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# New Techniques Drive Patient Enrollment for Trials

**T**he number of clinical trials for new drugs continues to grow, increasing the competition for patients. IMS data show that new drug-discovery technologies are fueling record worldwide growth. There are more than 13,000 studies projected for 2007, up from 9,000 just five years ago. Goldman Sachs data show that spending for larger U.S. clinical trials, Phases II and III, will rise from \$20.6 billion in 2006 to \$32.2 billion by 2010.

Yet the number of patients participating in trials is low. A telephone survey released by Medstat last year showed that only 3.9% of adults have participated in a trial. Less than one in five patients who considered participation actually did so. The advertising for clinical trials has built awareness, but there is a limit on who is available.

It is no wonder that a CenterWatch survey of trial sites reported that patient recruitment and enrollment is the second most time-consuming activity, after contract and budget negotiations. The same survey said 45% of respondents agree that patient enrollment and recruitment is a top cause of clinical-trial delays, up from prior years. In addition, almost every article about clinical trials acknowledges that trials run late. Another CenterWatch survey of sites said 70% of trials run at least one month behind schedule.

ical records from dictation. The analyst can electronically assess how many patients qualify under the inclusion/exclusion criteria of the sponsor, while preserving patient privacy.

The identification process also can establish whether mass media, such as radio or TV, are appropriate or whether to adopt more targeted efforts. These include getting referrals from other physicians, office literature, and emerging techniques, such as using advertising on Web search engines. Some organizations today are testing keyword advertising with search engine companies, for example, to reduce the media cost per enrolled patient.

## Stage 2 — Qualify

There has to be a structured process to learn about the patient and to ensure that the patient gets an appointment at the site. There needs to be a call-in center, Websites, or both.

Many consider the job done if they send a list of qualified patients over to the site, with no attention to the logistics. The ideal situation is to make the appointment for the patient immediately while the patient is still on the phone or online.

Smart companies today are building an enrollment management system **with a focus on patients.**

PharmaVOICE discovered that the solution for 74% of biopharmaceutical companies is to outsource patient recruitment. Why? There is a need for specialization and concentration on enrollment in the face of competition for patients.

Smart companies today are building an enrollment management system with a focus on patients at three major stages of recruitment.

## Stage 1 — Identify

It is necessary to find patients and to “fish where the fish are.” Traditionally, the sponsor or its agent does this exclusively through questionnaires sent to potential sites. Experienced managers know that the results overstate the available patients by at least a factor of two.

The more sophisticated approach uses both marketing research and electronic techniques. The research analyzes available patients based on disease prevalence patterns, ranking areas broadly and assessing prevalence in the area of each site. Within the site, it is possible to generate virtual med-

## Stage 3 — Manage

There needs to be a reporting and management system, supported by CRAs (contract research associates), who support sites and who make calls or visits. Sometimes things go wrong. In most large trials, for example, at least some sites never enroll the first patient, and they may even ignore referred patients.

In commenting on all its trials over the past six years, one major pharmaceutical company said 8% of investigators never enroll the first patient and another 11% enroll only one. In extreme cases, expensive media campaigns will gather patients, but then problem sites will not see them, wasting the time and money spent to recruit. An enrollment management system will provide early warning to prevent such outcomes.

Going forward, we can expect changes as competition forces adoption of newer and more effective processes for enrolling patients. Metrics and processes with data will create new standards of excellence. The industry should be prepared to embrace them. ■

**INCLINIX INC.**, Wilmington, N.C., is an enrollment CRO with experience recruiting investigators and patients for more than 130 diseases and therapeutic areas. For more information, visit [inclinix.com](http://inclinix.com).

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