

# CNS

## A Complex Therapeutic and Patient-Recruitment Market

An **explosion of new science** is leading to potential compounds to treat CNS diseases. **The challenge** for pharmaceutical companies and their partners **is recruiting and retaining patients for trials.**

### UNDERSTANDING THE BRAIN AND HOW IT FUNCTIONS HAS BEEN ONE OF THE GREAT, UNANSWERED QUESTIONS IN MEDICAL HISTORY.

As the healthcare community closes in on unraveling the mystery of the brain, conditions are being studied in more detail and solutions for these conditions are being aggressively sought. The biggest problem, however, is that central nervous system (CNS) diseases and conditions are so wide-ranging in their types, symptoms, and outcomes that the breadth of research in this area may equal that of the rest of the body. Equally problematic is recruiting for clinical trials to support this research.

CNS diseases range from neuromuscular conditions, such as ALS and Parkinson's disease to infectious conditions, such as meningitis and encephalitis, to depression and social phobia, to brain cancer, and to pain.

In all areas, doctors and researchers try to unravel the complexity of the human brain and its functions. But despite breakthrough medications and recent research advancements in the CNS product pipeline, brain-based conditions continue to affect millions of people of all ages.

CNS diseases affect an estimated 50 million Americans each year, according to the National Institute of Neurological Disorders and Stroke. Within the world's developed economies, it has been estimated that psychiatric and neurological conditions account for more than 15% of the disease burden, according to a recent report by Reuters Business Insight Ltd.

The number of people diagnosed with CNS disorders worldwide is steadily rising and in part is being driven by an aging population, improved diagnostic techniques, increased physician and patient awareness, and a gradual shift away from the social stigma traditionally associated with many psychiatric conditions, Reuters Business Insight analysts say.

An explosion of new science is leading to new compounds, for which trial participants will be needed for testing. According to Thompson CenterWatch, INDs for neuropharmacological drug candidates increased 10.43% in 2003 from 2002. This increase is higher than in other areas, including products to treat cardiovascular, gastrointestinal, reproductive and urological, and viral conditions (see chart on page 34).

"The CNS pipeline is the most robust in the industry, indicating that the need for new CNS therapies has been recognized and is being addressed," says Deborah Kniuksta, assistant director of patient recruitment at Kendle.

Furthermore, to maintain a competitive edge, pharmaceutical companies will need to take patient potential into account, through targeting niche CNS indications as a means of life-cycle management for blockbuster products under threat from generic competition, according to Reuters Business Insight. Increasingly, market opportunity lies in particular patient subsets for CNS disorders, for example severe Alzheimer's disease.



### Scott Connor

WE TYPICALLY DRAW A HARD LINE BETWEEN CHRONIC, AMBULATORY CONDITIONS AND ACUTE, DEBILITATING DISEASES because each of these broad categories requires a very different approach to recruitment.

In an increasingly competitive CNS market, companies also are looking to expand the number of CNS indications per product, as primary-care physicians and psychiatrists look to products that can treat a suite of disorders, particularly disease areas where comorbidities are frequent, for example depression and anxiety.

Pharmaceutical companies recognize CNS is an opportunity. Pfizer, for example, is investing 20% of its research budget in neuroscience research and development. Pfizer executives have said they consider this to be one of the last frontiers of drug discovery and development.

The global CNS market was valued at \$63.3 billion in 2003, an increase of 12.2% compared with 2002 revenue of \$58.1 billion, according to the Reuters Business Insight report. During 2003, the fastest growing area within the CNS market was Alzheimer's disease.

### Recruitment Challenges

The CNS patient population is one of the fastest growing markets with regard to clinical-trial recruitment efforts, says Scott H. Connor, marketing director at Acurian Inc.

"In terms of people in the United States actively seeking health information and clinical-trial opportunities, Acurian has witnessed a 30% increase in its patient panel of more than 8 million members for almost every neurological condition," he says.

