Observational Study of Contracts Processing at 29 CTSA Sites

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Abstract

We measured contracts final negotiation (FN) and full execution (FE) times using shared definitions in a prospective observational study of management of contracts for clinical trials at 29 CTSA institutions. Median FN and FE times were reached in 39 and 91 days, respectively; mean times for FN and FE were 55 and 103 days, respectively. Individual site medians ranged from 3 to 116 days for FN and 34 to 197 days for FE. The use of master agreements (MAs) and previously negotiated terms (PNTs) was associated with significant reduction of FN times by a mean of 33 days ($p < 0$) and 22 days ($p < 0.001$), respectively. PNTs, but not MAs, were associated with significantly reduced FE time (22 days, $p < 0.007$). Gap analysis revealed a gap of 22 days between contracts negotiation and Institutional Review Board (IRB) review and intervals of 33 days (contracts) and 48 days (IRB review) during which the process steps were being conducted alone, suggesting a potential benefit with parallel processing. These baseline data support a plan to investigate root causes of prolonged study start-up time by examining causes of variation and outliers. Clin Trans Sci 2013; Volume 6: 279–285

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Introduction

Negotiation of contracts related to clinical trials is inherently complex and often protracted.[1] Not surprisingly, it is often perceived as a major challenge to the efficient initiation of clinical trials.[2] Process mapping identifies dozens of intermediate steps[3,4] but does not motivate change by itself. To improve time and quality while reducing cost, some contracts offices have developed and tested management plans guided by process tracking data, systematic analysis, and testing of the implementation of planned interventions.

From its inception, the Clinical and Translational Science Award (CTSA) Program emphasized the importance of efficiency in clinical research.[5] The CTSA Consortium pursued efficient contract and protocol management, encouraging better, cheaper, and faster initiation and performance of clinical trials. In ushering in the National Center for Advancing Translational Sciences (NCATS), NIH Director Francis S Collins reemphasized concerns about challenges associated with clinical science.[6] In an updated funding opportunity announcement for the CTSA program,[7] NCATS emphasized the purpose of the pursuit of efficiency in clinical research with the following statement of its mission: "To bring the benefits of science more quickly into patient care, NCATS was formed with the mission to catalyze the generation of innovative methods and technologies that will enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions. The mission of NCATS includes strengthening the entire spectrum of translational research." Thus, the CTSA Consortium developed a virtual national laboratory to coordinate improvement in clinical research management,[8] which included the development and completion of studies of contract management, IRB approval, and study enrollment. Delay in the final execution of contracts was widely believed to be one of the major challenges to efficient start-up of clinical trials.

To gather baseline information, the Contracts Group of the CTSA Consortium Clinical Research Management Key Function Committee undertook a prospective, continuous registration, multisite observational cohort study of contracts processing at CTSA sites. The study employed standardized data elements that measure the time-to-completion of process milestones for contracts related to clinical trials sponsored by industry. The study also sought to evaluate the effect of contract and study characteristics and other factors that might impair or facilitate completion [full execution (FE)] of contracts. The larger purpose of the study was to motivate sites to identify potential interventions and implement changes to improve the efficiency and quality and economy of contracts management. To protect privacy, the names of the CTSA institutions and the industrial partners have been withheld.

Methods

Selection, characteristics, and involvement of participating sites

The Contracts Workgroup of the CTSA Consortium sought to track the process steps required to negotiate and execute contracts for clinical trials. In a preliminary study (unpublished), it emerged that process steps were nonuniform for contract negotiation both within and between CTSA institutions and that there was wide variance between the time it took to achieve final negotiation (FN) and FE of contracts. Hence, the Workgroup designed a protocol intended to provide primary observational data on a substantial number of contracts across the CTSA Consortium in order to obtain data that characterized the time durations that measure the achievement of defined milestones associated with the processing of all contracts. Each participating institution designated a staff member in the contracts negotiation office to provide data for the institution. Study data were collected and managed using Research Electronic Data Capture (REDCap) tools hosted at Vanderbilt.[9] REDCap is a secure, Web-based application designed to support data capture for research studies providing: (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation and export procedures;

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Eligibility criteria
• Assigned to a negotiator between October 1, 2009 and November 30, 2009.
• The first 25 Industry-sponsored contracts assigned to a negotiator
• The first 10 Investigator Initiated contracts assigned to a negotiator.
• Industry sponsor or Investigator sponsor with industry support or a CRO contracted by industry
• Related Clinical trial/study, financed by industry without other external support
• No required contract, subcontract, or award from a third-party for support, services, pharmaceuticals, or other materials.
• The product being evaluated is a drug, biologic treatment, vaccine, or device.

