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Part 1: I'm Responsible for What? Indemnification in Clinical Trials

Introduction

Negotiation of contracts in clinical trials often comes down to a select few commonly contested sections and terms. Behind these negotiations are a range of factors driving decision making including, but not limited to, internal policy, applicable law, regulations, and guidelines. In a series of brief articles, we will explore the most commonly disputed terms, strategies to resolve disputes among the parties, and an outlook on negotiating these terms in your agreements. In Part 1 of this series, we start with the basics of indemnification provisions in clinical trial agreements ("CTAs"), considering the differences and unique hurdles among the parties and solutions in the spectrum of market-driven constraints.

The parties to a CTA typically include the pharmaceutical or medical device company ("sponsor"), the clinical trial site ("institution" or "site"), and sometimes the medical doctor supervising the trial ("principal investigator"). Clinical trial sites come in all shapes and sizes, with some being world-renowned academic institutions and others being private for-profit research centers. Similarly, some sponsors are publicly traded Fortune 500 companies, while others are bootstrapped biotech firms reliant on a single investigational product that could either make or break them. With these differences in size and sophistication also come distinctions in risk tolerance, applicable law, and bargaining power.

In simple terms, indemnification is an assurance that one party to a contract will make the other party (to the contract) whole for liability, damage, or loss incurred by another. All else equal, a negotiation of indemnification by the parties would fall along the lines of what each party controls. In practice, however, we seldom see allocation of *identical* responsibilities, and thus it should come as no surprise then that indemnification is often among the most contested terms in a contract and that CTAs are no exception.

Uneven allocation of risk or a fair balance of responsibility?

It may seem fair that parties in a clinical trial would take on responsibility for what they control – that is, to indemnify the other party for liability, damage, or losses to which they may contribute or cause. However, there are other factors that come into play that are more practical and less about what seems fair. For example, business decisions, policy, insurance coverage, and risk tolerance have all muddied the waters in terms of equal share in responsibility. Clinical trial sites provide a patient population for clinical trials while sponsors fund a corresponding treatment protocol and provide the drug or device. Sponsors design and develop the methods of therapy via the protocol, and train site staff and doctors on the implementation of the treatment. In our experience, clinical trials sites prefer to take the position that with this ability to design and control of a clinical trial comes the responsibility to eliminate any risk of loss.

Indeed, sponsors of clinical trials are *expected* to indemnify clinical trial sites, although the opposite is not always the case – some sites refuse to provide any indemnification altogether. As an example of this, a number of state-funded institutions are statutorily prohibited from indemnifying a sponsor

– often arising out of the doctrine of sovereign immunity (which is its own unique topic that we will not address here). Nonetheless, these same state-funded institutions will demand sponsor indemnification. For sponsors, this indemnification paradox can create an increased risk of financial responsibility for actions outside of their control. This may include incidents or outcomes remotely related to the study design or participation, if not carefully managed via indemnification negotiation.

The above example illustrates that sponsors can be put in a position where the indemnification is one-sided. Even so, sponsors may still reduce risk through careful negotiation of their own responsibilities. Ways to lessen the impact of their own indemnification provision will necessitate a carving out of the circumstances in which a claim may be brought. For example, sponsors should consider,

(1) limiting liability to claims occurring as a direct result of the use of the study drug;

(2) limiting scope to exclude claims resulting from the natural progression of a disease or another underlying condition;

(3) refusing to indemnify for claims where the patient failed to follow directions of the principal investigator, sponsor, and informed consent; and/or

(4) limiting indemnification to the extent a claim is the result of the institution or principal investigator's negligence, willful misconduct, breach of the CTA, or an applicable law, regulation, or guidance.

Even where a site refuses to indemnify, it is still recommended to ask whether the institution will provide a general statement to remain responsible for the acts and omissions of site employees.

In addition to carveouts from the sponsor's indemnification obligation, sponsors may also consider the willingness of the institution to indemnify the sponsor when balancing the negotiation of the CTA as a whole. As mentioned above, clinical trial sites vary in what they can (and will) and cannot agree to, and some sites are going to agree to indemnify the sponsor. Clear communication between the parties is a key aspect of negotiating this provision because acquiring a good understanding of the parties' needs or concerns and learning the spectrum of risk tolerances from either side will allow for a more meaningful and fruitful discussion, which will result in a quicker resolution.

ICE Global Consulting's team of attorneys and experienced global negotiators work with sponsors, CROs, and sites to resolve common issues involving indemnification every day. If you are looking to navigate these issues or have deeper conversations on effective ways to reach an agreement, we encourage you to contact us at info@iceglobalconsulting.com and visit our website at www.iceglobalconsulting.com.