Mr. Connor attributes this increase in patients who are seeking clinical-trial opportunities to growing disease prevalence and



Elizabeth Moench

**THE RECRUITMENT TACTICS WE HAVE IMPLEMENTED FOR CNS CONDITIONS**, including Alzheimer's disease, dementia, depression, schizophrenia, and Parkinson's disease, have all involved strategies that reach out to family members and caregivers to make them comfortable with the decision to participate in a clinical study.



Tom Sturgis

**MANY OF THE POTENTIAL PATIENTS FOR CNS CLINICAL TRIALS ARE NOT ABLE TO PARTICIPATE ON THEIR OWN** for a number of reasons. Recruitment, therefore, requires the activation of efforts through a caregiver constellation.

people taking a more proactive approach to their healthcare needs.

"There is a more substantial need for increased intensive patient-recruitment support across the spectrum of neurological conditions," says Donald J. Greene, VP of sales and marketing at Veritas Medicine Inc. "The increase in clinical-trial activity is due to the potential therapeutic benefits not addressed by today's array of approved CNS drugs."

CNS patient recruitment, however, lags behind patient-recruitment efforts in other areas, for example oncology and cardiology, for several reasons, according to Harry Mansbach, M.D., chief medical officer and VP of clinical development at Cortex Pharmaceuticals Inc.

He says patients who have brain-based diseases often have impairments in their thinking process — because of conditions such as dementia, epilepsy, or stroke — and, therefore, experience difficulty consenting to, and participating in, the clinical-trial process.

"Only about 15% of patients are aware of clinical trials in general, and, of those, only one-third will participate in any clinical trial," says Jim Kremidas, global enrollment optimization specialist at Eli Lilly & Co. "Patient recruitment for the CNS patient population, therefore, presents additional bar-

riers that must be addressed by the entire industry"

Mr. Connor says the three issues to be considered when recruiting patients with chronic CNS disorders are motivation, location, and condition.

"One of the largest call centers in the United States documented these as the three major trial disqualifiers for people recruited by traditional methods," he says. "Therefore, it is necessary to prequalify study candidates based on these requirements to help sponsors avoid the cost of recruiting to the general public."

According to Mr. Greene, the key to conducting recruitment effectively lies in conducting an honest, early recruitment feasibility assessment to determine the idiosyncratic challenges posed by a given study and the development of an effective recruitment plan well in advance of first patient in. That might include appropriate timelines and contingency plans.

"As most sponsors have come to discover, the marginal cost per patient for a trial in rescue mode is typically two to three times greater than the cost of the same patient com-

ing from a recruitment program initiated with the trial itself," he says. "Each condition represents a unique patient population, caregiver constituency, and physician relationships, all of which factor heavily in the outcome of a successful recruitment program. In addition, each trial presents its own set of characteristics, for example, number of sites, choice of principal investigator by specialty and referral network, standard of care vs. drug under investigation, and trial design issues, and so on, which must be factored into assessing the feasibility of recruitment."

Ms. Kniuksta adds that patient-recruitment efforts will benefit from the general population developing a better overall understanding of clinical trials.

"An effective strategy is to consider the impact that trial participation will have on the lives of patients and caregivers beyond the realm of study visits and research sites," she says. "Participation in CNS trials will improve when we are able to identify strategies that overcome the obstacles affecting patients and families as a result of trial participation."

Considering the vast nature of neurologi-

cal conditions, the recruitment challenges faced are substantial for trial sponsors, particularly when the increased number of studies being conducted is taken into account, Mr. Greene says.

"In the past, sponsors could count on a

fairly well-defined pool of expert investigators to provide them with the patients required for their studies," he says. "While this pool of seasoned investigators has expanded modestly over time, it has not kept up with the industry's pace of research in terms of access to the

## A GLOBAL CNS MARKET ANALYSIS

### LEADING GLOBAL THERAPEUTIC CATEGORIES

**THE GLOBAL CNS MARKET** totaled \$63.3 billion in 2003, an increase of 12.2% from 2002 revenue of \$58.1 billion.

**IN 2003**, the fastest growing CNS market studied was Alzheimer's disease, for which the value of branded drugs increased by 27.8% to reach \$1.8 billion.