Table 1. Eligibility data for contracts negotiated at participating CTSA sites.

(3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for importing data from external sources.

Eligibility data are shown in *Table 1*. Each participating contracts negotiation office tracked a maximum of 25 consecutive sponsor-initiated contracts and a maximum of 10 consecutive investigator-initiated contracts. The protocol included collection of data on contracts first assigned to a negotiator between October 1, 2009 and November 30, 2009; data collection terminated on December 31, 2010. The original protocol required all participating sites to collect data until 90% of the still active contract negotiations reached FE. Contracts that achieved FN were included in the final analysis. Time points reported included the following dates: negotiation start, first comments provided, FN, institution executed, FE, IRB submission, and FE/IRB approval. Master Clinical Trial Agreement [Master Agreement (MA)], as used in this report, refers to a contract based on a formal agreement made in advance that was modeled from a master template or was a study order/addendum/exhibit to a master clinical trial agreement.

Contract negotiators had varied preparation for their work; they included attorneys, paralegals, scientists, licensing professionals, and research administrators. The locations of contract negotiation offices varied between participating sites; some were in a school of medicine, some in central administration, and some in a health center. Negotiators reported to different supervisory personnel, such as a provost or chancellor, a central administrator, or a dean.

Previously negotiated terms (PNTs) referred to informally agreed-upon terms accepted before the contract was received. Contracts were characterized as pertaining to multicenter clinical trials if more than one contracting institution was identified as participating in the study. Studies were characterized as involving a Contract Research Organization (CRO) if a CRO was involved in the contract negotiation process on behalf of the sponsor. Contracts were characterized as "investigator-initiated" if the studies to which they related were designed and planned by an investigator within the institution rather than by the corporate sponsor.

Results

Analysis of aggregated reports of CTSA consortium contracting times

Of the 38 CTSA sites activated in time to enroll in the study, 29 volunteered to participate by reporting consecutive contracts received during the period from October 1, 2009 to November 30, 2009 and to continue reporting achievement of process milestone until study closure December 31, 2010. Although 3 of the 29 institutions did not reach FE of 90% of their active contracts by the close of the study period, all had reached FE of 75%. CTSA sites entered 598 contracts into the database; 30 contracts were excluded because they did not meet eligibility criteria. Of the 568, FN times were reported on 467 (82%). Of the 467 registered contracts that were reported as having achieved FN, 454 (97%) were followed to FE. Characteristics of contracts reported are described in *Table 2*.

As shown in *Table 2*, 25% of the 467 contracts entered into the study were negotiated under MAs, 19% had PNTs for the contracts, 79% applied to multisite trials, 27% involved CROs, and 11% were investigator-initiated. Industry-sponsored studies (not shown) accounted for 414 (89%) of the reported contracts. Variables are defined and characterized within the Methods Section.

Table 3 shows the analysis of data aggregated across the CTSA Consortium for all eligible contracts that achieved the described milestones within the study period. Attention is drawn to the broad range of FN times, 14 days for the shortest quartile and 132 for the longest 10%. Mean performance times were longer than medians in all cases. Outliers with extremely prolonged processing times were noted in all categories.

Predictors of process completion

As shown in *Table 4*, we performed univariate and multivariable analyses to identify potential predictors of completion times.

	Characteristics of contracts reported			
Milestones	**Final negotiation (%)**	**IRB approval (%)**	**Full execution (%)**	**Full execution and IRB approval (%)**
Number of contracts	467 (100)	427 (100)	454 (100)	454 (100)
Variables				
Master agreement	117 (25)	105 (25)	112 (26)	105 (23)
Previously negotiated terms	88 (19)	79 (19)	84 (19)	79 (17)
Multicenter clinical trial	370 (79)	333 (78)	355 (78)	333 (73)
Contract research organization (CRO)	128 (27)	115 (27)	123 (27)	115 (25)
Investigator initiated clinical trial	53 (11)	46 (11)	51 (11)	46 (10)

Table 2. Characteristics of contracts reported. The table shows the number of contracts aggregated across 29 CTSA sites for which time interval data were reported.

