

Central Nervous System // Overview of Capabilities

Many conditions of the central nervous system signal a loss of control – be it muscles, memory, pain levels, or even mood. BBK recruitment and retention campaigns offer information and motivation that are delivered with empathy and empower patients to take action. With the right materials, training, and referral motivation from BBK, study staff facilitate both consent and participation, and achieve enrollment targets on time.

FREED MS II

// Multiple Sclerosis (MS)

Across all stages of MS, BBK has successfully supported many studies for this condition with care, concern, and creativity. Communications meet patients at their stage of disease, helping them to consider not only the potential benefits of participation in a particular study, but also the long-term approach to their care.



The Young Adult and Pediatric Bipolar Study

// Psychiatric Conditions

Conditions like schizophrenia, bipolar disorder, depression, and addiction are insidious and overwhelming, take many forms, and strike all ages and cultures. Over many years and across many studies, BBK has created compassionate and compelling campaigns that achieve enrollment by helping patients to understand their options.

MIGRAINE

// Migraine

BBK has conducted many campaigns – both patient recruitment and public health awareness – to help bring new migraine treatments to market and to raise migraine to the level of a legitimate medical condition. Our work in this area reflects the importance of understanding the patients' experience and their motivations.



// Epilepsy

BBK has successfully supported numerous epilepsy studies. We have also conducted a wide range of market research to determine study feasibility and country and site selection. Our campaigns have achieved enrollment by using a variety of tactics, tailored to the needs of the protocol and to the target patient.



// Alzheimer's Disease

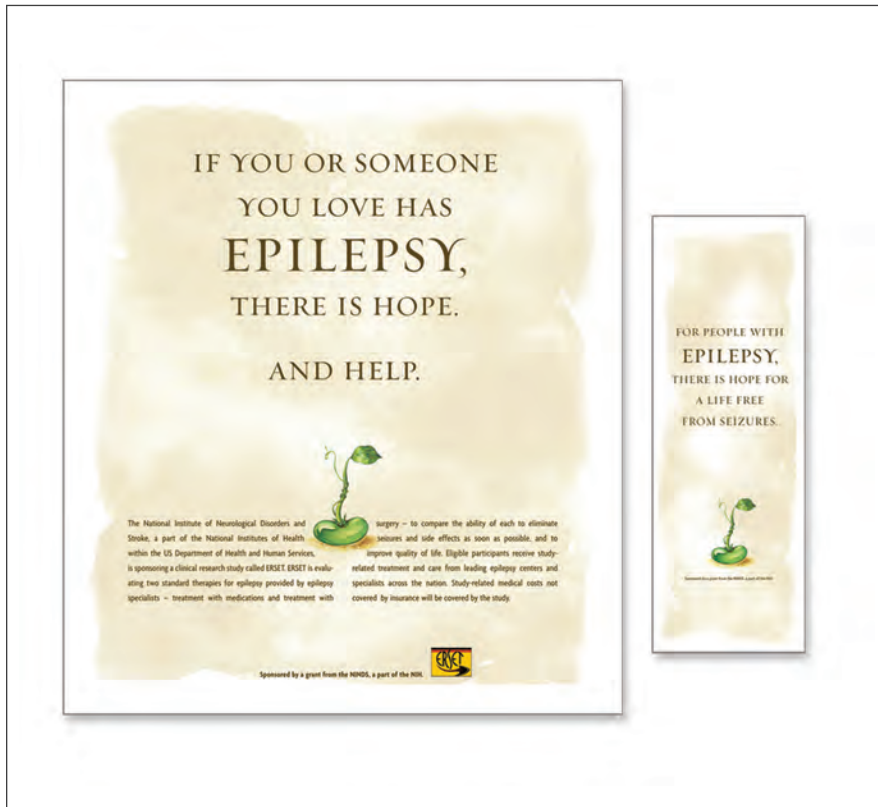
Because Alzheimer's renders many patients incapable of providing informed consent, BBK's recruitment programs have focused on supporting and informing caregivers just as much as patients. Appreciative feedback from caregivers, the patients in their care, and sites has reflected the resonance of our messaging.

DYSLEXIA

// Dyslexia

In the early planning stages of international dyslexia studies, BBK's multicountry market research assessments have helped define both the ideal investigator specialty and the parameters of the condition for each nation. The results of these assessments assist sponsor clinical teams in selecting countries and sites, and in planning recruitment support.

Surgical Procedure Study // Epilepsy in Children



Education Matters // BBK incorporated medical findings from highly authoritative epilepsy experts into campaign recruitment materials to support enrollment of this landmark study. Target audiences were educated about the potential benefits of early, aggressive treatment of epilepsy – including surgery – in children and adolescents and were motivated to consider the study as a worthy treatment option.

