wcg MAGI | Journal of Clinical Research Best Practices

Vol. 17, No. 4, April 2021 "Happy Trials to You"

Five Critical Investigator-Initiated Clinical Trial Agreement Clauses

By Tara Cowell and Christina Stanger

In a typical industry-sponsored clinical trial, a biopharmaceutical or medical device industry partner plays the role of sponsor and contracts with one or more physicians at clinical research sites to play the role of investigator. An investigator is an individual who actually conducts a clinical investigation. A sponsor is a person who takes regulatory responsibility for and initiates the clinical investigation. The contract between the industry sponsor and the principal investigator (or his/ her employer, most commonly) is called a clinical trial agreement (CTA).

In contrast, an investigator-initiated clinical trial (IIT) is both designed and conducted by a sponsor-investigator. He or she still plays the principal investigator role and may delegate certain of her/ his sponsor responsibilities to his or her employer — a clinical research site.

In some cases, the sponsor-investigator enlists a biopharmaceutical or medical device industry partner to support the trial in a limited manner. The contract between a sponsor-investigator and an industry partner can be called an IIT-CTA.

The sponsor-investigator is an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug (or device) is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator in 21 CFR Part 312 include those applicable to both an investigator and a sponsor.

With an IIT, an academic scientist can pursue a line of research outside of industry- or government-sponsored studies. The investigator (or his/her employer) owns the rights to any data or inventions generated by the study under an IIT.

Industry partners can use IITs to economically expand their research programs (e.g., to investigate use of an approved drug for a new indication). IIT-CTAs may grant them rights to data or inventions generated by the IITs. Some biopharma and medical device companies actively promote IITs with their products, others are open to investigator proposals, and others have no interest in them.

Industry partners can support IITs in various ways. For example, they can provide the study drug, financial support or data. They can also take on regulatory compliance responsibilities. IIT-CTAs spell out the nature of the support and the related rights and obligations. Typically, the more support the industry sponsor provides, the closer the IIT-CTA gets to the CTA for an industry-sponsored trial.

The five critical differences between CTAs and IIT-CTAs relate to subject injury, indemnification, confidential information, intellectual property and study data, and publication.

Subject Injury

The subject injury provision in a traditional CTA typically requires the industry partner to cover the cost of diagnosing and treating subject injuries.

© 2021 MAGI and the Author(s)

In contrast, IIT-CTAs typically do not include a subject injury provision because the sponsor-investigator, not the industry partner, developed the protocol and is responsible for subject safety. The industry partner may also disclaim any subject injury responsibility unrelated to their marketed-product warranty.

Indemnification

In CTAs, the industry partner typically indemnifies the investigator and the research site for (a) use of the study drug, (b) the performance of a procedure required by the protocol, (c) the partner's use of the study data and (d) intellectual property claims related to the drug. The investigator and research site may indemnify the industry partner if, for example, they injure a study subject due to negligence.

In contrast, in IIT-CTAs the sponsor-investigator provides the indemnification, typically for the sponsor-investigator's negligence or wrongful acts, violation of laws, or breach of a warranty in the agreement. Occasionally, an industry partner may indemnify the sponsor-investigator for the partner's use of study data.

Confidential Information

CTAs typically take protecting the industry partner's confidential information very seriously, especially with experimental products that the partner must protect from competitors. In some cases, CTAs also protect the research site's confidential information.

In contrast, IIT-CTAs are more likely to focus on protecting the sponsor-investigator's confidential information, along with any confidential information the industry partner provides.

Intellectual Property and Study Data

CTAs protect the industry partner's intellectual property and study data. Industry partners do not want research sites taking ownership of products the partner has been developing for years. CTAs typically grant the industry partner ownership of the study data. They may provide the research site with a nonexclusive license to use the data for its own internal noncommercial, quality and educational purposes. CTAs and IIT-CTAs typically confirm the research site's ownership of medical records.

IIT-CTA intellectual property terms depend on the nature of the study, the industry partner's support and other factors. IIT-CTAs may grant ownership of study data to the sponsor-investigator, who typically provides a nonexclusive license to the industry partner to use, reproduce and transmit the study data. The sponsor-investigator may grant to the industry partner a nonexclusive, sub-licensable, transferable, royalty-free license for drug- or device-related inventions, along with the first right to negotiate an exclusive license with full rights to any inventions.

Publication

CTA publication provisions typically include a complex system for industry partner reviews and the delay of research site publications until after a multicenter publication.

In contrast, IIT-CTAs typically give the sponsor-investigator authority over publication, including interim results and other topics (e.g., patient recruitment strategies). However, IIT-CTAs may grant the industry partner the right to review publications for use of its name, disclosure of its confidential information or interference with its intellectual property protections.

© 2021 MAGI and the Author(s)

Conclusion

IIT-CTAs must be tailored to the type of product, trial design, level and type of industry partner support, and other factors. IITs of marketed products can take advantage of public information on the product's safety and efficacy records.

Standard templates for CTAs and IIT-CTAs can be found at www.magiworld.org/Standards, but the wide variations in IIT-CTAs may call for involvement by experienced attorneys.

Authors

Tara Cowell is president of Cowell Law. Contact her at tara@cowelllaw.com.

Christina Stanger is assistant vice president of research administration for the MedStar Health Research Institute. Contact her at christina.m.stanger@medstar.net.

© 2021 MAGI and the Author(s)