CTSA Consortium milestone achievement												
	Final negotiation			IRB approval			Full execution			Full execution and IRB approval		
Percentile	25	75	90	25	75	90	25	75	90	25	75	90
Days	**14**	**83**	**132**	**29**	**89**	**132**	**55**	**140**	**196**	**82**	**164**	**235**
Median		**39**			**53**			**91**			**119**	
Mean		**55**			**65**			**103**			**137**	

Table 3. CTSA Consortium milestone achievement. Analysis of aggregated contracts data from the study for which required data points were available reported as calendar days. IRB approval times are included for all contracts for which they were available, regardless of whether the IRB approval preceded submission to the Contract Negotiation Office or FE or followed FE.

Predictors of full execution times					
	Univariate analysis			Multivariable analysis	
Milestone/variable	Present (days)	Absent (days)	$p <$	Mean days difference	$p <$
Final negotiation					
Master agreement	34	62	< 0.0000	−33	0
Previously negotiated terms	46	57	0.034	−22	0.001
Multicenter clinical trial	54	58	0.271	6	0.389
CRO	59	53	0.865	6	0.255
Investigator initiated	70	53	0.989	15	0.088
Full execution					
Master agreement	99	104	0.23	−10	0.165
Previously negotiated terms	88	106	0.009	−22	0.007
Multicenter clinical trial	103	100	0.728	8	0.401
CRO	115	99	0.992	16	0.019
Investigator initiated	107	103	0.682	9	0.437
IRB approval					
Master agreement	67	64	0.684	2	0.764
Previously negotiated terms	61	66	0.237	−5	0.474
Multicenter clinical trial	67	56	0.946	11	0.154
CRO	N/A	N/A	N/A	11	0.057
Investigator initiated	62	65	0.363	6	0.514
Contract and IRB approval					
Master agreement	126	142	< 0.062	−16	0.139
Previously negotiated terms	128	140	0.137	−16	0.182
Multicenter clinical trial	135	148	0.134	0	0.995
CRO	154	131	0.986	27	0.011
Investigator initiated	169	133	0.993	36	0.033

Table 4. Predictors of completion times. Table shows mean difference in calendar days related to variable. A negative value represents a reduction in the mean number of days to FE in comparison to the mean number of days for all contracts. Univariate analysis shows the duration of the process step(s) if the variant was present or absent. The Student's *t*-test (*p* value) was used as a test for significance.

Contracts associated with a MA (33 fewer days, $p < 0$) or PNTs (22 fewer days, $p < 0.001$) were negotiated significantly faster than the mean. Both reduce or eliminate negotiation. Contracts associated with PNTs (22 fewer days, $p < 0.007$), but not with MAs (10 fewer days, $p < 0.167$) had significantly shorter FE times. The use of a CRO was associated with prolongation of FN, FE and the composite of IRB Approval and FE times.

Management of negotiation finalization, FE, and IRB approval

The data in *Table 5* show median and mean and the range of FN and FE times for contracts related to sponsor-initiated protocols for each site. Attention is drawn to the number of contracts negotiated at the 29 sites, which ranged from 2 to 31 (mean = 16). Median process times at CTSA sites for contracts FN and FE ranged broadly. Short FN time could be associated with short or long FE time; long