**THE GLOBAL ANTIDEPRESSANT MARKET** was valued at \$15.5 billion in 2003, a moderate increase of 3.7% on sales in 2001 of \$14.9 billion.

**ALTHOUGH A LARGE PROPORTION OF PRODUCTS** within it have reached maturity, the largest CNS market – pain – recorded an increase of 2.4% over 2003 to reach \$19.6 billion.

**THE MIGRAINE MARKET** posted a 2.2% increase in value in 2003, to reach \$2.6 billion.

**THE SCHIZOPHRENIA MARKET** enjoyed another year of strong growth, with its value increasing 20.5% to reach \$10.6 billion in 2003.

**THE EPILEPSY MARKET** was valued at \$7.4 billion in 2003, an increase of 18.5% over its 2002 value of \$6.2 billion.

### LEADING GLOBAL PLAYERS

**OVER RECENT YEARS, THE GLOBAL CNS MARKET** has been dominated by four major players: GlaxoSmithKline, Johnson & Johnson, Eli Lilly, and Pfizer. The companies held a combined market share estimated at 67.3% of total branded revenue in 2003.

**GLAXOSMITHKLINE'S CNS PORTFOLIO** was the only portfolio to decline in value,

generating revenue of \$6.7 billion in 2003, down 1.5% from the previous year.

**IN 2003, J&J'S SALES** growth was the strongest in absolute terms, up proportionally by 21.9%, driven by sales growth of Duragesic, Concerta, and Risperdal.

**DESPITE THE CONTINUING DECLINE OF THE PROZAC FRANCHISE**, sales of which fell by 12.1% in 2003, Lilly's CNS franchise grew by 19.3% on the back of Zyprexa's sales performance.

**PFIZER IS THE MARKET LEADER** in terms of sales. The company's portfolio features blockbuster products such as Zoloft, Neurontin, Aricept, and Bextra/Celebrex, which together represented 81% of the total portfolio value of \$13.0 billion in 2003.

**OTHER PHARMACEUTICAL COMPANIES ALSO SHOWED GROWTH IN THE CNS ARENA:** Wyeth's sales growth was exceptionally strong in 2003, reporting growth of 23.5%, driven by rising Effexor sales, up 30.9% to \$2.7 billion in 2003; AstraZeneca's CNS portfolio continues to be dominated by Seroquel, which had sales growth of 29.9%, to \$1.5 billion in 2003; Sanofi posted sales growth of 15.6% in 2003 to \$2.8 billion; Abbott's sales grew by 5.4% in 2003, as modest sales increments related to Depakote were bolstered by growth from Ultane/Sevovane; Forest's growth was exceptionally strong in 2003, up by 38.0%, driven by sales of Lexapro, which reached \$879 million in 2003; and Novartis' CNS portfolio posted robust growth of 9.5% in 2003 reaching sales of \$2.4 billion in 2003 based on robust performances from Exelon and Tiletal.

Source: Reuters Business Insight Ltd., London. For more information, visit [reutersbusinessinsight.com](http://reutersbusinessinsight.com).



Donald Greene

**EACH NEUROLOGIC CONDITION'S PATIENT GROUP REPRESENTS A UNIQUE CONSTITUENCY WITH DISTINCT AND SPECIFIC BEHAVIORS AND PREFERENCES.**

*In some cases these conditions represent very small, targeted groups of patients who are best recruited directly through the specialists treating them.*

number of patients needed for clinical trials conducted today."

One of the most arduous portions of patient-recruitment efforts for CNS studies involves the initial patient screening visit and informed-consent process. Many of the diagnostic/evaluation tools required for trial protocols are extremely lengthy for CNS conditions to ensure that the subjects fall within the inclusion/exclusion criteria, adds Tom Sturgis, president of Integrated Clinical Trial Services.



