CTI Clinical Trial and Consulting Services

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CTI's Site Contract Process – Preserving Sponsors' Timelines

It is well-documented how critical time is in the clinical drug development process. Delays of only one month can cost a sponsor millions of dollars in lost opportunity, given the finite period of a drug's patent life. Since each clinical study necessarily begins with a site contract, the efficiency of the contracting process is of paramount importance to our sponsors.

The investigative sites utilized in studies that involve critically ill patients (e.g. hepatitis, transplantation, heart failure) are generally sophisticated academic or other institutional centers with legal departments following rigid institutional policies and contracting procedures. If the site contract process is not properly managed, the lead-time in negotiating a contract to full execution can be as much as six months to a year at some sites. As part of its site contract process, CTI maintains metrics which allow it to analyze and specifically measure the length of time it takes to fully negotiate and execute confidentiality agreements (CDA) and clinical trial agreements (CTA). Metrics are maintained by site, by study, and by sponsor since all of these factors influence the contracting timeline.

CTI's average time to complete the CDA process across all studies and all sites over the past ten years is 10 days.

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

Average Days	**10**
Quartile: Minimum Value	**0**
Quartile: First (25%)	**3**
Quartile: Second (50%)	**6**
Quartile: Third (75%)	**14**
Quartile: Maximum Value	**46**

BEST PLACES TO WORK WINNER

CTI Clinical Trial and Consulting Services is a repeat winner of "Best Places to Work" in Greater Cincinnati

Upcoming Medical Meetings CTI will be Attending ...

The European Society of Clinical Microbiology and Infectious Disease 2012
London, UK
March 31 – April 3

The European Association for the Study of Liver 2012
Barcelona, Spain
April 18 – 22

Cell Commercialization & Partnering Conference
Boston, MA
April 19 – 20

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

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In a summary and according to CTI's metrics, the average time needed to complete the CDA process at a particular site can vary from as low as 0 (i.e. same) day to as high as 46 days.

Once CTI has obtained a fully executed CDA ensuring the sponsor's intellectual property is protected, attention is turned to the CTA.

CTI's average time to complete the CTA process across all studies and all sites over the past ten years is 100 days.

Table 2. Average Number of Days to Complete U.S. CTAs (with Quartile Data)

Average	**100**
Quartile: Minimum Value	**22**
Quartile: First (25%)	**72.75**
Quartile: Second (50%)	**102**
Quartile: Third (75%)	**134**
Quartile: Maximum Value	**262**

The time needed to complete the CTA process can vary from as low as 22 days to as high as 262 days, on average, depending on the site selected.

There are several factors which significantly impact the contracting timeline. One factor is the negotiating authority entrusted to CTI by the study sponsor.

If CTI is given full negotiating authority, the average time to execute a CDA is reduced by 30%.

With respect to CTAs, the metrics reveal that the average time to full execution is reduced by 65% in instances where CTI is given full negotiating authority.

Another factor is the investigative site's responsiveness throughout the negotiation process. Some sites have institutional policies which prevent them from executing (or, even worse, negotiating) a CTA prior to IRB submission or approval. A factor beyond such institutional policy is the often heavy and demanding workload of the site's contract negotiation team. The backlog of contracts in the legal departments of some sites is reported to be as much as six to eight weeks. This means it could be up to two months before such a site will even initially review a CTA.

There are a number of things which may be done in order to better manage this process and help protect the timelines which are so crucial to our sponsors. Site selection is a significant determining factor. For studies with compressed timelines, knowing and avoiding those sites with restrictive review policies or heavy backlogs can greatly improve the contracting timeline. Likewise, persistent site follow-up and establishing a good rapport with the site's negotiating team, study coordinator and investigator are imperative to maximizing the efficiency of the entire process. CTI's contract negotiators have a methodical follow-up and tracking process which greatly enhances site responsiveness.

Site contracting outside of the United States (OUS) poses additional challenges unique to each country. Many countries have statutory contract templates which allow for limited, if any, revisions to language. Further, language, legal practice, and time differences are all factors CTI must manage when contracting OUS. Even with these additional considerations, CTI's legal team has been able to successfully negotiate and execute OUS contracts in over 15 countries with an average completion time of 120 days.

CTI is uniquely positioned to manage the site contract process in studies involving critically ill patient populations. Its contract negotiators average ten years of experience in site contract negotiation and are well-equipped to protect the rights and needs of it sponsors. Furthermore, CTI has well-established relationships with investigators, coordinators, and negotiators which run across several studies and often span multiple decades. These relationships afford CTI an opportunity to pursue many different angles in navigating through each site's contract process, saving critical weeks, or even months, of our sponsors' precious time.

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

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CTI Clinical Trial and Consulting Services (CTI) is a unique drug and market development company offering a full range of services which encompass the entire lifecycle of drug development. These services include regulatory pathway design, clinical trial management, data analysis, medical writing, CME and training program development, market analysis and development and other consulting services. CTI focuses on the specific disease areas of solid organ transplant, hepatitis, infectious disease, end-stage organ disease and hematology/bone marrow transplant. With its combined expertise of clinical knowledge and market experience, CTI is uniquely positioned to incorporate both clinical and market driven endpoints and interpretations to provide extraordinary results.