. Edwards, M.D.
Medical Director
CTI Clinical Trial and Consulting Services
10123 Alliance Road
Cincinnati, OH 45242
Phone: 513-598-9290
Mobile: 513-652-2139
Fax: 513-598-3426

jedwards@ctifacts.com

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.