OUR INVOLVEMENT

Before First-Patient-In Date

COUNTRY

United States

} 12 Total Sites

AUDIENCES

Children and Adolescent Patients

Parents

Referring Physicians

Site Staff

} Most Important to Engage

KEYS TO ENROLLMENT

Site-based In-reach

Media Outreach

100

Number That Counts // A change in perception was needed to enroll 100 pediatric patients in this landmark epilepsy study in which a surgical procedure was being evaluated. Usually a “last resort” intervention for older adults, surgery was presented in outreach materials as offering the best promise for young patients to possibly live seizure-free lives based on the research of U.S. epilepsy experts.

Objective // Enroll 100 patients with epilepsy within 10 months for a two-year clinical research study

Challenges // Brain surgery as a study treatment option; length of study; limited media budget

Results // BBK enabled study sites to meet their individual recruitment targets on schedule and within budget

Expert Analysis



The Early Randomized Surgical Epilepsy Trial (ERSET) was conducted to determine if brain surgery would reduce the frequency of seizures in children and young adults with the most common form of epilepsy. Messaging was a key ingredient in presenting the study as an opportunity to potentially eliminate seizures and improve the quality of life of these young patients. BBK developed a comprehensive patient recruitment toolkit designed to influence the perception among target audiences – doctors and parents – that these treatment options were strictly for adults. The study required that parents and pediatric patients elect the surgical procedure before the standard series of medications had failed. By clearly articulating the study opportunity, all 12 sites achieved their enrollment goals on time.

Public Education Initiative // Headache Pain



Big Idea // BBK created an award-winning public education initiative for the world's leader in headache therapy – a touring visual art show with headache-inspired art by sufferers – designed to legitimize severe headache as a bona fide illness. The award-winning campaign drew national attention and sent more severe headache sufferers to their doctors.

OUR INVOLVEMENT	
Awareness Campaign	
COUNTRY	
United States	100 cities
AUDIENCES	
Headache Sufferers	Key Demographic
Untreated Headache Sufferers	
Physicians	
Medical Community	
KEY TO ENROLLMENT	
Headache-Inspired Art	

2

Number That Counts // Seek care.

These two simple words were the call to action central to helping the world's leader in headache therapy prevail against its first competition in decades. The words, as well as the art created by fellow sufferers in BBK's landmark public education campaign, inspired the untreated to see their doctors.

Objectives // Help the leader in headache therapy beat competitors with superior brand recognition; reach headache sufferers and get them to seek care

Challenge // Linking the big idea of the touring headache-inspired art show to the action of patients seeking care

Results // Coast-to-coast media coverage resulting in widespread brand recognition; 15 creative awards for campaign

Expert Analysis



A simple call to action – “seek care” – formed the cornerstone of a landmark public education initiative designed to legitimize severe headache as a real illness. The centerpiece: a touring exhibit of headache-inspired art created by sufferers the

mselves. Championed by former Surgeon General Dr. C. Everett Koop, the exhibit traveled to 100 cities in a four-year tour de force that generated coast-to-coast media coverage and earned 15 awards. Moreover, this landmark campaign supported the client's key marketing goals: it drove previously untreated sufferers to seek care and forged lasting ties with physicians.

Phase II Study // Multiple Sclerosis (MS)



Encouraging a Proactive Approach // This study required patients who had experienced a first “event,” but who were not yet officially diagnosed with MS. Because most potential study participants would be young and otherwise healthy, they may not yet identify as MS patients.

OUR INVOLVEMENT	
Before First-Patient-In Date	
COUNTRY	
United States	42 Total Sites
AUDIENCES	
Patients	Most Challenging to Motivate
Family Members	
Study Coordinators	
Study Team	
KEYS TO ENROLLMENT	
Study Positioning	
Study Messaging	

1

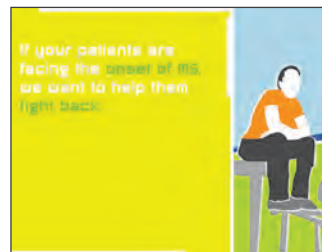
Number That Counts // Multiple sclerosis cannot be definitively diagnosed until at least two events have occurred; however, this study sought patients who had experienced just one event that might become part of an eventual diagnosis of MS.