Deborah Kniuksta

FOR MANY CNS TRIALS, WE DEVELOP OUTREACH MESSAGES THAT WILL TARGET FAMILY MEMBERS AND CAREGIVERS rather than the patient, especially if that patient is unable to respond to outreach and self-identify.

For example, Mr. Sturgis explains, the diagnosis assessments for Alzheimer's disease generally involve input from the potential patient, caregiver, and a clinician to establish a baseline from which expected improvement can be measured. Therefore, the person responsible for patient recruitment must understand that both patient and caregiver are going to be required to complete multiple tests and visits, keep diaries, and report observations.

"So many caregivers for Alzheimer's disease patients are overwhelmed by the condition that their loved one is suffering from that this extra burden can be too much for them," he says. "Sponsors and sites should design and implement caregiver programs that work in conjunction with the trial to allow the caregiver a few hours of respite while the patient is undergoing the long tests and procedures."

Christopher O'Brien, M.D., chief medical officer at Prestwick Pharmaceutical Inc. adds that for CNS clinical trials, proper selection of the study population is vital. Specifically, the inclusion and exclusion criteria must be stringent enough in Phase II and Phase III trials to minimize confounding factors, but broad enough to reflect real-world disease and to



permit recruitment as rapidly as possible.

Elizabeth Moench, president of Medici-Group Inc., agrees that patient recruitment for CNS studies requires extra attention.

"There is no one brush with which to paint a 'typical' scenario," she says. "CNS conditions more often than not impact the family. And the circumstances that bring families into centers are as unique as the patients themselves. Often family members have been struggling with a loved one's medical condition for some time and view a clinical study as a last resort. Families often are new to the system and are seeking direction and answers."

## Different Studies Require Different Tactics

According to Dr. O'Brien, for example, acute stroke intervention, for example,



Dr. Harry Mansbach

RECRUITING PATIENTS WITH NEUROLOGICAL DISEASES LAGS far behind patient-recruitment efforts in oncology and cardiology.

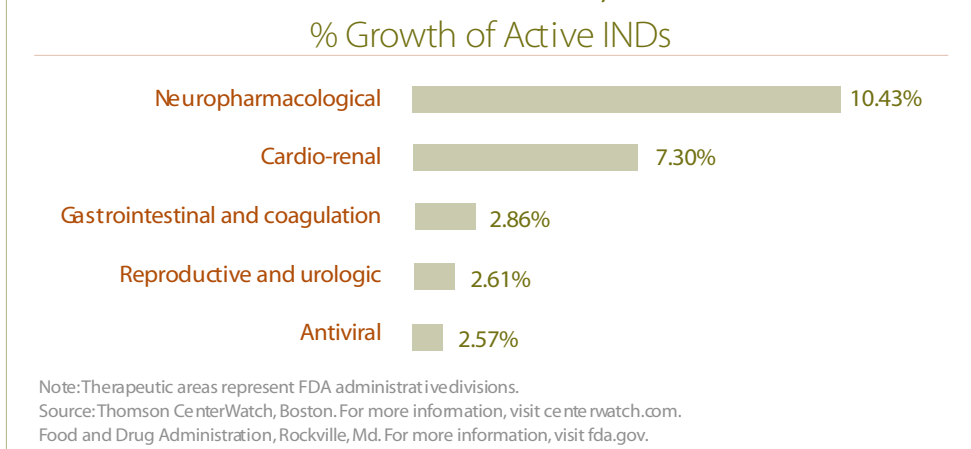
requires a very complex and regionally comprehensive network for patient and physician awareness and enrollment.

"The outcomes are fairly discrete, for example living or deceased, MRI infarct volume, or a stroke score," he says. "In contrast, slowly progressive disorders such as Alzheimer's disease depend on community-awareness programs to funnel patients into the research sites but the outcome measures are less clear. There currently is no accepted brain scan for Alzheimer's disease that indicates that an intervention worked. The clinical-development team must be expert in the therapeutic area with respect to the disease, enrollment challenges, and regulatory issues."

