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CTI Clinical Trial and Consulting Services

CTI Clinical Trial and Consulting Services named "Best Places to Work" in Greater Cincinnati for Second Consecutive Year

Expanded Access Programs

If you are considering an Expanded Access Program (EAP), CTI has extensive experience and would be happy to speak with you about obstacles that you might encounter.

EAPs provide a mechanism for making investigational drugs and medical devices available to patients who may not meet eligibility requirements for other currently active clinical trials. These programs enable physicians to offer their patients the potential benefits of agents that have not yet been approved as well as allowing pharmaceutical and medical device manufacturers to bridge the gap between later stages of development and product approval. These programs enable investigators to gain valuable clinical experience with innovative products, while patients receive access to potentially life-saving treatment.

Some Conditions Treated Through EAP Programs

Atrial fibrillation	Glycogen storage disease II	Lung Transplant
Autologous cell transplant	Graft vs. host disease	Macular degeneration
Cancer	Hemoglobinuria	Neoplasms
Compromised limb function	Hepatic veno-occlusive disease	Phenylketonuria
Congestive heart failure	Hepatitis B	Postoperative hemorrhage
Coronary artery disease	HIV	Pulmonary hypertension
Cystic fibrosis	Hydronephrosis	Renal transplantation
Diabetic neuropathic pain	Hypercalciuria	Retinopathy of prematurity
Diabetes mellitus	Inflammatory bowel syndrome	Rheumatoid arthritis
Fabry disease	Lambert-Eaton myasthenia	Varicella
Gaucher disease	Liver failure	

Although the single-patient emergency treatment IND process can be used on a case-by-case basis, and a program to support such use can be made a formal part of an EAP, it is also possible to develop an open-label treatment protocol that can be used to enroll any patient who meets eligibility requirements. Such a protocol may make an EAP more efficient. As with any clinical trial, these expanded access programs require submission to the FDA and approval, institutional review boards, and the maintenance of a patient database. Current FDA regulations permit sponsors to recover the actual costs of raw materials for drug, labor, shipment, monitoring, as well as the costs associated with administrative expenses and compliance with necessary regulatory processes.

CTI has assisted sponsors with all steps of design and implementation of expanded access programs, from the regulatory submission stages and drug shipment, through collection and monitoring of safety data. CTI is available to discuss considerations for your program.

Contact:

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Upcoming Medical Meetings CTI will be Attending …

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

StemCells USA, Regenerative Medicine Congress
Philadelphia
September 13th-15th

BioPharm America 2010
Boston
September 15th-17th

European Society of Transplantation Meeting
Nice, France
October 1st-3rd

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:

Tim Bockerstette - Director, Business Development Operations

Brian Johnston – Assistant Director, Clinical Trials