Objective // Recruit 120 patients who have had an event, but not an official diagnosis of MS, to a Phase II study investigating an approved cholesterol treatment for delaying the onset of MS

Challenges // Conveying unnerving messages to patients who were young and otherwise healthy, and who did not have a definitive diagnosis

Results // Increased enrollment, study profile, and funding with underwriting foundations

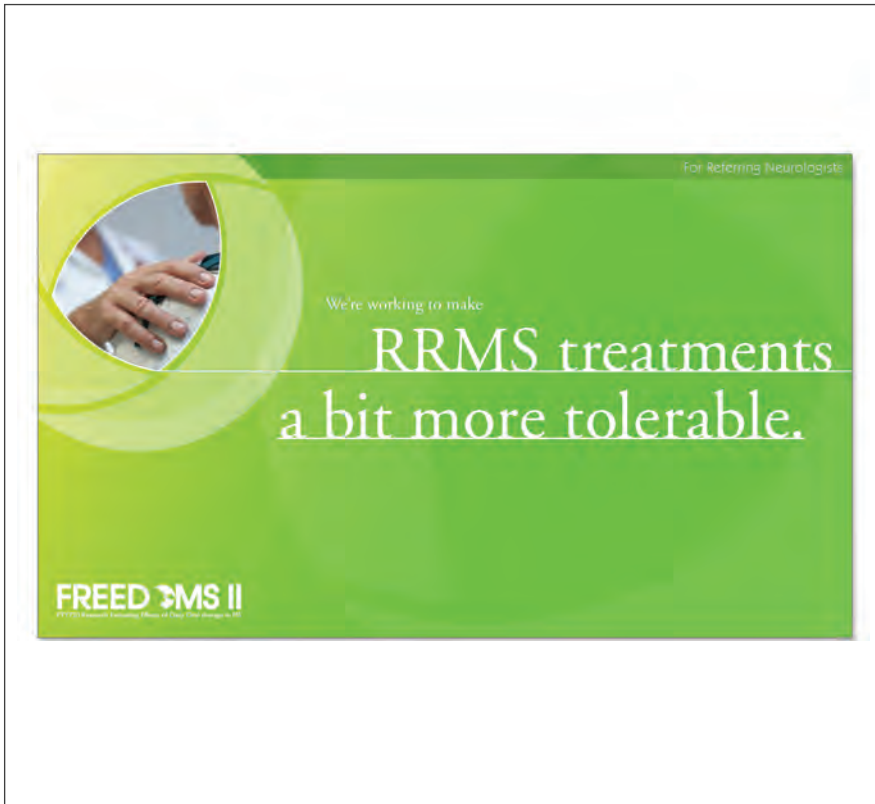
Expert Analysis



Communication with this audience would have to be sensitive, yet hard-hitting enough to be effective. BBK positioned study participation as a means of proactively responding to the potential diagnosis, rather than taking the standard approach of watchful waiting. BBK’s campaign

successfully communicated a proactive message that motivated these patients to participate in the study. The campaign was so effective that it helped the sponsor increase both its profile and funding with underwriting foundations.

Phase III Study // Multiple Sclerosis (MS)



A Proven Approach // Well-trained site staff armed with strategic recruitment tools and tactics made the difference in enrolling this MS study on time. With BBK's support and consultation, rejuvenated study staff built effective relationships with both potential participants and referring physicians that bolstered qualified referrals.

OUR INVOLVEMENT	
After First-Patient-In Date	
COUNTRY	
United States	} 100 Total Sites
AUDIENCES	
Patients	} Most Critical to Engage
Caregivers	
Site Staff	
KEY TO ENROLLMENT	
Study Messaging	

1

Number That Counts // Messaging that resonated with the MS patient population was one of the key tactics BBK developed to get enrollment back on the right track. "What if you could take one pill a day to treat your RRMS?" was the question that sparked interest in the study opportunity and prompted potential participants to learn more about a novel oral treatment option.

Objective // Reinvigorate patient recruitment and retention to achieve on-time study enrollment

Challenges // Placebo arm; wash off requirement

Results // BBK support helped sites get back on track to achieve on-time enrollment; raised awareness about a first-of-a-kind investigational oral drug

Expert Analysis



BBK conducted site assessments and discovered that site staff were enthusiastic and dedicated to enrolling the protocol, but lacked the resources to do so. BBK developed a comprehensive recruitment toolkit, providing study staff with proven tools and techniques to successfully enhance recruitment. By clearly positioning the study as a worthy treatment option for MS patients experiencing intolerable side effects from standard of care injections, BBK was able to address concerns about the placebo control arm – an obstacle that otherwise was likely to deter physicians from referring their patients. To address compliance and retention issues, BBK developed and trained site staff on effective relationship-building strategies to keep patients motivated to complete their study participation.

