INDUSTRY-SPONSORED CLINICAL RESEARCH

What you need to know.

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Partnership with industry supports innovation and addresses the medical needs of patients by providing them with access to new diagnostics, treatments, or therapies. Successful scientific collaboration is achieved when partners work as a team toward a goal. What unites the eye care industry and ophthalmologists is our shared goal: to enhance the lives of patients. This article is intended to provide you with actionable insights into developing and maintaining a successful clinical research partnership with industry.

CLINICAL TRIAL MANAGEMENT

Clinical research operates in a highly regulated environment with multiple sources of guidance and regulation (see *Clinical Research Governance and Guidelines*). The International Conference on Harmonization's good clinical practice (GCP) provides important guidance to investigators. The International Conference on Harmonization focuses on all aspects of the clinical trial process. GCP outlines the specific responsibilities of each investigator participating in clinical research to protect participants and collect high-quality data. GCP provides standardized guidance on the investigator's overall responsibilities, including the informed consent process, subject qualification oversight, the secure storage of study supplies, and adverse event safety assessments.

Key to clinical trial teams is the operations team, made up of a large group of functional area experts managing a complex set of activities that are running in parallel. The operations team may be internal, consisting primarily of employees at the sponsor, or it may be outsourced to an external clinical research organization. You will need to know specifically what the operations team expects from you. There is a standard set of criteria you are likely to be asked about, both informally through preliminary discussions and formally through a feasibility assessment.

Feasibility assessments help the industry sponsor understand the full capabilities of the site and any factors that may influence the conduct of potential clinical research activity. Assessments include

- the previous experience of both the investigator and the site in conducting similar trials
- the qualifications of site personnel
- specific equipment and facilities that are available
- medication storage
- a private setting for informed consent
- safeguards for study records
- electronic health records or paper documentation
- the availability of an appropriate patient population
- patient recruitment procedures
- adequate time and resources for staff to participate
- any Institutional Review Board, contractual, and budgetary requirements

Providing thoughtful responses to these needs is an ideal starting point for your discussions.

HOW TO DISTINGUISH YOUR PRACTICE

At a minimum, positioning your practice to engage in clinical research involves meeting the standard set of criteria detailed in GCP, the feasibility assessment, and

CLINICAL RESEARCH GOVERNANCE AND GUIDELINES

Clinical research operates in a highly regulated environment with multiple sources of guidance and regulations. Each agency has centered its respective guidance on ensuring patients' safety through careful risk-benefit analyses.

DECLARATION OF HELSINKI[1]

- developed by the World Medical Association
- first adopted in 1964
- guidance statement of ethical principles for physicians involved in medical research

BELMONT REPORT[2]

- published in 1979
- summarizes the ethical principles and guidelines for the protection of human subjects of research

INTERNATIONAL CONFERENCE ON HARMONIZATION[3]

- agreed-upon scientific guidance establishing common guidelines to ensure that safe, effective, and high-quality medications are developed and registered

US CODE OF FEDERAL REGULATIONS TITLE 21[4]

INSTITUTIONAL REVIEW BOARD/ETHICS COMMITTEE

- local or centralized committee ensuring that the study is ethical, that the rights and welfare of human subjects are protected, and that the study is conducted in accordance with all federal, institutional, and ethical guidelines

CLINICALTRIALS.GOV

- a searchable online registry of federally and privately funded clinical trials
- provides summary information on clinical trials and results to the public

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

- US law
- designed to provide privacy standards regarding the saving and sharing of an individual's medical information

1. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. WMA website. http://www.wma.net/en/30publications/10policies/b3/. Accessed February 11, 2016.
2. The Belmont Report. US Department of Health and Human Services. April 18, 1979. http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html. Accessed February 11, 2016.
3. Efficacy Guidelines: E6 Good Clinical Practice. ICH. http://www.ich.org/products/guidelines.html. Accessed February 11, 2016.
4. US Food and Drug Administration. CFR - Code of Federal Regulations Title 21. US Department of Health & Human Services. Updated August 21, 2015. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm. Accessed February 11, 2016.

protocol. If you would like to distinguish yourself from other potential investigators, first and foremost, look for alignment between the protocol and your clinical practice's activities. Most successful clinical investigators share a genuine scientific interest in the questions being asked in a study protocol. Delivering expert insight into your practice environment, a comprehensive assessment of who makes up your patient population, the workflow of your office, and available dedicated resources will show your core strengths and enable you to establish a unique profile. Dedicated resources such as an experienced or certified clinical trial coordinator can make a significant difference in ensuring that things go smoothly from startup to close.

Meeting timelines for reviewing and submitting documents, reaching targeted enrollment, and adhering to visit windows are just a few important elements of the overall clinical trial. Completing clinical trials late is costly and delays the sharing of information with both regulatory agencies and the scientific community.

Today, many industry sponsors use a competitive enrollment methodology in multicenter trials: once the targeted number of patients has been enrolled, all further enrollment ceases. This methodology makes enrolling patients as they happen to visit the practice impractical. Instead, having a database of patients who have previously expressed an interest and a willingness to participate in clinical research is an advantage.

Standardization to control for variability is essential to collecting the high-quality data that are the foundation of credible science. Realistically, no matter how carefully clinical forms are designed, all studies have to deal with errors during data collection—everything from typos and missing information to inconsistent relational information. Data monitoring and electronic data entry techniques help to forestall common errors. Nevertheless, the more attention your site pays to ensuring that all data are entered accurately, the better.

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AT A GLANCE

- What unites the eye care industry and ophthalmologists is our shared goal: to enhance the lives of patients.
- Look for alignment between the protocol and your clinical practice's activities. Do you have a genuine scientific interest in the questions being asked in the study?
- Two ways to get involved with industry-sponsored trials are connecting with a representative from an ophthalmic specialized clinical research organization or with an industry representative.

BEYOND THE CURRICULUM VITAE

In the absence of previous clinical trial experience, investigator certification in GCP and coordinator certification are your best options. If you have participated in previous trials, it is important to document key achievements such as how often you met your target enrollment, how long it took to recruit participants, and the turnaround time for responding to queries and clarifications. Communicate your strengths pertaining to therapeutic area expertise and other research-related experience. This set of documents demonstrating your practice experience and clinical trial capabilities is necessary. After all, a proven track record speaks volumes.

NEXT STEPS

Two ways to get involved with industry-sponsored trials are connecting (1) with a representative from an ophthalmic specialized clinical research organization or (2) with a research and development industry representative. You can meet representatives of these organizations at national congresses. Such interaction allows you to determine what each organization is looking for in potential clinical research collaborators.

This article has provided a high-level overview; you can learn more through online training and education courses. A few options to explore are nonprofit societies such as the Association for Clinical Research Professionals (www.acrp.net), the Society of Clinical Trials (www.sctweb.net), and the elected-member Association for Clinical Investigation (www.the-asci.org). ■

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