CTI Study Management Are Industry-Leading Experts in Complex Cell & Gene Therapy Trials

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CTI is a recognized industry leader in clinical trials of cellular and gene therapies - fields well known among researchers for added complexity in both the start-up and ongoing management of a clinical trial. The CTI Global Study Management team offers comprehensive experience in executing cell and gene therapy trials to treat complex patient populations in rare and orphan disease indications. CTI employs highly specialized knowledge and an adaptive management approach to mitigate risk and successfully navigate critical phases of regenerative cell and gene therapy trials.

Clinical trials evaluating cell and gene therapies require careful consideration of site selection, site regulatory approvals, chain of custody and manufacturing slot allocation.

- **Site selection** – Effective April 27, 2016, updates to NIH guidelines transfer the responsibility of determining whether a public NIH Recombinant DNA Advisory Committee (RAC) review is required to the first clinical institution's oversight body (Institutional Biosafety Committee (IBC) or Institutional Review Board (IRB)). Selecting a site that has experience with the revised RAC recommendation process and expedient regulatory turnaround time are imperative to accelerating start-up and enrollment timelines in the United States. Similar country-specific guidelines are in effect across the world. CTI leverages our industry knowledge and working relationships with large public institutions and small private research centers to strategically select qualified sites that achieve enrollment objectives. **CTI staff has overseen sites to open in as fast as 30 days (from CDA sent to site open for enrollment) on cell and gene trials.**
- **Site regulatory approvals** – Conducting cell and gene therapy trials requires multi-step regulatory committee and subcommittee review and approval. The site regulatory process is highly variable

among institutions. CTI's key to success is in its people and process. An experienced regulatory specialist is dedicated from the outset of the trial to facilitate regulatory submissions according to individual site committee processes and meeting schedules. This specialist remains on the project for the life of the trial, to oversee ongoing maintenance and fulfill site regulatory requirements beyond start-up.

- **Chain of custody (traceability) documents** – For autologous cell products, comprehensive chain of custody documentation throughout the transfer of the subject's cells is imperative for "vein to vein" oversight. CTI's key to success, for all cell and gene therapy products, begins with closely collaborating with sponsors to modify chain of custody and drug accountability documents to fit the individual program and satisfy ICH/GCP ALCOA and other global guidelines and regulatory requirements. The site staff undergo rigorous training on chain of custody and on the pillars of cell product administration (right patient, right product, right dose, right documentation, and right response) and their training is routinely assessed over the course of the trial.
- **Manufacturing slot allocations** – Contract manufacturing organizations (CMOs) preparing autologous cell products typically assign specific manufacturing slots to your program. Having clear direction from the CMO regarding slot availability and preferred shipping procedures is important, and sites must be informed about the manufacturing process and the availability of manufacturing slots for enrolling a subject on your trial. CTI's key to success is the effective implementation of key stakeholder communication pathways, efficiently managing the logistics of filling open manufacturing slots.

Cell therapies and gene therapies currently comprise approximately 50% of the trials managed by CTI. Our expertise in the special complex features of these trials and understanding the challenges that come with using cell and gene therapy technologies has made CTI successful in exceeding trial timelines and bringing cutting edge therapies to market. **Over 60% of CTI's clinical team has experience working on cell & gene therapy trials.**

CTI has contributed to one of the world's first approved stem cell drugs and to one of the first US gene therapy products.

Contributed by: Katie Westerkamp, Study Manager III, currently managing multiple global gene therapy projects

To discuss your program needs with a CTI Study Manager, call Katie Westerkamp at (513) 598-9290 or email Katie at kwesterkamp@ctifacts.com.

