Trials Without Tribulations: Are Clinical Trials an Option for Your Practice?

Conducting pharmaceutical studies in your office can boost practice revenue, but careful planning beforehand is needed to ensure success.

By Bryan M. Soronson

As medical practices look for opportunities to expand and enhance revenue, participating in clinical trials—as an increasing number of medical groups have learned—can achieve both objectives.

Clinical trials are one of the most important components of the drug-development process. The pharmaceutical industry uses the data to determine whether new compounds or devices are safe and effective; the Food and Drug Administration uses them in the drug-approval process.

Clinical trials comprise up to four phases (see chart); most studies in private practices are in Phase III: when an experimental study drug or treatment is given to large groups of people (up to several thousand) to confirm effectiveness, monitor side effects, compare it to commonly used treatments and collect information that will allow safe use.

A practice considering participation in clinical trials must:

- Ensure physician support.
- See involvement as part of its mission.
- Have the patient base to participate.
- Have insurance to cover such activity.
- Have study coordination and administrative/clerical staff to support the activity.

Advantages of Participation

Clinical trials can bring numerous benefits to a medical group. Trials can:

- Provide new therapies to patients at no cost, since neither they nor their insurers are billed for research-related medical care (you must establish a system that prevents third-party billing for study related activities).
- Generate revenue (reimbursement for study patients is generally higher than reimbursement from commercial insurance).
- Cover fringe-benefit expenses for physician and nurse/coordinator salaries.
- Support administrative and clerical staff salaries, rent, utilities, information technology costs and other overhead through allocations for indirect costs (generally 20 percent to 35 percent of the study's direct cost).
- Boost your group's reputation, helping increase your patient base.

Challenges to Clinical Trials

Your practice can lose money if you don't budget to cover all costs, if subject enrollment doesn't meet projected targets or if a significant number of subjects drop out of the trial.

The budget for a clinical trial is developed and paid on a per-subject basis, covering physician and coordinator costs, procedures, and ancillary and related expenses. You project revenue by calculating the agreed-upon cost per subject multiplied by the proposed number of subjects. The pharmaceutical company bases payments to your practice on the number of subjects enrolled multiplied by the actual time they participate.

Establish a system to prevent third-party billing for study-related activities. In some instances, costs related to the trial can be billed to third-party insurers for life-threatening conditions, but a compliance specialist should review such cases beforehand.

Ensure that the contract for a clinical trial is favorable to the practice; pay particular attention to indemnification and publication clauses. The sponsor must cover the cost of medical expenses directly related to adverse events from the study drug; the group's malpractice insurance must cover any problems arising from "negligence, recklessness or willful misconduct"[1] by the physician and/or study coordinator. A sponsor should have the right to review and delay— but not prohibit—publication.

The practice must have a qualified study coordinator, often a nurse. Funding this position can be difficult because revenue from trials comes irregularly. The coordinator should have a formalized relationship with the principal investigator (PI). He or she should review the trial protocol and provide feedback to the PI before the practice commits to participate.

Before commencement, the study must be submitted to an investigational review board for approval. Most sponsors will identify a board and describe how to submit required documentation.

Participation in clinical trials can be a positive experience for your practice as long as you plan properly. Helpful hints for participating in clinical trials are as follows:

- Get to know the sponsor contact.
- Overestimate time required when calculating coordinating effort.
- When calculating the timeframe of the project, start from when the group first works on the study to when the last subject has completed treatment.
- Ensure that employees understand

Phases of Clinical Trials in the Drug Development Process

	Duration	Type of Subjects	No. of Subjects	Goals of Study
Phase I	Days to 1+ years for follow-up	Healthy	5-100	Determine dosing level and safety issues.
Phase II	Weeks to a few months	Diseased	Tens to a few hundred	Determine dosing and safety, drug kinetics, side effects.
Phase III	Months to several years	Diseased	Hundreds to several thousand	Efficacy, safety, optimum dosage, regulatory parameters, risks/benefits.
Food and Drug Administration Approval				
Phase IIIB/IV (postmarketing)	Varies	Diseased	Several thousand	Expanded population, other indications, long-term effects, comparing drug to competitors' products.

Sources: *MerckManual Home Edition. Overview of drugs, topic design and development. February 2003.*
Tonkens R. An overview of the drug development process. The Physician Executive,May-June 2005:48-51.

regulatory requirements and good clinical research practices.

• Request nonrefundable, pre-award start-up costs to cover principal investigator and coordinator time.

• Ensure that the sponsor provides payment for screening failures, unscheduled visits and additional work related to adverse events. **PN**

1. Baer I, Feiler ME, Regulski A, Switzer S. Clinical trial contracts: A discussion of four selected provision. Association of American Medical Colleges, January 2004:14.

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