ARTICLE 05

THE CLINICAL STAGE IS THE CRITICAL STAGE

By Laura Nelson

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For Drugs and Devices, the Clinical Stage Is the Critical Stage

Making it to the clinical trial stage is an exciting milestone in the development of a new drug or device. To conduct the clinical trials required for FDA approval and necessary for further development and refinement of the drug or device, most companies will need to contract with several clinical sites.

While companies that are not using a CRO should begin negotiations with their own template clinical trial agreement, negotiation of the agreement with each site can quickly become overwhelming. Companies should focus on the key terms in a clinical trial agreement to ensure that the desired data is obtained from each trial and the company's interests are protected.

Intellectual Property. For sponsoring companies, it is critical to protect existing and future intellectual property, including all rights associated with the drug/device to be studied, the study data itself, and any inventions or developments related to the trial.

No company wants to discover a groundbreaking idea only to enter into protracted negotiations with the local university to perfect ownership rights.

Clinical trial sites, however, often also wish to preserve rights to use study data for their own research, teaching, healthcare, and, sometimes, commercial purposes. Compliance concerns may also inform sites. For example, sites conducting sponsored research in tax-exempt bond-financed space are required by law to secure certain rights in clinical trial data and inventions to obtain fair value for the use of their space and to avoid subsidizing for-profit entities.

Each party's tolerance for IP concessions will depend largely on the type of trial and the perceived value of the associated intellectual property.

Publication. Academic clinical trial sites regard publishing rights as sacrosanct and typically resist any constraints on publication of study results. However, when sponsoring companies are coordinating publication among several clinical trial sites, it may be necessary to restrict individual site publication until after the cooperative publication is released.

Additionally, sponsoring companies should review any proposed publication to ensure proprietary information and trade secrets are not publically released and to preserve the opportunity to file patent applications, if necessary.

Allocation of Risk. Indemnification is often a heavily negotiated provision in clinical trial agreements.

Certain clinical trial sites, for example state-sponsored educational institutions that are governmental entities, may have state law or policy restrictions on their ability to indemnify private parties. The approach to study-induced injuries can also be influenced by Medicare's interpretation of the MSP laws.

The parties' willingness to assume risk generally varies by the amount and type of risk at issue in the trial, which is informed by many factors, including whether the drug or device will be administered as part of the trial.

Payment Structure. The payment structure should be clearly defined in the clinical trial agreement and consistent with the overall structure of the trial. The sponsoring company should ensure that each payment is associated with a clearly defined task or metric that can be readily verified.

Payment should not be contingent on the achievement of a particular outcome.

IRB Approval. No clinical trial can proceed until the clinical site's institutional review board approves the trial's protocol, informed consent form and associated materials.

