Clinical trials

The proof is in the practice

By John McCormack

The Tanner Clinic recently conducted a trial for a pediatric vaccine to prevent respiratory syncytial virus/parainfluenza virus, a condition for which there are no vaccines currently available. "If a safe and effective vaccine is approved, it will save lives, lessen the severity of the infection in our children, and … save in medical costs," says Melanie Gibb, CCRC, clinical research site director at the Layton, Utah-based medical group.

Clinical trials are studies in which participants receive one or more interventions (or no intervention at all) so that researchers can evaluate the effects of medications, therapies, or medical devices.[1] These studies are typically funded by pharmaceutical companies, academic medical centers, device manufacturers, voluntary groups, federal agencies, or other organizations.

"Sometimes we participate in clinical trials because we can then provide drugs to patients who can't afford them. If patients know that they are going to get free medications for a year or two, then they will gladly participate," says Lynn Kincaid, CMA (AAMA), a practice manager at the Northern Virginia Center for Arthritis in South Riding, Va.

Certainly, altruism stands out as a great reason to get involved in clinical trials. But less philanthropic incentives exist for medical practices, as well:

- **Improved reputation.** Taking part in clinical trials can position physicians and their practices as leaders in their medical specialty.
- **Competitive edge.** Consumers often assign greater status to physicians who conduct research studies.
- **New revenue stream.** Many pharmaceutical and medical device companies pay medical groups to conduct—and patients to participate in—clinical trials.

"Patients … seem to associate clinical trials with cutting-edge therapy and a high level of care—and are actively looking for providers that are conducting trials," says Rhonda Paz, PhD, CRCP, senior vice president of clinical research at Guide Star Clinical Trials Management, a consulting company based in New Orleans.

In regards to added revenue, some physicians earn more from clinical studies than they earn through their regular practice.[2] In fact, contract research could provide individual physicians with up to $300,000 in annual income.[3]

No easy task

Establishing and running a trial site is a substantial undertaking. To successfully launch a trial, medical groups need to do the following:

- **Gather knowledge.** Study regulations that address clinical and financial issues. Become familiar with "good clinical practice (GCP)," which ensures that the rights, well-being, and confidentiality of study subjects are protected.
- **Find a clinical trial.** Clinical trials are often listed on the websites of pharmaceutical and medical device companies. Such sites as Clinicaltrials.gov and CenterWatch.com also list clinical trials.
- **Establish the infrastructure.** Practice leaders need to find space for drug storage, archives, and equipment. Clinical research associates (CRAs) also might need dedicated workspace.
- **Complete essential documents.** Several forms are often required. For example, required documents for an investigational new drug (IND) trial in the U.S. include a confidential disclosure agreement (CDA); curriculum vitae for the principal investigator (PI) and sub-investigators; and the investigator's financial disclosure statement.
- **Participate in an inspection.** The sponsor will conduct a preliminary

site visit to evaluate staff experience, expertise, and interest, as well as the potential patient population.

- **Get IRB approval.** All sites are required to obtain approval from an institutional review board (IRB), a group designated to review all aspects of a trial in order to protect the rights, safety, and well-being of the patients involved.[4,5]

Every trial is led by a clinical investigator who is typically a medical doctor. In addition, someone in the practice assumes the role of clinical research coordinator (CRC), or the group can hire a coordinator from outside the practice. A CRC handles the management and documentation of the trial. Clinical studies also could employ a research team that may include physicians, nurses, social workers, and other health care professionals.

Trials and tribulations

Practice leaders need to understand potential pitfalls before jumping in. There is always the possibility that a patient can become seriously ill or even die during the course of a clinical trial. In such cases, the medical practice could be named in a lawsuit.

Medical offices can mitigate this risk by making sure that all trial participants are informed of the potential risks during the consent process, which should include having the patient sign an IRB-approved form. If the medical group has followed protocol and is not negligent, the sponsor typically will indemnify medical practices against damages and pay for their defense.[6]

Leaders also need to understand the scope of any proposed clinical trials, since these studies can potentially turn into time-consuming endeavors. "Practice leaders need to think of clinical trials like a business venture. They really have to watch the finances and make sure that they are making a good return on their investment," Dr. Paz says.

What's more, practices should ensure that the physicians are truly committed to the clinical trial before signing on the dotted line. "The physicians are the ones seeing the patients. So, ultimately, they are the ones who can make the trial a success. If the physicians lose interest, then a practice could really suffer financially," Dr. Paz says.

Medical groups need to have access to the right patient population before enrolling in a clinical trial. "If your practice is operating in an area of the country where pancreatic and breast cancer [levels] are high, and your office opens a prostate cancer trial, then you might end up investing in all the infrastructure required to open the trial but you won't realize a return on the investment because you won't get the patients," Dr. Paz warns.

Unforeseen outcomes

Keeping patients involved can emerge as another challenge. "A lot of times you might think that you have plenty of patients who would be interested and qualified to participate. But sometimes when patients start reading about the potential side effects or about the time commitment required to participate in a trial, they decide not to enroll," Kincaid says.

Leaders also need to be prepared to help patients cope with disappointment when the investigational drug or therapy falls short of expectations. "We want all subjects to have a positive experience … but occasionally a subject is regretful that they participated. That can be a difficult situation to handle, and sensitivity and follow-up care must be implemented," Gibb says.

All in all, the effort is well worth it, though. "It is very satisfying to see an investigational product that you worked with come to market and be available to the general public," Gibb says.

Test patterns

The U.S. National Institutes of Health organizes trials into six different types[7]:

- **Natural history studies** provide valuable information about how disease and health progress.
- **Prevention trials** look for better ways to prevent first-time occurrence or reoccurrence of a disease.
- **Screening trials** test the best way to detect certain diseases or health conditions.
- **Diagnostic trials** are conducted to find better tests or procedures for diagnosing a particular disease or condition.
- **Treatment trials** test experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.
- **Quality-of-life trials** (supportive care trials) explore ways to improve comfort and the quality of life for individuals with a chronic illness.

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