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

We are recruiting for CRAs in the US, UK, France, Belgium and the Netherlands!

Upcoming Medical Meetings CTI will be Attending ...

American College of Gastroenterology
Las Vegas, NV
October 19 – 24

Stem Cell Meeting on the Mesa
La Jolla, CA
October 29 – 31

American Society of Nephrology
San Diego, CA
November 1 – 4

Special Protocol Assessments

The opportunity to request the Food & Drug Administration (FDA) to perform a special protocol assessment resulted from adoption of a Prescription Drug User Fee Act (PDUFA) goal in 1997. The FDA issued guidance on Special Protocol Assessment in May of 2002. A special protocol assessment is performed at the request of a Sponsor in order to gain input and agreement from FDA on the adequacy of studies intended to support the development and ultimately the approval of a human drug product.

FDA has a 90% on time PDUFA goal of providing an assessment within a 45 day time clock. Over the last five years there has been a range of 232-459 original requests for special protocol assessments with a range of 81-89% of on time versus the 90% goal. There are three defined types of protocols for which FDA will grant a special protocol assessment including: animal carcinogenicity protocols, final product stability protocols and phase 3 clinical protocols intended to serve as the primary basis of an efficacy claim. These clinical protocols can support an original or efficacy supplement to a new drug application or to a biologics license application.

It is recommended that a Sponsor request a special protocol assessment at least 90 days prior to the anticipated initiation of a study in order to allow an adequate amount of time for the assessment by FDA and potential revisions to the protocol by the Sponsor. As part of the request letter, the Sponsor must specifically note in the letter: REQUEST FOR SPECIAL PROTOCOL ASSESSMENT and direct the request to the appropriate review division with the Center for Drug Development or the Center for Biologics Evaluation and Research. Within the request, the Sponsor should provide focused questions to address specific issues that can be answered by FDA based on their knowledge of the development program for the product. The Review Division may also seek additional perspective from selected Advisory Committee Members, government employees or consultants if

they think it is appropriate to do so. If this is the case, the Review Division will notify the Sponsor of this intent within the 45 days and also advise of the anticipated date of such consultation as well as the reasons for the consultations.

After receipt of a response from the FDA to the special protocol assessment, a Sponsor may request a Type A meeting for further discussion or clarification. The outcome of such a meeting can also serve as the documentation of the agreement regarding the protocol between the FDA and the Sponsor. These agreements are considered binding unless there has been a substantial scientific issue related to the efficacy or safety of the product after the study has begun or if any false information contributed to the original assessment or if the Sponsor does not follow the agreed to protocol. The agreement based on the special protocol assessment can be modified if both the FDA and Sponsor agree and if the modification improves the protocol.

CTI regulatory and clinical consultants have extensive experience in the development of protocols for clinical development as well as working with Sponsors to request special protocol assessments in order to reach clear agreements to support development of both drug and biologic products.

To learn more about special protocol assessments and how CTI may be of assistance, please contact:

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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:

Elaine Moorman – Study Manager

Ramona von Eick – Research Assistant Germany

Amy McGinley - Clinical Safety Scientist

Congratulations to the following CTI employees recently promoted:

Ryan Gifford – Senior Manager, Business Development and Client Management

Cathy Klose - Senior Director, Business Development and Client Management

Joe Schroeder – Senior Research Associate

Jeff Smith – Senior Research Associate

Theresa Crouch – Senior Regulatory Specialist

Katie Westerkamp – Assistant Project Manager

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