CTI
Clinical Trial and Consulting Services

# March Newsletter

Volume 11, Issue 3

**We are recruiting for CRAs in the US, UK, France, Belgium, Sweden, Germany, Poland, Italy and the Netherlands!**

**Upcoming Medical Meetings CTI will be Attending ...**

Regenerative Medicine
Investor Day
New York, NY
April 17

Bio International
Chicago, IL
April 22 – 25

The International Liver Congress (EASL)
Amsterdam, Netherlands
April 24 – 28

Stem Cell Commercialization and Partnering Conference
Boston, MA
April 29 – 30

**If you are interested in scheduling a meeting with CTI, please contact Nick Schatzman at**

## The Value of a Successful Pre-IND Meeting

Suppose the FDA determined, from a review of its own records, how sponsors could take years off a drug's clinical development? Wouldn't saving years of clinical development provide benefits to patients, physicians, and sponsors? **CTI has helped sponsors succeed with a strategic action that, according to FDA, shortens average clinical development time by more than 3 years.** For orphan drugs used to treat rare diseases, FDA has found that this strategic action shortens clinical development time by 6 years.

The strategic action that can accomplish this substantial improvement in development times is the "Pre-IND Meeting." Early communication with FDA can clarify many questions surrounding the development of novel drugs, and also helps to establish mutually respectful and collegial relationships with FDA reviewers.

The Pre-IND Meeting is one of the "Type B" meetings that are described by PDUFA, the "Prescription Drug User Fee Act." FDA will honor a request for a Type B meeting except in the most unusual circumstances, and these meetings are scheduled to occur within 60 days of the Agency's receipt of a written request for a meeting.

However, FDA grants only one Pre-IND meeting for each application. It is therefore important to get the most out of the opportunity. The unique circumstances surrounding each novel drug's development mean that the timing and the content of the Pre-IND meeting should be carefully planned.

**CTI has successfully managed Pre-IND meetings for numerous sponsors. Our experienced and passionate clinical development experts can help our sponsors formulate the important questions, prepare the meeting request, develop the Briefing Package, and participate in the face-to-face meeting at FDA.** Our goal is to help sponsors develop a clear and concise story for the FDA, which in turn results in guidelines for the clinical development of the drug, saving time, money and valuable resources.

*For more information contact:*

*William S. Aronstein, Ph.D., M.D., F.A.C.P.*
*Senior Medical Director*

**513-598-9290 or via email at nschatzman@ctifacts.com**

## Employee Update

Congratulations to the following CTI employees recently promoted:

**Joe Schroeder** – Contract Specialist

**Dave Flick** – IT Support Analyst

Please welcome the newest additions to CTI:

**Cheryl Chapman** – Clinical Safety Associate

**Michelle Clifford** – Research Associate

## Quick Links…

Our Website

Email

Join Our Mailing List!

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# About CTI

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

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.