LETTER FROM THE EDITOR

Large, multicenter, randomized clinical trials lay at the foundation of virtually all areas of medicine. While a case report, single-center study, or retrospective chart review certainly offers some value—indeed, *Gastroenterology & Hepatology* publishes 1 or 2 case studies in each issue—these smaller studies are no substitute for large-scale clinical trials, especially when it comes to proving the effectiveness of a particular treatment or intervention. Particularly in the case of new drugs, several successful clinical trials are usually required before a drug can gain approval from the US Food and Drug Administration.

For many gastroenterologists and hepatologists, the clinical trial process is something to be observed from the outside; such individuals may stay abreast of the latest developments and await the approval of new drugs but feel no desire to be actively involved. Others, however, choose to play an integral role in this process. Drug development almost always begins with in vitro tests and animal trials, but eventually novel compounds must be administered to patients who have the condition the drug has been designed to treat. At this stage, clinical trial investigators become essential, as they are the ones to manage these patients and oversee the day-to-day details of the trials in which such patients are enrolled.

As Dr. Seymour Katz and colleagues discuss in this month's Practice of Medicine column, "Keys to Success with Clinical Trials," on page 100, participating in a clinical trial requires the investment of time on the part of the doctor and the office's staff, and it forces the practice to open itself to oversight from the trial sponsor. As with almost any endeavor, being involved in a clinical trial means extra work (and paperwork), and it can also involve travel and other commitments. For a small or busy practice with no resources to spare, assuming such obligations may not be possible.

For clinicians who have the time and resources, however, participating in a clinical trial is a way to be on the forefront of medicine. Just as today's "tried and true" medications are the result of previous studies, tomorrow's medications are among the new agents being tested today. A single practice may only provide data on a few patients, but when these data are combined with those from other patients at other sites, it can eventually lead to the noteworthy findings presented at major medical meetings.

Of course, not every clinical trial leads to a blockbuster drug; some agents are shown to be ineffective and never come to market. Thus, patients and clinicians who elect to test these new agents must be comfortable with the potential risks and benefits of these agents. On the one hand, the test agent may not work—or the patient may be assigned to a placebo or standard-of-care control arm. In addition, the side effects of new agents may be incompletely understood, so extra care must be taken to monitor clinical trial participants closely. On the other hand, a new drug may offer an effective treatment for patients who previously showed little response to available medications. For clinicians who have the time, resources, and inclination, becoming involved in a clinical trial can be a great opportunity. I therefore encourage such individuals to read Dr. Katz's article and consider the pros and cons of such an endeavor.

Other articles in this month's issue of *Gastroenterology & Hepatology* include a feature on traveler's diarrhea and 2 case studies: a case of hepatocellular carcinoma (HCC) that was diagnosed using endoscopic ultrasound–guided fine-needle aspiration of a portal vein thrombus, and a report in which midodrine was used to reduce the need for large-volume paracentesis in hypotensive cirrhotic patients with refractory ascites. This month's columns address the current status of alpha-fetoprotein testing for HCC, the treatment of acute cholangitis, the utility of transabdominal ultrasound with oral contrast for assessing Crohn's disease, and the management of rumination syndrome.

As always, I hope this information encourages both ongoing learning and new insights.

Sincerely,

Gary R. Lichtenstein, MD, AGAF, FACP, FACG