CTI CLINICAL TRIAL & CONSULTING

Where Life-changing Therapies Turn First®

Newsletter

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Volume 14, Issue 11

Clinical Trial Agreements - How CTI's Legal Experts Can Save Sponsors Valuable Time and Money

There are many obstacles through which a sponsor of a clinical trial must navigate. One of those obstacles is the Clinical Trial Agreement (CTA). CTI, like most CROs, will not perform a site initiation visit until the CTA has been fully executed. This puts the spotlight on the efficiency and expediency of the CTA negotiation and execution process, making it time-critical to the initiation of a clinical trial.

Time is money and nobody knows that better than a sponsor of a clinical study. Delays of only one month can cost a sponsor millions of dollars in lost opportunity. The CTA negotiations can be challenging as one must overcome several different types of hurdles, including varying regulations, laws, social background and cultures. If the contract process is not properly managed, the lead-time in negotiating a contract to full execution can be as much as six months to even a full year at some sites.

CTI is uniquely positioned to manage the CTA process in our therapeutic areas of expertise. More than 90% of CTI's research takes place in academic medical centers, which are notorious for prolonged legal negotiations. CTI's well-established relationships with key site personnel at these centers span multiple decades. These relationships afford CTI an opportunity to pursue many different angles in navigating through each site's contract process.

CTI maintains metrics which allow it to analyze and specifically measure the length of time it takes to fully negotiate and execute CTAs. Metrics are maintained by site, by study and by sponsor since all of these are factors influencing the contracting timeline.

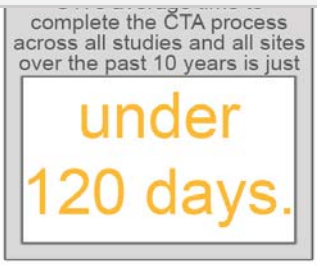
CTI's average time to complete the CTA process in academic medical centers across all studies and all sites over the past ten years is just under 120 days.

CTI Cares Spotlight

The program uses athletics to teach critical lessons about leadership, discipline, strong work ethic, responsibility, communication and respect. These lessons are central to the work we do at the Academy and are essential qualities that every young person can rely on throughout their life to be a better person, worker and citizen.

Nominated by: David Vessey

Learn More and Donate!

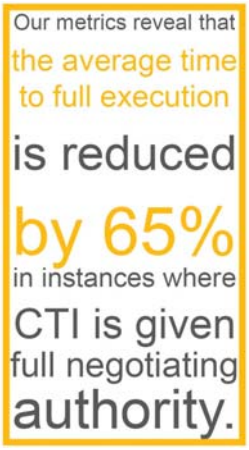


According to CTI's metrics accumulated over the past 15 years, the time needed to complete the CTA process in academic medical centers can vary from as low as 22 days to as high as 550 days, on average, depending on the site selected and several other key factors.

Table 1. Average Number of Days to Complete U.S. CTAs (with Quartile Data)

Average:	Quartile - Minimum Value:	Quartile - First (25%):	Quartile - Second (50%):	Quartile - Third (75%):	Quartile - Maximum Value:
119	22	67	116	163	550

One of these key factors which can significantly impact the contracting timeline is the negotiating authority entrusted to CTI by the sponsor. **Our metrics reveal that the average time to full execution is reduced by 65% in instances where CTI is given full negotiating authority.** If CTI's negotiating authority is limited, the sponsor can still help these numbers by being as flexible as possible. This flexibility includes being open to site templates and limiting the rounds of negotiations by considering reasonable language change requests to key areas such as subject injury, intellectual property, confidentiality and indemnification.



Another factor is the site's responsiveness throughout the negotiation process. Some sites lack the urgency or have resourcing issues, while others have institutional policies which make it difficult to meet study deadlines. CTI's contracting metrics can be an invaluable tool in the site selection process. For studies with tight timelines, knowing and avoiding those academic institutions with restrictive review policies or heavy backlogs can greatly improve the contracting timeline. If an academic medical site is prevented from negotiating a CTA prior to their Institutional Review Board submission and/or approval or if a site has a heavy backlog (six to eight weeks at some sites), it may not be in the sponsor's best interest to select that site.

Site contracting with academic medical centers outside of the United States (OUS) poses additional challenges often unique to each country. Many countries have multiple statutory contract

language. Further, local language barriers, legal practices, and time differences are all factors CTI must manage when contracting OUS. Even with these additional challenges, **CTI's legal team has been able to successfully negotiate and execute OUS contracts with academic centers in over 20 countries including Germany, France, Italy, Australia, Brazil and South Korea with an average completion time of 120 days.**

Once the CTA becomes a priority to the site, it is imperative that it stay there. For this reason, establishing a good rapport with the site's negotiating team, study coordinator and investigator are of paramount importance. CTI's contract negotiators average 10 years of experience and have negotiated and executed numerous CTAs with these academic institutions. The relationships our negotiators have built with these sites often make it easier to keep our CTA's top-of-mind, facilitating quicker turn-around times.

CTI's contracting metrics, processes and experienced negotiators facilitate the site selection and CTA negotiation process, ultimately saving the sponsor valuable time and money.

To learn more about CTI's site contract negotiation process and how we may be of assistance, please contact Paul Ritter, CTI Senior Vice President and Chief Legal Officer at pritter@ctifacts.com or by phone at 513-598-9290.

For more information:
www.ctifacts.com
513.598.9290

New Additions & Promotions at CTI

Oluwaseyi Akinbobola joins as Clinical Monitoring Associate II

Dan Beach promoted to Senior Developer

Robin Brown promoted to Senior Clinical Data Associate

Bobbi Burleson joins as Clinical Research Coordinator I

Sonya Cradle joins as Clinical Research Assistant

Sara Fedorchak joins as In House CRA

Lindsay Fischer joins as Research Associate

Upcoming Meetings We Will Be Attending

American Society of Hematology
San Diego, CA
December 3 - 6, 2016

Biotech Showcase
San Francisco, CA
January 9-11, 2017

American Society of Transplant Surgeons - Winter Symposium
Miami, FL
January 26 - 29, 2017

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

Join our Team!! We're looking for individuals to fill these positions:

Assistant Manager, Clinical Systems (Cincinnati, OH)

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

Clinical Data Manager (Cincinnati, OH)

Clinical Safety Scientist (Cincinnati, OH; Raleigh, NC)

Data Architecht (Cincinnati, OH)

Clinical Systems Analyst

Dana Hackett joins as Assistant Director, Clincial Trials

Jamie Hilfer joins as Senior Study Coordinator

Adenike Igoh promoted to Senior Clinical Project Manager

Ryan Imhoff promoted to Senior Research Associate

Janette Montani promoted to Assistant Director, Marketing & Business Development Operations

Isaac Schoultheis joins as Statistical Programmer II

Joe Schroeder promoted to Manager, Contracts and Facilities

Nimra Tariq promoted to Biostatistician II

Kevin Wesley promoted to Senior Clinical Data Associate

Human Resources 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)

Operations Manager, Japan

Statistical Programmer (Cincinnati, OH)

Study Coordinator (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!