

February Newsletter



Where Life-changing Therapies Turn First™

Volume 12, Issue 2

Join us February 24th – 28th
for a week of free
educational webinar
trainings in celebration of
Rare Disease Day.

Visit our website or click here to register!



CTI Cares Spotlight of the Month

Safe Haven Farms

nominated by Hadley Decker, MS

- Associate Director, Clinical
Trials

Safe Haven Farms is an organization offering residential, day, and community services for individuals on the autism spectrum. It provides a variety of meaningful living, working, learning and leisure activities in a safe and accepting farm environment, where every individual is respected as a valued and contributing community member.

Click here to learn more and donate

Join CTI to Celebrate Rare Disease Day

In honor of Rare Disease Day, CTI Clinical Trial and Consulting Services (CTI), is hosting a series of free webinars (February 24 to 28) to bring widespread recognition of rare diseases and the challenges in drug/device development in this important This unique niche of area. research is complicated by low patient numbers, challenging recruitment, complex logistics, costly development, and specialized regulatory requirements. In an effort to promote research and development for rare diseases, CTI experts will share their experiences overcoming these hurdles in the development of new lifechanging therapies for these unique populations.

Quantifying the economic impact of a rare disease in a community (familial, medical, etc.) is important to support regulatory pathway decisions, generate investigator/KOL interest, and assist in

Unmet Need in Rare Disease

Monday February 24, 2014 - 11am – 12pm EST "Tricks and Traps for Estimating the Economic Burden of Illness for Rare Diseases"

Candace Gunnarsson, EdD - Vice President, Health Economics & Outcomes Research

Tuesday February 25, 2014 - 12pm – 1pm EST "Issues in Designing Clinical Trials for Rare Disease"

William Irish, MSc, PhD - Vice President, Biostatistics & Health Outcomes Research

Wednesday February 26, 2014 - 12pm – 1pm EST "Rare Disease Trial Participants - Recruitment to Retention"

Hadley Decker, MS - Associate Director, Clinical Trials

Thursday February 27, 2014 - 11am - 12pm EST
"Orphan Drug Designation: What, Where, and How"
Kathy Wekselman, PhD, RN - Director, Regulatory & Scientific
Affairs

Friday February 28, 2014 - 12pm – 1pm EST
"Commercialization of an Orphan Drug"

Joseph McCafferty - Vice President Sales, North America



fundraising necessary to move a new therapy from discovery to the clinic. Please join our Vice President of Health Economics, Dr. Candace Gunnarsson, on February 24 (11AM to 12PM EST) for more information.

Upcoming Meetings CTI will be Attending ...

GTC's 2nd Orphan Drug Research and Commercialization San Diego, CA February 20-21

Partnering Conference
San Diego, CA
February 26-27

BIO EuropeBarcelona, Spain
March 11-13

Benefit - Cost Analysis for
Evidence = Based Decision
Making
Washington DC
March 13-14

American College of Cardiology
Washington DC
March 29-31

If you are interested in scheduling a meeting with CTI, please contact Nick Schatzman at 513-598-9290 or at nschatzman@ctifacts.com

Congratulations to these recently promoted CTI employees:

Colleen Colson – Senior Global Manager, Quality Assurance

Teresa Rodriguez – Clinical Project Manager

Kyra Graham – Study Coordinator Developing appropriate study designs that are powered sufficiently to show benefit in small numbers of patients is a common challenge of rare disease research. Patient identification and recruitment can also be difficult for a variety of reasons including low numbers of patients and/or pediatric or neonate populations. Complex lodging and travel logistics can create retention issues. We welcome you to join our Vice President of Biostatistics & Health Outcomes, Dr. William Irish on February 25 (12PM to 1PM EST) and our Associate Director of Clinical Trials, Hadley Decker on February 26 (12PM to 1PM) for more information on study design, statistical implications, and recruitment in rare disease trials.

Orphan drug designations can streamline the development of new life-changing therapies in rare diseases by significantly reducing the time and costs associated with bringing new treatment options to patients. Please join our Director of Regulatory & Scientific Affairs, Dr. Kathy Wekselman on February 27 (11AM to 12PM) for more information. Developing a comprehensive commercialization plan is important to getting new therapies into the hands of treating physicians and ultimately to the patients that need them. We welcome you to join our Vice President of Sales, North America, Joseph McCafferty on February 28 (12PM to 1PM EST) for more information regarding the commercialization of orphan drugs.

CTI has been working in rare disease research since its inception 15 years ago. We are passionate about turning life-changing therapies from conceptual visions into real-life solutions for patients and are excited to be a part of Rare Disease Day. By sharing our experiences with you, we hope that as a community we can continue to pursue new and life-changing therapies in these small but important patient populations. Please click here to sign up for these free informational webinars.

About CTI

CTI Clinical Trial and Consulting Services is an innovative, international drug and device development organization that delivers a full spectrum of clinical trial and consulting services from bench to commercialization with a focus on immunology and a passion for helping life-changing therapies succeed in chronically and critically ill patient populations. CTI's focused therapeutic approach provides pharmaceutical, biotechnology and startup firms with clinical and disease area expertise from a unique mix of academic, medical and industry specialists; rich intellectual capital in transplantation, immunology, infectious diseases, hematology, cardiology, nephrology, hepatology, regenerative medicine and rare diseases; flexible study designs that accelerate development programs and deliver high approval ratings that are among the best in the industry; and exceptional global project management and gold standard safety and data management systems that strengthen their program's success potential. Established in 1999 and headquartered in Cincinnati, OH; CTI has offices in North America, Europe and South America.

Katie Westerkamp – Study

Coordinator

Ramona von Eick – Clinical Trial Assistant

Looking for a job?
CTI is looking for qualified and passionate individuals to fill these positions:

Clinical Research Associate – US, Spain, UK, Germany, Poland, Australia

Information Technology Support
Specialist – Europe

Biostatistician – Cincinnati, OH

Medical Writer – Cincinnati, OF

Quality Assurance Auditor – Europe

Senior Director Health
Outcomes Analyst – Cincinnati,

Please visit our website for complete job descriptions and to apply!

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