

Managing Clinical Trials in an Ophthalmic Practice

Tips for integrating research studies into busy daily schedules.

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An ophthalmic practice's primary function is to provide high-quality care to patients. Clinics also play an integral role in the development of new treatments for ophthalmic diseases, however, by serving as sites for research studies. Physicians and technicians who participate in clinical research add new responsibilities to their regular duties. This article describes the tasks involved in clinical research, breaks down the responsibilities of the investigative team's members, and provides tips for integrating new tasks into established ophthalmic practices.

CAST OF CHARACTERS

The key figures involved in clinical trials include a sponsor (the company that is testing the product through the clinical trial process), investigators (an individual physician or group of physicians who perform the trial at a specific site), an Investigational Review Board (IRB), and the study's coordinator.

Clinical trials are either managed internally by sponsors or externally by an unbiased clinical research organization (CRO) hired by the sponsor. A monitor who works for the sponsor or a CRO manages the trial at the study site.

Investigators are responsible for conducting and overseeing the trial as well as for guaranteeing that all participating personnel under their supervision receive the proper training. They must also understand the information provided in the Investigator's Brochure prepared by the sponsor, become familiar with the risks and benefits of the investigational product, and maintain adequate and accurate accountability records.

The study's coordinators oversee all aspects of the clinical trial's protocol at the site, including scheduling patients for evaluations and special testing. Along with

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the study's investigators, coordinators record, collect, and relay data from the patient's visits to the sponsor and/or the CRO. They may also be responsible for reporting to an IRB, or even the FDA, to ensure the quality of the clinical trial. In some cases, the coordinators may even be responsible for the receipt and accountability of the investigational product.

A REGULATED INDUSTRY

Participants in clinical research are protected by regulations and guidelines designed to ensure their safety and prevent their mistreatment. These guidelines, called Good Clinical Practices (GCP), are set by the International Conference on Harmonization. GCPs define the international ethical and scientific quality standards for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Sponsors, CROs, and monitors enforce GCPs by ensuring that investigators obtain the necessary informed consent from patients and adhere to the study's protocol. These agencies also ensure that the investigative site receives approval from an IRB prior to initiating any studies and that the data produced by the study can be verified independently by an IRB, an internal quality assurance process, or an audit by the FDA.

For example, investigative sites, through their IRBs, must seek approval of the protocol, the informed consent, and any advertising to be used during the trial. In addition to obtaining informed consent from each patient enrolled in the study, the investigators are also obligated to inform the IRB of any adverse events potentially caused by the investigational product, notify the board of any significant violations or any changes in the study's protocol, and obtain the board's approval for amendments to the protocol. The investigators are also responsible for informing patients of any newly identified risks that are not covered by the original informed consent.

FINDING A TRIAL

Once the physicians in a clinical center determine what types of studies fit their practice's specialty, they need to find a trial that is seeking research sites. Representatives from companies that manufacture drugs or medical devices can be good sources of information, because they often attend national and regional meetings to recruit investigators for new trials. These representatives can also provide physicians with contact information for their companies' clinical operations director or regulatory department during their regular sales calls. Another excellent method for locating clinical trials is to ask colleagues and peers for recommendations.

THE PAPERWORK

After a sponsor has agreed to consider an ophthalmic practice as the site of its clinical trial, the potential investigators must sign a confidentiality disclosure agreement before the sponsor releases any information about the investigational product. This binding contract, as the name suggests, states that the physician and everyone working under his employ or within his group will not disclose any confidential information about the trial's details to anyone, including the media. As the investigators soon find out, the confidentiality disclosure agreement is only the first of many regulatory documents they will sign before the completion of the trial.

Occasionally, a sponsor or a CRO will forward a feasibility questionnaire to the investigative center to determine the facility's potential for enrollment and its ability to complete the trial within the necessary timelines. If the sponsor or CRO decides the site is acceptable, it may send a monitor to the site to assess its facilities and staff. The evaluation can also be performed through a telephone interview. Because the assessment is the final factor that determines a site's acceptance into a study, investigators and their staff should present a positive attitude, highlight their ability to attend to details, and be on their best behavior.

Staff members should always answer phone calls from assessors promptly. Putting an assessor on hold or waiting several days to return his phone call could give the impression that the facility is too busy or too poorly organized to take on a clinical study. Investigators and their staff should also answer the assessor's questions honestly. Overpromising and underdelivering a practice's capacity for enrollment will inevitably create problems later.

The sponsor's next step is to negotiate a budget and a contract with the investigator. This process is often handled personally by the investigator, an office manager, or a practice administrator, frequently with the assistance of a lawyer retained by investigator. The study's coordinators occasionally participate in this portion of the negotiation, depending on their experience and position in the practice.

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The paperwork begins to pile up at this point in the process. Investigators are required to submit an application outlining the trial's proposed protocol, if they have not yet completed one, and any other required regulatory documents to their center's IRB panel. This panel includes scientific and lay members who review the study's protocol and informed consent guidelines to ensure that patients' rights are protected. If the panel is satisfied that the clinical trial meets certain ethical criteria, the IRB will approve the site to conduct the trial for a specified period, at the end of which it must undergo further review and approval.

Before the site's paperwork is filed with the IRB, the sponsor, CRO, or monitor should ensure that it is complete and free of errors to avoid a significant delay in processing. The investigational site should also retain copies of the original signed documents submitted to these agencies and file them in a clearly labeled folder reserved for that study.

JUGGLING DUTIES

Incorporating a clinical trial into an already busy practice can be challenging, but it is not impossible. The key is to stay organized.

Before the investigators begin seeking approval for a clinical trial from their IRB, they should meet with their

staff to assign roles and responsibilities to individual members. To avoid problems, investigators and the study's coordinators should designate backup personnel who can perform specific tests and tasks in the event of a primary team member's absence.

Scheduling quarterly staff meetings will help investigators review the study's progress, update team members on any changes, and manage patient flow. Every month, investigators should meet with coordinators to review patients' charts, track adverse events, and obtain required signatures. Participants should expect to spend approximately 1.0 to 1.5 hours per study during these meetings.

The study's coordinators should plan to dedicate 2 to 3 uninterrupted hours per week to complete case report forms, and regulatory documents, catch up on correspondence, answer queries, satisfy accountability requirements, and maintain patients' files.

CONCLUSION

With the proper preparation and organization, ophthalmologists can easily incorporate clinical trials into their daily routine. The most important guideline to remember is that deadlines are not negotiable. The individual who oversees a clinical trial's day-to-day operations—whether it is the investigator or the study's coordinator—must be constantly aware of the IRB's requirements and GCPs. These include keeping track of and meeting deadlines for re-approving the study's protocol and informed consent form. Time-sensitive materials should never be left to the last minute.

Any changes made to a document should be crossed out with a single line and accompanied by the initials of the person who entered the change and the date it was made. If the reason for the change is not evident, the person documenting the correction should include that information next to the crossed-out text. To avoid introducing inaccuracies in the data, a study's coordinator and other team members who record results should transfer data from the source documents to the case report forms provided by the sponsor or CRO within 1 to 2 days of a patient's evaluation. A speedy transfer will give the recorder a chance to catch and correct an error or omission. Finally, investigators, coordinators, and other ophthalmic professionals involved in clinical trials should never hesitate to contact the study's monitor with any questions or doubts they have about the project. □

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