CTI CLINICAL TRIAL & CONSULTING

January Newsletter

Where Life-Changing Therapies Turn First™

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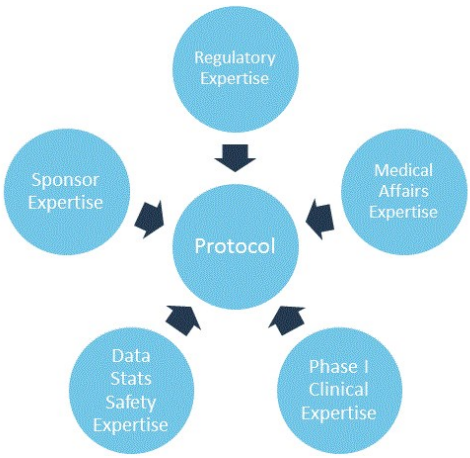
CTI's Integrated Approach to Phase I Trials Leads to Shorter Timelines, Fewer Hurdles & Clean Data

Phase I clinical trials are constantly evolving and changing, with pharmaceutical and biotechnology companies seeking new and innovative ways to cut time and costs, while simultaneously increasing complexities as they strive to capture the critical data necessary for future development. Increasingly, Phase I studies are designed to capture as much data as possible in one protocol to allow sponsors to make that critical go/no-go decision as early as possible.

Designing a study to encompass all of these angles doesn't come without its challenges. Success in early phase clinical trials starts with an informed, comprehensive development strategy that not only meets the requirements of the FDA/other international regulatory authorities and IRBs/ECs, but simultaneously captures the complexity and creativity necessary to obtain results that ultimately feed future development initiatives.

Sponsors come to CTI with innovation and a passion to see their product succeed, not necessarily knowing how best to achieve the outcomes they desire. **CTI's mission is to provide full, in-house support leveraging our experience and expertise to ensure their success. CTI's team of experts in Regulatory, Medical Affairs, Safety, Data, Statistics, and Phase I Clinical Operations work hand-in-hand with our sponsors to create early clinical development programs that are comprehensive, efficient programs, ultimately leading to shorter timelines, fewer hurdles, and clean data.**



Sponsor Expertise	• CTI will work with our sponsors to ensure the protocol design is appropriate for the endpoints and timelines required
Regulatory Expertise	• CTI has direct experience with multiple regulatory authorities, ensuring fewer hurdles and faster timelines
Medical Affairs Expertise	• CTI can support protocol development and writing to ensure all necessary procedures and testing will be included, allowing for comprehensive results • CTI provides expert medical support and therapeutic knowledge throughout the duration of the trial
	• CTI's experienced Phase I Unit, CTI CRC, has 60 beds, is located on a hospital campus, and is in close proximity to our headquarters.

CTI Cares Spotlight

SJU KINNEY CENTER For Autism Education and Support

Kinney Center for Autism Education and Support

The Kinney Center for Autism Education and Support has a two-fold mission: to educate and train the autism professionals of tomorrow, while supporting and serving the individuals and families affected by autism today.

Nominated by:
Debbie Kull
Senior Office Manager

Click here to learn more and to donate!

CTI is proud to support Rare Disease Day 2015 - February 28th

Phase I Clinical Expertise	• leading to efficiencies across departments • CTI CRC has all of the necessary equipment and therapeutic experience to complete trials, including complex and specialized processes • CTI CRC has been conducting trials for over 20 years, developing an organically grown, robust database of research subjects, leading to meeting and exceeding enrollment timelines
Data Management / Statistics / Safety Expertise	• CTI's expert teams assist with protocol design to ensure meaningful results, allowing sponsors to do a thorough assessment of future endeavors with their product portfolio

"CTI Clinical Research Center's core Phase I team has been together for nearly a decade, and we have an incredibly low staff turnover rate which translates into consistent, high quality data for our sponsors," according to Gail Kushner RN, BSN, CCRC, Clinical Site Director. "Sponsors don't always consider the logistical considerations of a trial design, so providing input early on in the development process allows for a more realistic, fluid, and manageable study. Our expertise, knowledge, and strong track record are all reasons our sponsors work with us time and time again."