Individual CTSA site contract processing							
		Final negotiation			Full execution		
Site #	*n*	Median	Mean	Range	Median	Mean	Range
1	30	35	48	0–182	78	81	1–198
2	13	39	48	3–163	70	75	26–179
3	18	15	27	0–132	79	99	34–219
4	22	52	75	4–202	135	135	8–305
5	20	66	83	8–200	118	136	28–299
6	6	42	58	6–145	49	67	6–152
7	28	89	95	14–257	122	125	29–277
8	12	12	13	1–26	84	81	7–163
9	16	104	100	0–259	187	179	36–293
10	6	23	38	8–72	53	57	29–91
11	27	38	45	0–161	48	62	3–201
12	17	53	64	8–174	92	96	21–200
13	13	96	99	0–264	197	190	77–264
14	13	42	49	5–93	99	102	39–164
15	15	22	46	0–116	81	95	29–176
16	24	56	70	9–107	101	111	13–205
17	4	48	54	29–89	101	99	55–138
18	25	41	44	0–141	65	70	4–153
19	9	33	41	7–97	70	77	26–137
20	18	56	72	0–218	69	88	3–223
21	19	17	20	0–23	34	39	0–128
22	31	28	54	0–247	115	141	41–420
23	15	57	59	0–190	107	102	23–235
24	20	3	23	0–144	165	154	56–278
25	26	36	42	11–123	75	76	36–158
26	11	10	41	0–174	55	65	1–188
27	4	16	16	1–32	87	95	70–137
28	10	49	62	1–202	94	91	14–204
29	2	116	116	112–119	146	146	115–231
Mean		45	55		96	101	

Table 5. Individual site contracting data. Data are presented for 29 CTSA sites. The table contains mean FN and FE times and the range from shortest to longest in calendar days for each site, *n* is the number of reported completed contracts for each site.

FN time could be associated with short or long FE time. Examples of long FE times with relatively short FN times include sites 8, 24, and 26. Examples of sites with the short FE times that did not have the shortest FN times include 6, 11, and 21. Data from a single site (*Table 6*) provide an example of within site variance in FN and FE times. The site registered 27 contracts during the study period. Mean FN times and FE times for the shortest third were 5 and 19 days, respectively. Attention is drawn to fairly consistent and efficient completion of contracts-related processes for 13 of the contracts and prolongation of the process for the remainder.

Management of process steps

Most of the CTSA sites involved in this study reported that FE was influenced by the management of other required study start-up processes that were not under the control of the contracts office. Accordingly, the Contracts Workgroup surveyed the 29 study participants regarding the timing of required process steps thought to influence FE times. Of the 27 sites that responded, 9 (33%) reported no consistent time relationship between contracts negotiation and IRB review. At 14 (50%) of the sites, reporters were unable to identify a consistent relationship between the start times for budget negotiation and contracts processing. Similarly, at 11 (44%) of the sites reporters stated that the completion date for budget negotiation followed FN of the contract and at an additional 4 (16%) of sites they reported that there was no consistent relationship between completion of budget negotiation and final contract negotiation.

Single site contract management		
Final negotiation	Interval (FN→ FE) Days	Full execution
0	3	3
0	7	7
0	12	12
0	44	44
3	29	32
6	11	17
9	12	21
14	5	19
14	18	32
18	19	37
21	12	33
25	27	52
26	5	31
38	6	44
40	23	63
49	8	57
49	22	71
52	14	66
53	11	64
63	35	98
71	30	101
79	7	86
88	10	98
93	48	141
114	12	126
122	4	126
161	40	201

Table 6. Single site performance characteristics. The table shows mean FN and FE times and the interval between them (all in calendar days) for the 27 contracts negotiated and executed at a single institution during the study period.

Gap analysis

Table 7 shows an analysis of contract FN and IRB approval for the 427 contracts for which the relevant dates were available. Negotiation proceeded alone on an average of 33 days; a gap of 22 days intervened between contract negotiation and IRB approval. IRB review processing proceeded alone on a mean of 48 days. The two overlapped on a mean of 22 days.

Discussion

In this prospective, observational study of contracts management we gathered descriptive data for process steps related to negotiation and execution of contracts and protocol approval for clinical trials at 29 CTSA-associated academic institutions. We report here only those contracts that were negotiated and executed during the study time frame, from October 1, 2009 to December 31, 2010, a total of 457 days. Thus, contracts that were terminated, withdrawn, or unreported and contracts that had not reached FN when the study was terminated were not included. Of 598 contracts entered into the database, 568 met the eligibility criteria and 467 (82% of the eligible contracts) reached FN during the study. Of the 467 finally negotiated contracts, 454 (97%) were followed to FE. We trained and supported data managers in each participating contract negotiation office and developed a central report form using the Web-based, REDCap electronic data capture tools hosted at Vanderbilt. Individual sites were permitted to stop recording data when 90% of the contracts entered into the study reached FE. Thus, we excluded 18% of registered contracts from analysis because they were unreported or did not reach FN and another 3% that were negotiated but were subsequently terminated, withdrawn, unreported, or open at the time of study closure.