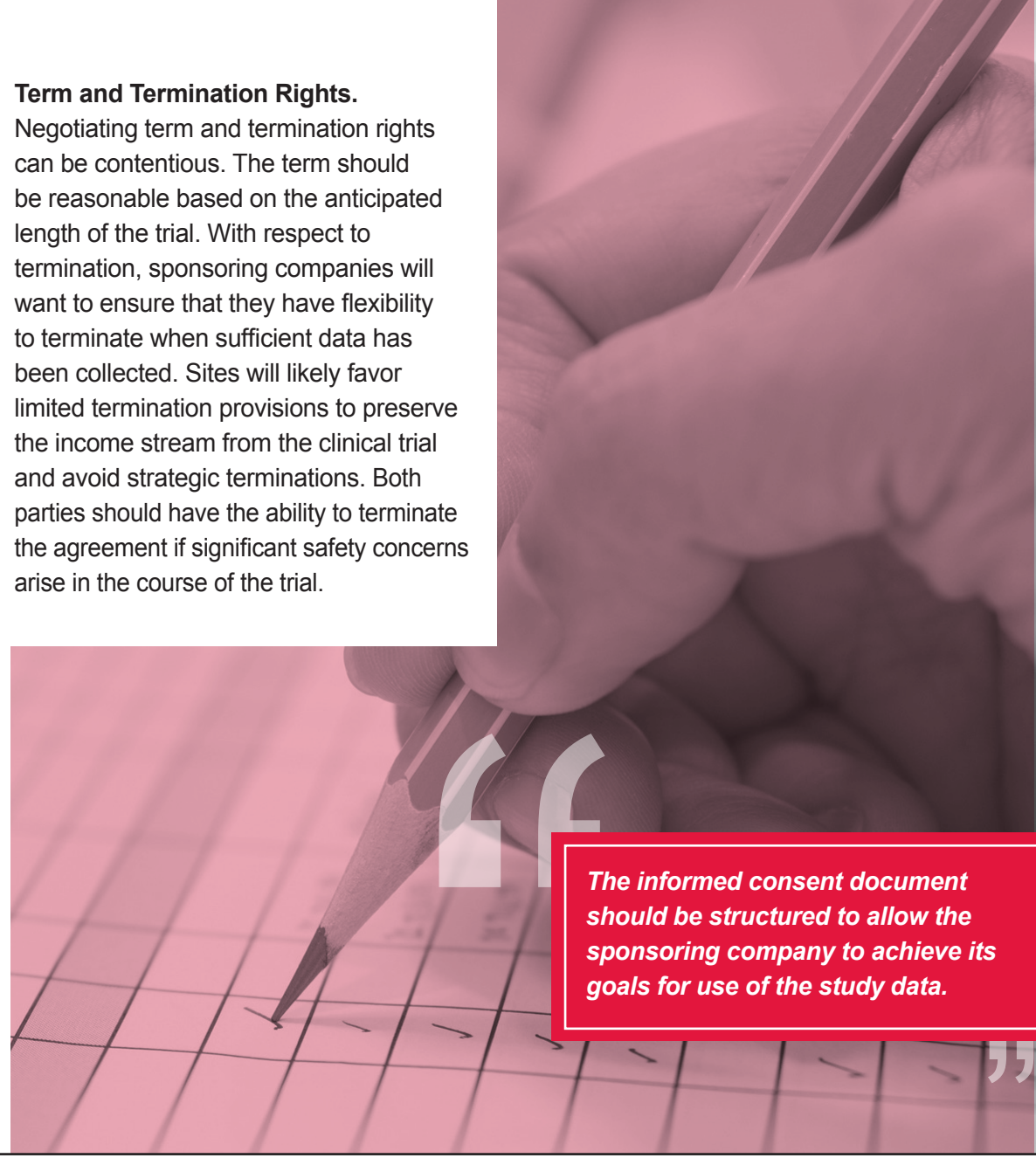
The agreement should clearly designate the party responsible for shepherding the protocol through the IRB process. All parties should be required to cooperate and make available any information requested by the IRB. The agreement should also address termination rights if the IRB does not approve the protocol or makes material changes to the protocol that impair the value of the data obtained from the trial.

Principal Investigator. Each clinical trial must have one or more principal investigators who are responsible for conducting the clinical trial in accordance with the protocol and all regulatory requirements. Issues related to the principle investigator include whether or not the particular investigator is critical to the study, provisions for replacing investigators and whether or not the principle investigator will be a party to the agreement.

Informed Consent. The informed consent document provides the research subject with information regarding participation in the clinical trial and describes how the research subject's protected health information may be used and disseminated. Key elements are:

- What information will be collected
- Who will see and use the information
- When and why the information will be used and distributed
- Any other specific permissions or restrictions

Term and Termination Rights. Negotiating term and termination rights can be contentious. The term should be reasonable based on the anticipated length of the trial. With respect to termination, sponsoring companies will want to ensure that they have flexibility to terminate when sufficient data has been collected. Sites will likely favor limited termination provisions to preserve the income stream from the clinical trial and avoid strategic terminations. Both parties should have the ability to terminate the agreement if significant safety concerns arise in the course of the trial.



The informed consent document should be structured to allow the sponsoring company to achieve its goals for use of the study data.

Move Ahead with Confidence

This article covers briefly the key elements of a sound clinical trial agreement and seeks to identify some of the typical areas of tension. Ultimately, the strength of any agreement resides in how the details are scrutinized and addressed. How will you protect your IP rights? What termination rights align with your investment and data goals? How do you shepherd the IRB process? Getting these and other details right is critical.

Our life sciences attorneys have deep experience reviewing and preparing clinical trial agreements. For more information on how we can help you, contact one of the attorneys noted on the right.

Supply Chain Series Contributors

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