Because stroke is a moment-in-time condition, it is extremely difficult to recruit patients for a study compared with a chronic or even a progressive condition, such as Alzheimer's disease, Mr. Connor says.

"If a sponsor is developing a compound that requires immediate administration after

## SELECTED THERAPEUTIC GROWTH AREAS, 2002 TO 2003



the stroke, it's obvious that a recruitment advertisement isn't going to be effective," he says. "A sponsor needs to engage investigators who are either affiliated with an emergency-room department or have a referral network with an active emergency-room hospital. Even then a trial is a tough sell because of the condition of the patient; distraught family members are rightfully focused on the trauma of the event itself. To ask anyone in that situation to focus on the concept of clinical research, which is still a foreign topic to most people, and to read and sign an informed consent form is really tough. In those cases, the sponsor's message has to be crystal clear in terms of the benefits and requirements of trial participation; there is no margin for error. While stroke is prevalent, the universe of

investigators who can channel patients to such a study is very limited."

According to Dr. Mansbach, most trials try to recruit subjects who have suffered an acute stroke within a certain timeframe, often within six to 12 hours of the stroke onset.

"Unfortunately, most stroke victims do not quickly recognize what has happened to them, which leads to delays in medical treatment," he says. "Additional issues arise because stroke too often is considered a nonemergency diagnosis by healthcare systems, thus making it difficult to get patients to stroke-treatment centers in time to be entered into a clinical trial. Finally, in more severe stroke cases, issues of informed consent can arise since the patient may be unable to understand what is being asked of him or her."

## TELEVISION: A PATIENT-RECRUITMENT TACTIC FOR A POSTHERPETIC NEURALGIA TRIAL

### PATIENT RECRUITMENT FOR CNS TRIALS IS DIFFICULT, AND POSTHERPETIC NEURALGIA (PHN) IS NO EXCEPTION.

PHN is a painful condition resulting from an outbreak of herpes zoster, also known as shingles. The disease typically affects the elderly, with a cumulative incidence of 50% by 60 years of age and increasing to 80% in those over age 80.

In a recent U.S. Phase II trial to examine the effectiveness of a potential new therapy for PHN, a change in patient-recruitment strategy three months into the study expanded the reach of targeted messages to the elderly patient population to deliver 184 participants by the enrollment deadline.

Whereas feasibility data collected from investigative sites prior to study start-up indicated the availability of subjects for the trials, challenges such as a complicated study design, a transient condition, and patients not meeting the criteria (i.e., symptoms too mild for study inclusion or ineligibility as a result of prior medication use) were making it difficult to meet the enrollment goal. Site-initiated radio and print advertisements to recruit additional patients yielded a low

response rate, and, when coupled with a high rate of screen failures, resulted in few incremental subjects.

To reach a larger audience and drive eligible subjects to the sites, a broad-scale direct-to-consumer television campaign was launched in 21 markets nationwide in just four weeks.

One of the keys to success was reviewing the demographics of the viewers to drive placement of the ad schedules. The appeal to a larger audience was successful: while site-placed print and radio advertisements yielded 207 subjects for screening over a six-month period, television advertising resulted in 185 subjects for screening in just three weeks, resulting in the enrollment deadline being met.

Monthly site-motivation programs implemented by the sponsor and CRO helped to keep the study top of the mind with the investigators and site personnel and helped build momentum for the final enrollment push.

Source: Kendle, Cincinnati. For more information, visit [kendle.com](http://kendle.com).

## Enhancing the CNS Patient-Recruitment Process

Ms. Kniuksta says it is important to be aware of the size of the patient population being targeted and then, based upon specific protocol requirements, determine how these requirements will impact the size of the available patient pool. As treatment becomes more specific, she explains, the number of available patients generally decreases.

