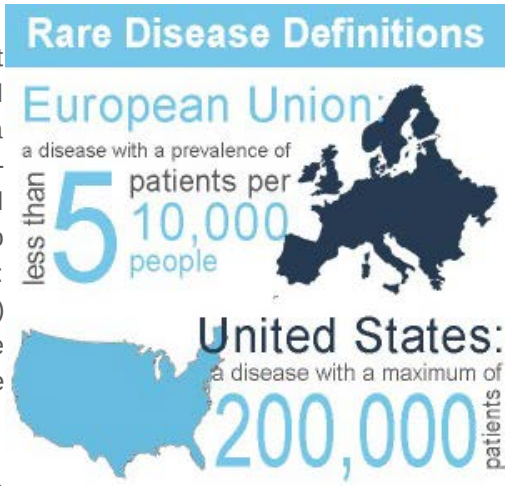
New Brazilian Regulatory Resolution Helps Rare Disease Research

New rules give more flexibility in the drug registration process and in the evaluation of clinical trials in Brazil

The Brazilian Health Authorities (ANVISA) recently established a special procedure for the approval of clinical trials for the treatment, diagnosis, or prevention of rare diseases through a new resolution put into place February 27, 2018. The new resolution seeks to streamline the ANVISA approval process for rare disease trials, reducing the total evaluation time of up to 6 months to approximately 90 days.



To be classified as a rare disease, the disease must affect up to sixty-five people out of every hundred thousand individuals, based on national official data or, when nonexistent, on data published in technical-scientific documentation. In addition, ANVISA shall consider a drug for a rare disease if it is intended to treat, diagnose or prevent the rare disease in which: (i) it is used in a serious debilitating condition; and (ii) it proposes to change in a clinically significant way the progression or make possible the remission of the disease.

To submit the drug development dossier for rare diseases under this new resolution, the sponsor must request a pre-submission meeting to present the dossier to ANVISA, which will be held within 60 days of the request. After the meeting,

the sponsor must then submit for evaluation the regular dossier, along with the specific documentation required per the resolution. The analysis will be made by ANVISA, and they will issue a demand or approval letter within 30 days upon submission.

The analysis of the request for registration of a new drug will be made within 60 days after submission, with issuance of a demand or approval letter. In addition, it also encourages the marketing of registered medicines through the criteria of this resolution, establishing a period of up to 365 days to be marketed after approval of the registration.

The new resolution encourages access to and increases therapeutic options for the treatment of rare diseases in Brazil, making it a more attractive place for rare disease trials to take place. For comparison, in the US, the FDA Accelerated Approval takes 4-6 months on average for a regulatory response, and in the EU, the EMA Accelerated Assessment takes 5-7 months typically.

CTI's rare disease regulatory and clinical experts are well versed in the requirements of all global regulatory agencies, and can help sponsors navigate the many regulatory pathways, finding the best route for getting rare disease drugs or medical devices approved and to the patients that need the therapy as fast and efficiently as possible. Read more about CTI's rare disease expertise here or contact us directly for more information.

Contributed by: Jaqueline Aguiar, RPh, Operations Manager - Latin America
With nearly two decades of experience in clinical research across Latin America, Jaqueline is one of our many experts who can help you with your regulatory needs in Brazil and across the region.

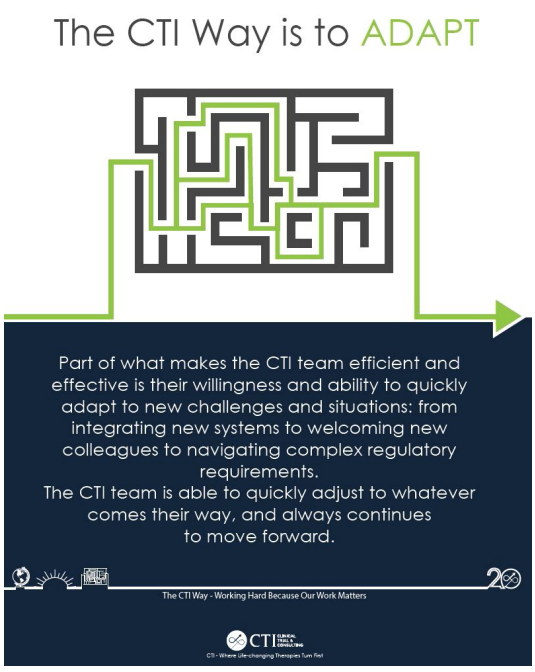
Additional Highlights

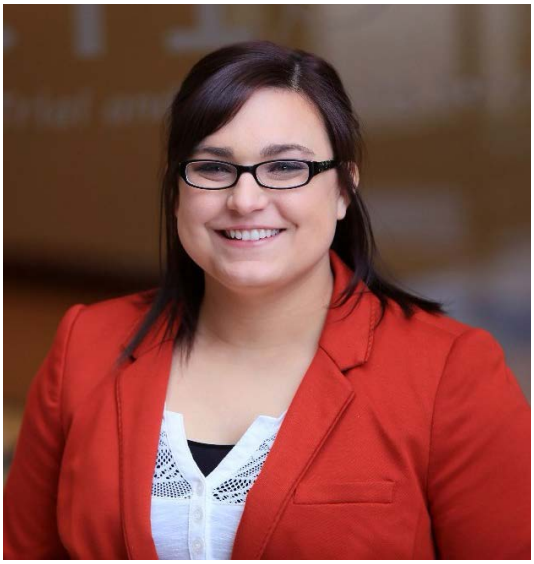
The CTI Way

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 April is **"Adapt."**

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

Chelsea Jones

Chelsea currently holds the position of Study Manager I at CTI. While Chelsea exemplifies strength in CTI's core values and consistently demonstrates outstanding performance, her remarkable ability to adapt is what really sets her apart.

Chelsea is truly valued by her study teams and is always able to quickly adjust to the ever-changing demands of research and the study teams she serves. No matter what is going on, Chelsea always rises to the occasion and embodies the value of teamwork and getting the job done. She is a self-directed learner and always willing to share her knowledge. Her insight and experience is greatly respected and appreciated at CTI.

Congratulations, Chelsea, on your well-deserved award!

Upcoming Meetings CTI is Attending

The European Conference on Rare Diseases & Orphan Products (ECRD)
Vienna, Austria
May 10-12

Biomed 2018
Tel Aviv, Israel
May 15-17

World Advanced Therapies & Regenerative Medicine Congress
London, England
May 16-18

American Society of Gene & Cell Therapy (ASGCT)
Chicago, IL
May 16-19

Non-alcoholic Steatohepatitis (NASH) Biomarkers Workshop 2018
Washington, DC
May 18-19

ISPOR 23rd Annual International Meeting
Baltimore, MD
May 20-23

Outsourcing in Clinical Trials (OCT) East Coast
Philadelphia, PA

May 22-23

American Society of 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

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 Partners for Krabbe Research (P4KR). P4KR's mission is to increase awareness and raise funds for research to improve the lives of those born with Krabbe's Disease, an inherited disorder affecting the central and peripheral nervous systems.

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 Announces Expansion Into Israel

CTI Clinical Trial and Consulting Services (CTI), a multi-national, privately held, full-service contract research organization announces it has expanded its presence into Israel with the completion of its incorporation in Israel under the wholly-owned subsidiary, CTI Clinical Trial & Consulting Services Israel.

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