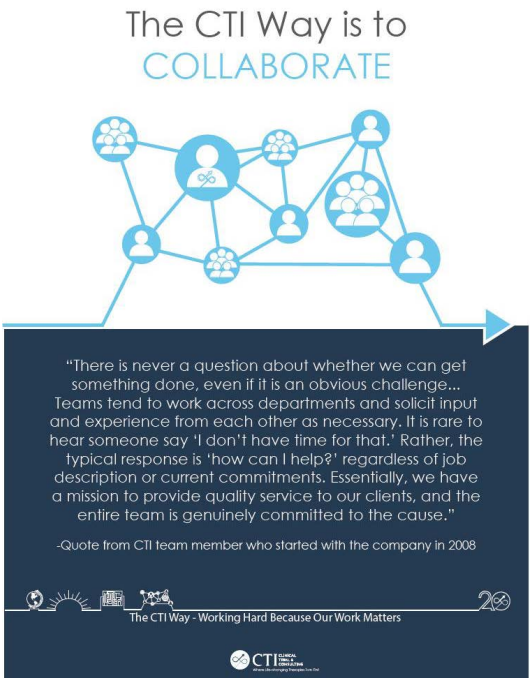
Additional Highlights

The CTI Way

There is a unique culture that exists at CTI, a method of approaching our work and interacting with our coworkers that we have come to refer to as "The CTI Way."

As we make our way towards our 20th year, each month we will be highlighting a different theme or aspect of "The CTI Way." The theme for the month of May is **"Collaborate."**

The employee of the month is awarded to the candidate who exhibits strength in CTI's core values, best exemplifies "The CTI Way" theme of the month, and consistently demonstrates outstanding performance.



Employee of the Month

Michael (Mike) Karwisch

Mike has been with CTI for more than 15 years, and currently holds the position of Controller. There may not be a better example of collaboration than what the Controller position entails. Not only does Mike work closely with the Finance Team, but he also collaborates with Business Development, Sales, Consulting, International, etc. - there really isn't a department at CTI that he doesn't interact with or advise throughout the course of performing his job.

Mike is a tireless leader and works extremely hard each and every day, all while maintaining an upbeat and lighthearted working environment. He is a joy to work with, he appreciates his team, and provides constant guidance and support in order to maintain and improve current processes for the good of the company. Mike has truly been instrumental in the growth and success of CTI throughout his 15 years with the company.

Congratulations, Mike, on your well-deserved award!

Upcoming Meetings CTI is Attending

American Society of Clinical Oncology (ASCO)
Chicago, IL
June 1-5

American Transplant Congress (ATC)
Seattle, WA
June 2-6

Digestive Disease Week (DDW)
Washington, DC
June 2-6

SLEEP Meeting 2018
Baltimore, MD
June 2-6

Bio International Convention
Boston, MA
June 4-7

International Vicenza Course on Acute Kidney Injury (AKI) & Continuous Renal Replacement Therapies (CRRT)
Vicenza, Italy
June 12-14

23rd Congress of European Hematology Association (EHA)
Stockholm, Sweden
June 14-17

DIA 2018
Boston, MA
June 24-28

AASLD/EASL NAFLD Endpoints Conference
Alexandria, VA
June 29-30

Non-alcoholic Steatohepatitis (NASH) Meeting
Paris, France
July 5-6

International Symposium on MPS
San Diego, CA
August 2-4

CAR-TCR Summit 2018
Boston, MA
September 4-7

Outsourcing in Clinical Trials (OCT) Southern California
La Jolla, CA
September 26-27

Outsourcing in Clinical Trials (OCT) New England
Boston, MA
November 6-7

AASLD - The Liver Meeting 2018
San Francisco, CA
November 9-13

Join Our Team!

We are currently seeking qualified individuals to join our team!

Search Open Positions

CTI Cares

This month, the CTI family is raising money to support The American Cancer Society's Hope Lodge. Hope Lodge offers cancer patients and their caregivers a cost-free, temporary home away from home when they travel to Cincinnati for cancer treatment.

Learn more and donate

New Hires & Promotions

CTI is thrilled to welcome all of our new employees, and to congratulate our recently promoted employees!

View New Hires and Promotions

CTI in the News

CTI Regulatory Director to Present at American Society of Gene and Cell Therapy and Serve on Government Relations Committee

CTI Clinical Trial and Consulting Services (CTI), a multi-national, privately held, full-service contract research organization will present as part of The American Society of Gene and Cell Therapy (ASGCT) Annual Meeting, taking place May 16-19, 2018 in Chicago, IL.

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