"For example, advertising for patients who are newly diagnosed with Parkinson's disease may be a useful enrollment tactic," she says. "But advertising for patients who have failed on specific therapies or who have developed psychosis will be much less effective and more costly because of the inclusion/exclusion specifications. In these cases, it may be wiser to devise alternate means of patient identification, such as using patient advocacy or support groups. Frequently, it is advisable to develop outreach messages that will target family members and caregivers rather than the patient, especially if that patient is unable to respond to outreach and self-identify."

Interactive training at investigator meetings also will help enhance patient-recruitment efforts, Ms. Moench says.

"A well-trained study staff can address CNS patient-recruitment issues by painting a clear picture of what the benefits of participation may be, while dispelling any unrealistic expectations," she says. "Recruitment companies need to involve sites in peer-to-peer sharing of best practices to ensure readiness for the patient-family encounter. A study staff's ability to exhibit empathy, to allow family members/caregivers and patients an opportunity to talk, to invite questions, to lay out as clearly as possible to both the family and patient what the study experience will be, including the timeline and commitment level involved, to identify areas of ambiguity, and to address misconceptions, creates an open environment where families are encouraged to speak freely and ask questions. This approach within the site yields positive results for recruitment and retention and leads to a successful study."

Investigators and coordinators can affect recruitment success, whether it's managing their own patient populations or managing referred patients who are recruited outside the practice, Mr. Connor says. The top quartile of sites will consistently out enroll the bottom quartile by a factor of four- to six-times.

"We've found that to be the case on more than 90% of the trials we support," he says.

## Sound Bites from the Field

### INDUSTRY EXPERTS ADDRESS THE CHALLENGES OF PATIENT RECRUITMENT WITHIN THE DIFFERENT AREAS OF CNS PRODUCT DEVELOPMENT.



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Phase I to Phase IV clinical trials for the pharmaceutical, biotechnology, and medical-devices industry. For more information, visit [gminstitutes.com](http://gminstitutes.com).

“Patient recruitment varies depending on available treatments. Currently, it is fairly difficult to recruit a placebo-controlled study in Parkinson’s or Alzheimer’s disease. But add-on treatments versus placebo are more acceptable. Patients with some illnesses, such as schizophrenia, may not recognize their illness by nature and can be reluctant about taking medications. The last decade has brought many new medications to market for depression, anxiety, schizophrenia, seizure disorders, and Parkinson’s disease, so we are on the right path. Not only must we recruit well but we need to find good patients. I believe good patient selection will reduce some issues, including the problem of placebo response. Educating the public is important. There are so many misconceptions regarding the level of care in clinical trials. We need to emphasize the high level of medical care received in a clinical trial versus a managed-care setting.”



**JOHN J. DENT JR.** is Patient Recruitment Director of Patient Interaction (Pi), The Clinical Trial Experts at First Marketing, Pompano Beach, Fla., which helps

facilitate, accelerate, and enhance the study enrollment and retention process. For more information, visit [patientinteraction.com](http://patientinteraction.com).

“Several potential barriers exist to enrolling CNS patients in clinical trials — the top two being impaired cognitive abilities associated with many of the CNS diseases and conditions and the resulting limited physical mobility, which can be moderate to severe. Likewise,

many CNS patients may be under the care of a surrogate or caregiver, be it a spouse or family member, who would have to elect participation on behalf of the patient. Several CNS conditions make it emotionally difficult for an individual to leave the home; others make maintaining a commitment to the study protocol quite challenging.

CNS patient-recruitment efforts can be enhanced by more clearly understanding the concerns and reservations of caregivers in looking to clinical research as a possible treatment option for their loved ones who may suffer from CNS disorders. Research should be done into these specific concerns, and any reservations should be taken into consideration when crafting messages to motivate caregivers to consideration. Clearly articulating the study expectations of prospective subjects and outlining the protections provided to human subjects in clinical research are vital to addressing any potential concerns.

The informed-consent process, in general, needs to be revamped so that it presents information in a more consumer-friendly way.