The duration of aggregated CTSA Consortium contracts negotiation and execution ranged from 0 to 264 (median 39, mean, 55) days and 0–420 (median 91, mean 103) days, respectively. Ranges within institutions also ranged from 0 to hundreds of days. The length of time between receipt in the contracts offices and FN had no simple relationship to the time to FE between sites as demonstrated by comparison of mean performance data from the most efficient sites for the milestones. Within some sites with relatively short times to FE for as many as half of their contracts, relatively long FE times were reported for the remainder.

Master Clinical Trial Agreements ("Master Agreements"), as defined by our protocol, included were subject to formal agreements (PNTs) made in advance. Of the 467 registered contracts that were reported to reach FN, 117 (25%) were subject to MAs. The 34 day mean FN time associated with these formal agreements makes it clear that MAs do not uniformly predict for the shortest FN times. Indeed, PNTs were associated with a mean FN time of 46 days, suggesting only a modest, 10-day increase in efficiency associated with formal agreements. Furthermore, the inclusion of PNTs, but not MAs, was associated with significantly shortened FE times by an average of 22 days. In contrast, under the defined milestones adopted in this study, use of a third party negotiator such as a contract research organization (CRO) was associated with significantly longer FE times and combined IRB approval and FE times by 27 days (p = 0.019 and 0.011, respectively).

Analysis of gaps and overlap for contracts negotiation and IRB processing					
Percentile	**25**	**50**	**75**	**90**	Mean
Overlap days	0	9	33	66	22
Gap days	0	0	12	65	22
Contract only days	2	20	48	86	33
IRB only days	9	32	62	103	48

Table 7. Effect of a gap in processing contracts and IRB submissions.

We caution readers not to extrapolate effects on intermediate contract processing steps as evidence of an effect on the overall time from project inception to study start-up, because we have no data bearing on that interval.

The spread of time for FN times reported by a single site suggests a processing variance. It might be profitable to search for explanations within the institution or between the institution and its contracting partners. A study of outliers might provide clues to the causes of inconsistent performance and inform proposals to implement improvement. Lessons might also be learned from sites that have consistently short FN and FE times with the caveat that sites that complete critical, time-consuming processes such as budget negotiation before contract negotiation begins may appear more efficient at contract execution when measured from the initiation of contract negotiation, but be no more efficient than other sites at achieving study start-up when measured from the inception of all study-related processes. Thus, any effort to shorten FE times must take into account the complete list of process steps required before both parties are willing to sign the contract and the order in which they are performed.

Processes unrelated to contract negotiation are the subject of ongoing concern in clinical research management and the joint responsibility of all those involved, including outside partners in sponsoring organizations. Here we report several potential targets such as a lack of coordination of processing between IRB review, budget negotiations, and contracting and a wide variance between academic sites in their process streams. Success is important to all parties to clinical research including trial participants, investigators, institutions, sponsors, and the public. The shared goal of performing high quality clinical research more efficiently and economically prompted the CTSA Consortium to give high priority to the sharing of effective clinical research management process improvements.

It is important to stress the limitations of this study. This was a baseline, observational study, initiated in 2009 at CTSA sites that had been funded for no more than three years. We conducted the study in response to concerns that contract execution might make a significant contribution to protraction of study start-up. Our Workgroup anticipated the measurement of the effects of implementing process interventions designed to shorten the duration of contract-related procedures. Since 2006 when the first CTSA sites were funded, many sites have reported significant progress in achieving efficiency in clinical research management. Our study did not include the training requirements and auditing procedures associated with Good Clinical Practice. The line of responsibility for contracts, IRB approval, and study start-up was not established for each institution's entire portfolio of clinical research. Indeed, at some CTSA sites the contracts office was not under the jurisdiction of institutional research faculty, thus increasing the challenge of coordinating its management with other processes required for clinical trials. At the time of publication, there are 61 CTSA sites and more than 120 partner institutions, raising the possibility that our cohort of 29 sites does not represent average performance across the CTSA Consortium. Of the contracts registered, 21% were excluded from analysis, potentially introducing a bias against reporting delays in contracts processing that resulted in greatly prolonged achievement of FE. Process sequences differed across institutions, which might have influenced contracts processing time but were not reflected in the data analysis. Our choice of the starting date as the one on which the contract was assigned to a negotiator might have biased the results by eliminating the time taken to complete process steps that were performed by some, but not all sites, in anticipation of contracts negotiation. By ending the study at FE and not including study start-up, we may have failed to discover other causes of significant delays in study start-up. As a result, our analysis is limited in significant ways to a component of contracts management and should not be taken to apply to clinical research management overall. Wide variance within and between institutions underscores the hazard of extrapolations from this dataset.

