CTI Clinical Trial and Consulting Services

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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 ...

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

Massachusetts Bio Meeting
Boston, MA
March 25 -27

The European Society of Clinical Microbiology and Infectious Disease 2012
London, UK
March 31 – April 3

The European Association for the Study of Liver 2012
Barcelona, Spain
April 18 – 22

Expanded Access Programs

Under certain conditions, FDA will facilitate the delivery of an unapproved investigational agent to physicians caring for patients who can be expected to benefit from its use, and will allow manufacturers to recover the actual costs of providing the drug to the patient. For many years, sponsors customarily provided small amounts of investigational drugs to small numbers of patients, outside of clinical trials, on the basis of what was called "compassionate use." No charge was usually made for such applications.

However, with the much higher costs of manufacturing and shipping biologic agents, and with increasing demands from patients whose medical needs for serious and often life-threatening conditions are unmet by conventional therapies, FDA in 2009 promulgated rules for establishing "expanded access programs" for drugs whose efficacy can be provisionally evaluated from Phase II or Phase III studies, but which are not yet approved for marketing.

These "expanded access programs" include arrangements that can be made for single patients, for small groups of patients, or even from large numbers of patients. If the number of patients who can be expected to benefit from the investigational agent is sufficient to warrant it, a formal "expanded access program" can be set up to enroll patients in an open-label treatment protocol. The treatment protocol should be designed to identify clearly the patients who can be enrolled, and in such a way that any ongoing concurrent enrollment in Phase III pivotal trials is not jeopardized.

In general, patients who are eligible to be treated in an expanded access program have a serious and often immediately life-threatening disease or condition for which there is no comparable or satisfactory therapeutic alternative.

In some cases, tens of thousands of patients have been able to receive novel treatments under the auspices of a treatment protocol and an expanded access program. Sponsors have been

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:

Melanie Bruno, PhD – Vice President, Clinical Trial Operations

Roberto Campos – Corporate Counsel

Congratulations to the following CTI employee recently promoted:

Emily Wiggins – Human Resources Generalist

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able to recover the actual direct costs associated with the drug's development, and the costs of providing such treatments to the patients enrolled, including the administrative costs of managing the program.

CTI is experienced in the management of expanded access programs. One recent program that CTI managed made possible the emergency use of Voraxaze® (glucarpidase) for patients with methotrexate toxicity and impaired renal function. CTI maintained the US stock of the drug and provided 24/7 coverage, ensuring regulatory compliance and managing more than 165 oncology sites in the US, as well as shipping drug for delivery within 24 hours for more than 115 patients.

To learn more about expanded access programs or any other activity associated with clinical research, please contact CTI.

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