Additionally, creating a strategy that incorporates the proper mediums to reach caregivers is key to the success of any CNS patient-recruitment campaign. Understanding the demographics and psychographics of this target audience is instrumental to ensuring that the proper message and outlets are being used. Likewise, site support and site optimization are critical to recruiting the amount of CNS patients necessary for ongoing trials and to accomplish these goals within the timeframe required by the sponsor for completing the trials on time. Developing close ties and partnerships with CNS advocacy and support groups both on a national and local level is an important part of any recruitment campaign strategy. Both CNS patients and their caregivers turn to advocacy as clearinghouses for information on important new advances being made for the treatment of CNS disorders.”



**BILL SIETSEMA, PH.D.**, is VP of Clinical Development at Kendle, Cincinnati, a global CRO delivering innovative and robust clinical-development solutions to help the world’s

biopharmaceutical companies maximize product life cycles and grow market share. For more information, visit [kendle.com](http://kendle.com).

“In some CNS areas, for example stroke, the recruitment process can be compounded by the patient’s inability to sign a consent form. For instance, patients who have experienced an acute stroke may be unable to comprehend the consent form. In these cases, a legal guardian has to give consent, and this is a difficult thing to pursue when a loved one is seriously ill.

Additionally, patients who have had a stroke present a challenge because there is a limited time frame during which they can be assessed for inclusion in a prospective trial. Most stroke studies relate to first-time stroke patients who must be identified, screened, and assessed within a limited time window of being hospitalized. These patients are incredibly difficult and costly to enroll, given the dynamics of the disease and its sudden onset.”



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world’s leading pharmaceutical and biotechnology companies. For more information, visit [clinphone.com](http://clinphone.com).

“CNS conditions, such as depression, involve subjective criteria, and it is often a challenge to filter through large numbers of candidates to find those who truly qualify for a particular study. For example, in one depression study, almost 33,000 candidates responded to a recruitment ad, but there was no practical way to have a trained, qualified clinician evaluate each of the respondents. We used a validated interactive voice response (IVR) questionnaire to evaluate the huge volume of candidates in a very brief period of time. In the end, fewer than 700 of these potential subjects qualified for the study so a tremendous amount of clinician time and cost was saved.”



Dr. Christopher O'Brien

**WE NEED TO IMPROVE THE CLIMATE REGARDING PARTICIPATION IN RESEARCH PROJECTS AMONG PATIENTS AND FAMILIES. Patients face challenges regarding transportation, fears of privacy, concerns about the ethical conduct of studies, and so on.**

“For acute CNS trials, the investigator is critical because most of the subjects will be recruited from within. Therefore, sponsors and contract research organizations need to apply serious due diligence to finding and hiring sites that have successful trial experience for the indication, that have a sizable patient population within and outside the practice, that have access to and relationships with inpatient facilities when they are required, that can support the logistical

specifics of the protocol, and that are in a non-competitive situation. Too much focus is placed on what a site promises or on the reputation of an investigator.”

According to Mr. Sturgis, patient recruitment is not a commodity, and the low-cost option is not always an apples-to-apples comparison.

“Patient-recruitment efforts are improved when there is an understanding that each protocol provides unique challenges,” he

says. “The more intrusive the study design, the more difficult the patient population is to identify in each community; and the less time we have to develop and implement a strategy the greater the cost per patient enrolled.”

Pharmaceutical companies, he says, have to give the investigators the proper tools and tracking matrices to do the job more efficiently.

“The sponsor’s goal should be to identify and predict a physician’s probable enrollment based on his or her in-house abilities,” Mr. Sturgis says. “This is not a simple mathematical model based on the total number of patients required divided by the number of sites and again divided by the number of months in the projected recruitment period for an enrolled patient-per-month average.” ♦

PharmaVoice welcomes comments about this article. E-mail us at [feedback@pharmavoices.com](mailto:feedback@pharmavoices.com).

## EXPERTS ON THIS TOPIC

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