Our evidence suggests that the use of MAs and PNTs are associated with shorter duration of FN times and that PNTs are associated with shorter FE times. Other institutional processing factors that might be associated with shorter FE times include implementation of procedures to (1) process budgets and review protocols in parallel with contracts negotiation, (2) identify and remediate causes of variance, (3) partner with other sites to devise and test process changes for their effects on efficiency, quality, and economy, (4) address human resource allocations, (5) address sponsor-related issues early and seek satisfactory solutions, and (6) identify and terminate failed contracts negotiations promptly. Importantly, the impact of any implemented change should be measured and evaluated for cost and effect on quality and efficiency of contract management. We encourage institutional leaders to prioritize the goals of maintaining or improving the quality of clinical research, reaching study start-up more efficiently, and conserving resources.

Management issues include a plan to ensure (1) coordination of the efforts of institutional staff responsible for required study start-up steps, (2) timing of processes to potentiate their orderly and efficient conclusion, and (3) leadership by an individual with authority to track, analyze, and address issues related to study start-up to ensure that it is consistent in its efficiency and quality. Processes required for FE vary at academic health centers, but may include budget negotiation, IRB approval, finance office approval, scientific review, management of conflicts of interest, and other special reviews and approvals.

Note should be made that some investigations related to novel products, untested approaches, and interventions to address serious human health needs may require more time to plan, prepare, and execute. Institutions should expect increased costs and delays associated with risks that are difficult to calculate such as serious adverse events, complex procedures, reconfigured facilities, technological innovation, and specially trained staff. We recognize that such studies may be crucial in the search for evidence to support the development of these products and interventions. It is not our intention to discourage investigators from the pursuit of such research. Rather, it is our purpose to support the conduct of all clinically related research in an optimally managed environment that endorses methodology that seeks to make efficient use of its resources.

Conclusion

All CTSA sites stand to benefit from careful review of processes needed for study start-up. Sites might benefit from reexamining their clinical research management plan if they have prolonged processing times for contracts with median times in excess of 39 and 91 days for FN and FE, respectively. Sites with what appears to be timely completion of these tasks might also benefit from examining outliers and variances that cannot be attributed to novel investigative pathways alone. We think all sites should

develop and/or maintain a metrics-driven system of continuous process improvement to demonstrate overall efficiency, quality, and economy from inception of plans for clinical studies to the time of their completion and publication. Process improvement is an unending continuous activity for which fresh data and a state of heightened awareness are invaluable aides.

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Author Contributions

Each of the authors listed below made a substantial contribution to the collection, analysis, interpretation, and description of the study results. In addition.

James Kiriakis, served as co-chair of the Contracts Committee of the Clinical Research Management KFC that did the final analysis of the study, supervised the drafting of the report, performed the primary editorial review, and managed the communication issues. Nicholas Gaich, served as the lead data coordinator for the program, provided a preliminary data analysis with his team at Stanford, and led the primary communications efforts with regard to the study.

S. Claiborne Johnston, performed the secondary analysis and interpretation of the results.

Darlene Kitterman, served as co-chair of the Contracts Committee of the Clinical Research Management KFC that did the final analysis of the study, performed a detailed review of the drafts of the report. Daniel Rosenblum, served as NCATS Coordinator of the study, made major editorial contributions to the publication, and supervised the preparation of the draft in publishable format. Libby Salberg, former co-chair of the Contracts Committee of the Clinical Research Management KFC that developed the protocol and conducted the study, instrumental in guiding the project to a successful conclusion, co-editor of final draft. Adam Rifkind, former co-chair of the Contracts Committee of the Clinical Research Management KFC that developed the protocol and conducted the study, instrumental in guiding the project to a successful conclusion, co-editor of final draft.

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