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The anatomy of a clinical trial agreement

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Clinical trials and contracting

Those involved in clinical trial agreements (CTAs) are intimately aware that the agreements are lengthy, complex to negotiate, and riddled with compliance pitfalls. If new to this area, it may be easy to overlook a key section or consideration in contracting—especially when time is of the essence in developing new products. Pressure comes from different parties to get an agreement executed so that testing may continue and development timelines are met.

This article explores the hallmark agreement in the research associated with any investigational product: the CTA. CTAs memorialize the agreement among the companies that develop the investigational product, the site at which the investigational product will be tested, and the physician overseeing the testing at that site. The following outlines the basics of any clinical trial, including the various stages of testing, an overview of the CTA, and a deeper dive into the core sections of any CTA. In this deep dive, compliance professionals may note risk areas of which to be aware. Parties are more likely to enter a compliant CTA when understanding the required elements and potential pitfalls.

Clinical trial basics

Companies develop new drugs, biologics, devices, and other medical interventions (investigational product) that must be tested through clinical trials to ensure safety and efficacy. Clinical trials involve human subjects and require collecting, storing, and sharing of subject data. They are conducted at many locations, including facilities in the United States and abroad. This process is regulated by the U.S. Food and Drug Administration (FDA), Centers for Medicare & Medicaid Services (CMS), Office of Civil Rights (OCR), and foreign counterparts.

The development process for an investigational product follows multiple stages: (1) discovery and development, (2) preclinical research, (3) clinical research, (4) FDA review, and (5) FDA postmarket safety monitoring. The clinical research phase is the main component of the process that involves testing the investigational product in human subjects and is when contracting occurs. This research phase has various steps that must successfully demonstrate safety and efficacy before the FDA is willing to review the proposed investigational product for approval. This phase is generally referred to as the clinical trial or clinical study phase.

Companies that develop new drugs, biologics, devices, and other medical interventions sponsor the clinical trial and are therefore referred to as the "sponsor" in all contracting documents. The sponsor's responsibilities include selecting the principal investigators (PIs), providing those PIs with a roadmap to conduct the clinical trial (typically called the "protocol"), ensuring proper monitoring of the study, confirming all necessary reviews and approvals are obtained for the study, and making sure all reviewing entities and regulatory agencies are informed of the information before, during, and after the study. The protocol is developed, and the study is conducted, in accordance with the FDA regulations relating to good clinical practice and clinical trials.[1] These regulations outline requirements pertaining to informed consent forms, electronic records, institutional review boards (IRBs), and much more.

The sponsor typically hires a clinical research organization (CRO) to assist in administering and managing the clinical trial. The CRO often has site-specific and country-specific knowledge to efficiently manage the contracting process, which is integral to a successful clinical trial. With this knowledge, CROs often recommend site selection, provide patient recruitment support, assist with biostatistics and clinical monitoring, and offer clinical data management.

The sponsor and CRO choose facilities where the clinical trial will be conducted, referred to as "sites." The site is often an academic facility, referred to as an "institution." Each site employs or contracts with a PI. The PI is the physician who will oversee the clinical trial at the institution. The protocol is approved by the site's IRB. The IRB is made up of physicians, researchers, and members of the community. Its role is to ensure the study is ethical and that the rights and welfare of participants are protected. Abroad, many countries use an ethics committee (EC), which serves a similar function as the IRB.