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January Newsletter

How the RACE for Children Act Could Impact Clinical Programs

Congress passed [H.R.1231 - RACE for Children Act](#) in 2017, and it is slated to go into effect in 2020. As that deadline approaches, we have begun to field questions from our friends and clients wondering how the act will impact them and what they should know to set their programs up for success. Keep reading for our answers to some of the most frequently asked questions.

What is the RACE for Children Act?

The Research to Accelerate Cures and Equity for Children Act, or RACE for Children Act is not a new law, but is actually an amendment to the [Pediatric Research Equity Act \(PREA\)](#) from 2003. PREA required sponsors of drugs and biological products for the treatment of adult cancer to include pediatric assessments of safety and effectiveness for claimed indications, “with exceptions.”

How will the Act impact future clinical programs?

The largest impact of the RACE for Children Act is the limits it imposes on those exceptions allowed by the original PREA. The act redefines the PREA exemption for diseases that do not affect children. Under the original PREA provisions, this exemption covered any treatment for a cancer not normally found in children, and those cancers were defined by the organ they affected. Under the new RACE for Children guidelines, the exemption is determined not by the type of cancer and where that cancer occurs, but

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immediately exempt from PREA requirements. These changes mean that many more programs will be required to include pediatric programs than ever before.

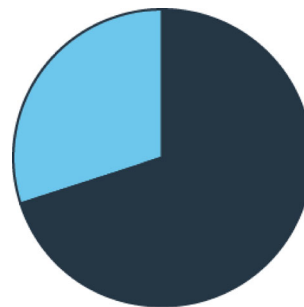
What should I know when I start designing a pediatric arm of my program?

First and foremost, a pediatric trial is not just a study in small adults. When designing a pediatric program, you should factor in challenges like regulatory requirements regarding the treatment of vulnerable populations, recruitment restrictions and longer consent processes, and even logistical details like taking into account accommodating an entire family if the program necessitates transporting patients from their homes to the treatment site.

When choosing your partners, it is important to choose a CRO, vendors, and research sites with experience both in oncology and pediatric programs. Working with teams who can anticipate the challenges ahead will help you work proactively and consequently expedite your program.

How CTI Can Help

CTI has a primary focus on complex and critically ill patient populations, which has led to a long history working on programs in therapeutic areas like [oncology](#), [regenerative medicine](#), and [rare diseases](#). Many of these complex programs involve both [pediatric and neonate populations](#). In fact, currently about 30% of our active programs involve pediatric populations, which is double the industry average. We have physicians, nurses, and pharmacists with extensive pediatric research expertise and direct patient care experience. We are acutely aware of the unique program development and execution challenges pediatric research presents. Our experienced team can provide guidance, expertise, and efficiency to pediatric development programs for our sponsors.



If you would like more information about how CTI can help you with your pediatric oncology programs, [contact us here](#) and we would be happy to have further discussions with you.

Interested in working on complex programs like pediatric oncology? Join our team!

We are growing and need experienced clinical research professionals to join us as we work to improve the lives of critically and chronically-ill patients around the world.

[Click here](#) to learn about our culture and see a list of open positions, then [fill out our contact form](#) to start up a conversation with a member of our HR team!

Learn about who we are, what we do, and why we like being a part of the CTI team.

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The CTI Way

Every month, we choose a theme highlighting characteristics of our company culture, something we describe as "The CTI Way." This month's theme is "thrive" and we've chosen to spotlight our [Research Associate \(RA\) program](#). CTI's RA program introduces young professionals to the world of clinical research and provides them the experience and support it needs to flourish. Evidenced by the presence of former RAs in every department and level of the company (up to Vice President), this unique program is one that allows our young talent not only to grow, but to thrive.

The CTI Way is to
THRIVE



Additional Highlights

Upcoming Meetings We'll be Attending

WORLD Symposium

Orlando, FL
February 3-8

SCOPE Summit for Clinical Ops Executives

Orlando, FL
February 18-21

American Society of Transplant Surgeons Winter Symposium

Adult Stem Cell & Regenerative Medicine

New York, NY
March 14

ARM Cell & Gene Therapy Investor Day

New York, NY
March 21

European Society for Blood and Marrow Transplantation

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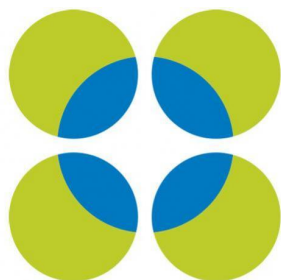
London, UK
February 26-27

ARM Cell & Gene Meeting on the Mediterranean

Barcelona, Spain
April 23-24

American Society for Clinical Pharmacology & Therapeutics 2019 Annual Meeting

Washington DC
March 13-16

**BE THE MATCH®****CTI Cares**

This month, the CTI family is raising awareness and money to support Be The Match, a foundation that works to deliver cures for blood cancers.

[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](#)

**Join Our Team!**

We're growing across the United States!

We're looking to build our team in following new cities:

- Atlanta, GA
- Boston, MA
- Chicago, IL
- Dallas, TX
- Houston, TX
- Indianapolis, IN
- San Diego, CA
- Washington DC

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