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Points to consider in drafting and negotiating a clinical trial agreement

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Clinical trials are research-based studies that are performed to determine whether a drug, device, or medical procedure (depending on the stage of the study) is safe and effective. A complete set of clinical trials that includes all phases may cost hundreds of millions of dollars, which is usually paid for by a sponsor such as a government agency or a for-profit company. Increasingly, clinical trial activities are contracted out to a service provider such as an academic medical center (AMC), a contract research organization (CRO), or a physician's practice, and this outsourcing requires negotiation and execution of a clinical trial agreement (CTA). Therefore, a CTA is required between the sponsor and the organization to conduct the clinical trial. This article will examine several critical points to consider when drafting and negotiating a CTA from the perspective of an AMC.

It is important to note that a CTA is essentially a document that governs the relationship between: (1) the sponsor that may be providing the study drug or device, the financial support, and proprietary information; and (2) the organization that will conduct the trial, provide the results, or further intellectual property. The CTA is crucial because it sets forth each party's responsibilities with respect to the conduct of the study and identifies the deliverables. Thus, substantial time and effort may be necessary to draft and negotiate these types of agreements.

Elements of a clinical trial agreement

When drafting and negotiating a CTA, it is vital that the parties have an in-depth knowledge of the relevant laws and regulations that may impose additional requirements upon them, although the laws and regulations are not reflected in the CTA. Furthermore, parties need to be aware of and comply with the internal policies and procedures to which they must adhere. Because each study is unique, each CTA must be negotiated individually, although there are certain key elements that are common among all CTAs. Although not limited to the foregoing, the following elements may be of utmost importance in a CTA especially where an AMC is the party conducting the clinical trial.

Parties

In a CTA, it is crucial to identify the party with whom the AMC is negotiating. This may sound odd, but it is vital to ensure that the party is a legal entity or authorized to act on behalf of the sponsor in the case of a CRO. In addition, the corporate identifier and address should appear in the agreement. The individual signing the agreement must be an authorized representative who can legally bind that entity to perform the obligations stated in the agreement. It is also important to identify the principal investigator (PI) who is assigned to conduct the study and whether the PI is an employee of the organization. Otherwise, the PI may be considered an additional party to the CTA with personal obligations under the CTA.

Services

The CTA should set forth the parties' mutual rights and obligations in connection with the conduct of the study. Therefore, it is important that the CTA clearly and succinctly reflect what each party will be responsible for. The language in the CTA should not be vague or general, and the wording should be exact and precise; otherwise a party's expectations or understanding may be misplaced and the CTA may be inadvertently breached.

Laws

Life sciences are a highly regulated industry subject to local, state, and federal laws and regulations. In addition, if the sponsor is a foreign entity or has a foreign presence, there may be a set of additional laws and regulations that will influence the CTA. The laws and regulations may include country-specific requirements related to subject injury, adverse events, publications, privacy, data retention, confidentiality, intellectual property, and insurance requirements. Again, the type of organization conducting the study may influence the type of foreign legal requirements it may agree to in the CTA.

Intellectual property

Allocation of ownership rights to the data and inventions that may result from the conduct of the study is very important in a CTA. The allocation of rights may depend on several factors: Is the sponsor a startup or an established company? Is the product/use thereof approved or investigational? What is the phase of the study? What type of organization is conducting the study? These factors will influence what ownership rights the parties seek in the agreement. For example, the CTA may recognize each party's rights to solely and/or jointly developed inventions. These rights may also burden the parties with greater future responsibilities, financial expenses, or involvement in future patent prosecution. In a CTA, the parties may also briefly address license negotiation terms. Because an AMC may be the recipient of federal funding and/or enjoy non-profit designation, the AMC must ensure it does not violate any laws or regulations it is subject to.

Payments and payment schedule

Because the sponsoring party will pay the AMC for the conduct of a trial, consideration is an indispensable element in the CTA. The payment amount(s) and the frequency thereof should appear in the CTA, whether in the body of the CTA or as an exhibit to the CTA. Accordingly, a carefully drafted budget is an integral part of a CTA and will ensure that the payments referenced in the agreement are accurate.

Insurance/indemnification

A court judgment, or even being named in a lawsuit, can ruin an entity's reputation or its financial standing. Thus, a CTA should address whether a party will indemnify, defend, and/or hold harmless the other party. Depending on the type of organization conducting the study, the conditions of indemnification may be crucial, and thus, the CTA should explicitly set forth the conditions of indemnification, including any notice and/or cooperation requirements and exclusions from liability. Furthermore, it will be a party's insurance coverage and even its liquidity that may determine how much and to what extent the party may actually fulfill the obligations of indemnification it undertakes. Therefore, the CTA should require that each party (i.e., the sponsor and the AMC) carry insurance in the type and amount appropriate and customary for the conduct and sponsorship of the trial or maintain a comparable program of self-insurance. In addition, if one of the contracting parties is a foreign entity, it may have coverage limitations or additional insurance obligations, which the AMC must be aware of.

Subject injury

When negotiating a CTA, the parties should assign responsibility in the event a study participant is injured as a result of participating in the clinical trial. Several considerations will determine whether the sponsor should pay the medical bills of the study participant, such as what type of study is being conducted, the phase of the study, whether the product is FDA-approved or not, if the product is being used off-label, if the use of the product is considered standard of care, if federal or foreign laws specify who is responsible, and whether a private insurer would pay for the costs. Answers to these questions will enable the parties to properly assess who should bear the responsibility of subject injury.

Period of performance and timelines

When do the parties' responsibilities start and when do they end? From reporting adverse events to inventions, from routing regulatory notices to reports, from terminating the agreement to proposing a publication, from safeguarding confidential information to returning it, from invoicing to making payments, the agreement is replete with timeframes that govern the parties' responsibilities. Therefore, it is important to negotiate timeframes that are realistic. Failure to adhere to the timeframes in the agreement may result in nonpayment or breach of the agreement.

Confidentiality

A CTA will set forth the parties' confidentiality obligations. It is most likely that the parties had previously entered into a confidentiality disclosure agreement (CDA), and the CTA may reflect similar terms. Thus, similar to a CDA, the CTA will define what information is confidential (or not) and the circumstances under which the information may be used or disclosed to third parties. Defining what is and is not confidential is important. For example, trade secrets are often included in the definition; however, the reality is that a trade secret is afforded protection until it is disclosed or reverse engineered. Accordingly, a trade secret should not be included as confidential information. In addition, the CTA should stipulate the duration of the obligation of confidentiality, as well as what will happen to tangible confidential information after the clinical trial ends or is terminated.

Ownership of data, record keeping, and access

Normally, all rights in the completed case report forms, any electronic databases required to be created under the study protocol, and any reports prepared by the AMC for the sponsor are the property of the sponsor. However, the AMC conducting the study should negotiate to retain "access" to such information for internal purposes. Thus, the CTA should identify who owns the data and what can be done with it. In addition, the CTA should define how and when the sponsor may audit the data and the premises where the study is being conducted.

Publications and presentations

Publication rights included in a CTA may depend on the type of organization conducting the clinical trial. The CTA will set forth a review period by the sponsor of the manuscript, and the review may allow the sponsor to request deletion of confidential information, provide comments, or even request a delay of the publication so that the sponsor may seek patent protection. When negotiating publication, it is important for an AMC to adhere to its mission, and thus, safeguard its freedom to publish and disseminate information. It is also essential to ensure that any proposed use of the publication by the sponsor be subject to copyright laws. Because the sponsor's use of the organization's name may improve its market share, it is important to limit how a party's name may be used by the other party.