CTI CLINICAL TRIAL & CONSULTING

Newsletter

Where Life-changing Therapies Turn First™

www.ctifacts.com

Volume 13, Issue 6/7

CTI Experts Can Help Navigate Asia-Pacific Trials

The Asia-Pacific region is one of the fastest-growing pharmaceutical markets globally, as nearly 60% of the world's population is located there. Industry experts see major growth ahead in Asian countries that have significant patient populations and maturing healthcare systems, including China, Korea and Japan.

Opportunities in Asia-Pacific Trials

The pharmaceutical industry has developed dramatically in Asia-Pacific (APAC) since the last decade, in part due to individual country standards and government involvement. Since 2009, the standards of clinical trials in APAC countries have been more efficient and have produced promising quality of data, leading to a surge in clinical trials in the region. ICH-GCP guidelines have been adopted in the region for over 10 years now, and quality is constantly improving.

Many countries throughout the APAC market have country-specific research tax credits that are incentives to drug development companies. **CTI's international finance and clinical experts are able to work with our sponsors to identify countries with research tax credits that may be applicable to the projects and programs in their development pipeline.**

The biggest single driver for conducting trials in the APAC market is the availability of large numbers of treatment naive patients. There is a high prevalence of certain diseases, such as diabetes, hepatitis B, cardiovascular diseases, and rare diseases. Such a large population means that there is less competition for patients. There is also a strong presence of academic institutions and investigators. The high population density and large hospital infrastructures have lead to a greater number of trials in the region.

Another major benefit of the APAC region for clinical trials is that costs are relatively lower in some countries, compared to the US

CTI Cares Spotlight

4 Paws for Ability is a nonprofit whose mission is to place quality service dogs with children with disabilities and veterans who have lost use of limbs or hearing; help with animal rescue, and educate the public regarding use of service dogs in public places.

Nominated by: Liz Valentine - Regulatory Specialist II

Learn More and Donate!

Big Brothers Big Sisters of Greater Cincinnati

Big Brothers Big Sister of Greater Cincinnati has a mission to provide children who are facing adversity with strong and enduring, professionally supported one-to-one relationships that can change their lives for the better. The goal and vision of the relationships built through Big Brothers Big Sisters are meant to give children the opportunity to achieve success not only in school, but in life.

and EU.

Risks and Challenges in Asia-Pacific Trials

Due to rapid expansion and economy growth, the APAC market also has its challenges. Recruitment in APAC countries can be challenging, despite the huge population. Only 35% of the patients in Asian countries live in metropolitan areas with sites that take part in clinical research, which can make recruiting and retention difficult. There is also low awareness for clinical trial opportunities and an overall aging population, both of which are hurdles to recruiting.

Besides recruitment, regulatory submissions can be a challenge in Asia. Unlike North America or the European Union, Asia currently does not have a harmonized regulatory body and standards vary for each country in the region. Another regulatory challenge is drug registration regulations in some countries require a local or regional population to be included in a clinical study if the goal is to market the product locally.

Language barriers also exist across the region, which require necessary local support for executing clinical trials. There are also other limitations of conducting clinical trials in developing Asian countries, such as expensive biologicals may not be available or commonly used as the standard therapy. **CTI's global regulatory experts can help navigate the complicated regulatory challenges throughout Asia.**

CTI's local experts can help navigate Asia-Pacific Trials

While regulatory start-up times and language barriers can be challenging for some countries, the ability to recruit large numbers of patients once the sites are active is a major benefit in terms of meeting the project timelines and staying on budget. **CTI's local regulatory and project management experts can help with all parts of Asia-Pacific trials, including regualtory submissions, identification of research tax credits, site selection, monitoring, and more.** Our experts understand the unique challenges of conducting research in the Asia-Pacific region and use their country-specific knowledge to ensure our clients' timelines and budget are met.

For more information:
www.ctifacts.com
513.598.9290

In 2015 1,132 children, ages 7-18 were provided supportive relationships through Big Brothers Big Sisters of Greater Cincinnati.

Nominated by: Cindy Schulten - Executive Assistant to the CEO

Learn More and Donate!

New Additions &

Upcoming Meetings We

Join our Team!!

Promotions at CTI

Christine Ames joins as Study Coordinator

Angie Bowens promoted to Clinical Safety Scientist II

Caitrin Cardosi promoted to Senior Business Development Associate

Christine Eby promoted to Study Manager II

Brandon Felton joins as Research Associate

Liz Froese promoted to Research Associate

Larry Gache promoted to Manager, Health Outcomes Research

Cristina Garcia joins as CRA Manager, Europe

Susan Giese joins as Billing Specialist

Patricia Havenga joins as Senior Manager, International Business Development and Client Management

Heather Holbrook joins as Research Assistant

John Kane joins as Associate Director, Global Safety & Pharmacovigilance

Michelle Kroger joins as Study Coordinator

Cassie Lampe promoted to Senior Study Coordinator

Ying Li joins as Biostatistician I

Matt Makepeace promoted to Administrative Assistant

Ellen Maue joins as Research Associate

Allison McAllister joins as Administrative Assistant/Receptionist

Tracy Reed-Kessler joins as Study Manager I

Alexandra Stevenson joins as Study Coordinator

Nermina Soskic joins as Clinical Trial Assistant, Germany

Stephanie Zeidan joins as Study Coordinator

Will Be Attending

CAR-TCR Summit 2016
Boston, MA
September 13-16

2016 Cell and Gene Meeting on the Mesa
La Jolla, CA
October 5 – 7

NORD's Annual Summit
Arlington, VA
October 17-18

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

We're looking for individuals to fill these positions:

Clinical Research Associate (US, Germany, France, Spain, Australia, Brazil, Korea, Taiwan, Japan, Argentina)

Clinical Research Coordinator (Cincinnati, OH)

Manager, Business Development & Client Management (Europe & US)

Manager/Director/Executive Health Economist (Cincinnati, OH; Raleigh, NC; Philadelphia, PA)

Manager/Director/Executive Health Outcomes Research (Cincinnati, OH; Raleigh, NC; Philadelphia, PA)

Medical Director (Cincinnati, OH)

Medical Writer (Cincinnati, OH)

Study Manager (Cincinnati, OH; Raleigh, NC; Philadelphia, PA; San Francisco, CA; Ulm, Germany; Paris, France; Madrid, Spain)

Click here for more information and to apply!