"Additionally, we have been able to utilize our collective experience to provide sponsors with insight and perspective during the protocol development phase in order to ensure that studies are fluidly and efficiently designed from an execution standpoint," says David Mayleben, PhD, Vice President, Research Site Services. "Incorporating clinical execution into the development phase mitigates logistical challenges, allowing start-up activities to begin as soon as the protocol is finalized. By the time the protocol reaches the clinic, our team is familiar with the study and ready to go."

CTI is in a unique position to offer our partners full-service, in-house support. Many efficiencies are gained by having a seamless transition from concept creation and protocol development through clinical conduct. Furthermore, we have a robust database of patient populations, covering a broad range of therapeutic indications that allows us to bridge efficacy and proof-of-concept into a Phase I, early clinical development setting.

"We're excited that sponsors are looking to CTI Clinical Research Center to manage the ever changing dynamics of early development studies," states Jessica Sheridan, Manager, Business Development and Client Management. "We're helping our sponsors create cost effective, comprehensive, efficient study designs, allowing them to make informed decision earlier in the development process. It is a trend that we believe will continue to grow across the industry."

For more information:
www.ctifacts.com

Upcoming Meeting Spotlight:

American Society for Clinical Pharmacology and Therapeutics Annual Meeting
New Orleans, LA
March 3 - 7, 2015

Stop by and visit us at Booth #318 throughout the meeting!

To schedule a meeting with us while we're here, please click here.

Recent CTI Publications:

Bilder DA, Noel JK, Baker E, Irish W, Winslow BJ, Jain R, Chen Y, Merilainen MJ, Prasad S. **A systematic review (SR) and meta-analysis (MA) to assess the prevalence of neuropsychiatric symptoms in adults with phenylketonuria (PKU).** *Jlnherit Metab Dis*. 2014;37(Suppl 1):S178.

Bilder DA, Noel JK, Baker ER, Irish W, Winslow BJ, Jain R, Chen Y, Merilainen MJ, Prasad S. **A systematic review (SR) and meta-analysis (MA) to assess blood phenylalanine (Phe) levels in adults with phenylketonuria**

(PKU). *JInherit Metab Dis.* 2014;37(Suppl 1):S178.

Bilder DA, Noel JK, Baker ER, Irish W, Winslow BJ, Jain R, Chen Y, Prasad S, Merilainen MJ. **A systematic review (SR) of the effectiveness of reducing blood phenylalanine (Phe) levels in adults with phenylketonuria (PKU) on neuropsychiatric symptoms.** *JInherit Metab Dis.* 2014;37(Suppl 1):S62.

Upcoming Meetings We Will be Attending

American Society of Transplantation: Cutting Edge of Transplantation
Chandler, AZ - February 5 - 7

American Society of Blood and Marrow Transplantation (ASBMT) / Center for International Blood and Marrow Transplant Research (CIBMTR) Bone Marrow Transplant Tandem Meeting
San Diego, CA - February 11 - 15

American Society for Clinical Pharmacology and Therapeutics Annual Meeting
New Orleans, LA - March 3 - 7

To schedule a meeting with us at one of these, please click here

New Additions & Promotions at CTI

Ira Davis, MD joins as Medical Director

Christine Eby, AuD joins as Assistant Study Manager

Maria Izzo joins as Associate Study Manager

Katharina Kiechle joins as Administrative Assistant, Europe

Chris Laber joins as Assistant Manager, Business Development Operations

Peter Mallow, PhD promoted to Associate Director, Health Economics

Ligia McDonald promoted to CRA Manager

Swetha Palli joins as Senior Manager, Health Outcomes Research

Brian Poole joins as Document Archivist

Join our Team!! We're looking for individuals to fill these positions:

Clinical Trial Assistant (Cincinnati, OH)

Clinical Research Associate (US, Germany, France, Australia, Brazil)

Director, Health Outcomes Research (Cincinnati, OH)

Manager, Proposal Development

Study Manager (Cincinnati, OH; Raleigh, NC; Philadelphia, PA; San Francisco, CA)

Click here for more information and to apply!