BBK conducted site assessments and discovered that site staff were enthusiastic and dedicated to enrolling the protocol, but lacked the resources to do so. BBK developed a comprehensive recruitment toolkit, providing study staff with proven tools and techniques to successfully enhance recruitment. By clearly positioning

Phase III Study // Parkinson's Disease



Tools of the Trade // BBK's recruitment capabilities were tapped to optimize patient enrollment. Using our sophisticated tools to assess and rank potential study sites, BBK pinpointed the sites most motivated to enroll patients and provided them with patient education and retention materials to get the job done.

OUR INVOLVEMENT	After First-Patient-In Date
COUNTRY	United States
AUDIENCES	Patients Caregivers Site Staff
KEY TO ENROLLMENT	Site Motivation

25 Total Sites

Most Important to Engage

9

Number That Counts // The nine study sites had lost their motivation to recruit. BBK created individualized local and centralized outreach materials that engaged patients and their caregivers with compelling information about a new drug. The treatment option offered the potential of making the debilitating side effects of the most effective Parkinson's drug more tolerable.

Objectives // From the 25 study sites, select and support the nine most motivated sites with recruitment materials to bolster patient screening and enrollment

Challenges // Limited number of eligible patients due to commonly prescribed exclusionary drugs; multiple time-consuming site visits; competing clinical studies

Results // Screening and enrollment re-energized by site-specific outreach campaigns

Expert Analysis



To support the nine sites in achieving their enrollment goals, BBK created individual recruitment campaigns. Using its proprietary approaches to site assessment, BBK first determined the strengths and weaknesses of each site and then used the findings to plan local and centralized outreach. Study staff were motivated to present study participation as an opportunity to benefit both patients and their caregivers. The possibility of a better quality of life motivated potential participants to consider the study as a worthy treatment option.

Phase IV Study // Partial Epilepsy



Forward Motion // With enrollment falling behind schedule, the sponsor asked BBK to identify and provide solutions to country-specific recruitment challenges. To this end, BBK conducted a comprehensive feasibility and cost benefit analysis, and identified the precise countries in which to conduct recruitment activities.

OUR INVOLVEMENT

After First-Patient-In Date

REGIONS

Asia Pacific

Europe

Latin America

70 Total Sites
in 19 Countries

AUDIENCES

Patients

Investigators

Site Staff

Most Difficult
to Engage

KEYS TO ENROLLMENT

Creative Concepts

Direct-to-Patient Outreach

7

Number That Counts // BBK's expertise in evaluating and analyzing recruitment opportunities was key to reinvigorating this global epilepsy study that was facing enrollment shortfalls. Through a comprehensive assessment of the study countries, BBK was able to identify the seven countries that could help put study recruitment back on track so that target enrollment would be met on time.

Objective // Reinvigorate study site recruitment to enroll 570 patients for a 19-country clinical research study

Challenges // Lack of cost benefit in some countries; availability of anti-epileptic drugs; placebo arm; limited budget

Result // Direct-to-patient outreach increased patient screening by 31 percent

Expert Analysis



The enrollment timetable for this multicountry study comparing two epilepsy medications was unlikely to be met before BBK was brought in. After a comprehensive analysis of the study landscape, BBK recommended and implemented outreach in seven of the 19 countries – and only in those countries with a healthcare system that provided epilepsy patients a clear motivation to participate. Compelling creative concepts and culturally adapted and localized patient materials clearly articulated the study opportunity to potential participants across all countries in their own language. And reallocation of the study budget ensured that effective print advertising with local site contact information was placed only in the identified countries.

Phase III Study // Pediatric Bipolar I Disorder



Distinctive Campaign // Not only did BBK's distinctive campaign garner significant response, but it did so with only a small budget. This was because the central visual concept accurately and artistically expressed the condition in a manner that successfully crossed cultures, thereby simplifying and streamlining cultural adaptation.

OUR INVOLVEMENT

Before First-Patient-In Date

COUNTRIES

Argentina

Mexico

United States

40 Total Sites

AUDIENCES

Parents

Children and Adolescent Patients

Study Investigators

Referring Physicians

Most Difficult to Engage and Motivate

KEYS TO ENROLLMENT

Creative Concept

Study Messaging

3

Number That Counts // BBK's creative campaign successfully engaged the three key target audiences: 1) for parents, it presented a portrait of their child that motivated them to seek help; 2) for patients, it expressed what they were feeling; and 3) for physicians, who were enthusiastic about the materials, it energized their efforts. Ultimately motivating all three audiences was the key to enrollment.

Objective // Recruit 190 patients for a multinational study seeking a pediatric indication for an approved treatment for bipolar I disorder

Challenges // Investigational drug commonly prescribed off-label; parents wary of psychiatric meds; modest budget

Results // BBK enabled the study sites to meet their individual targets and the study enrolled on time

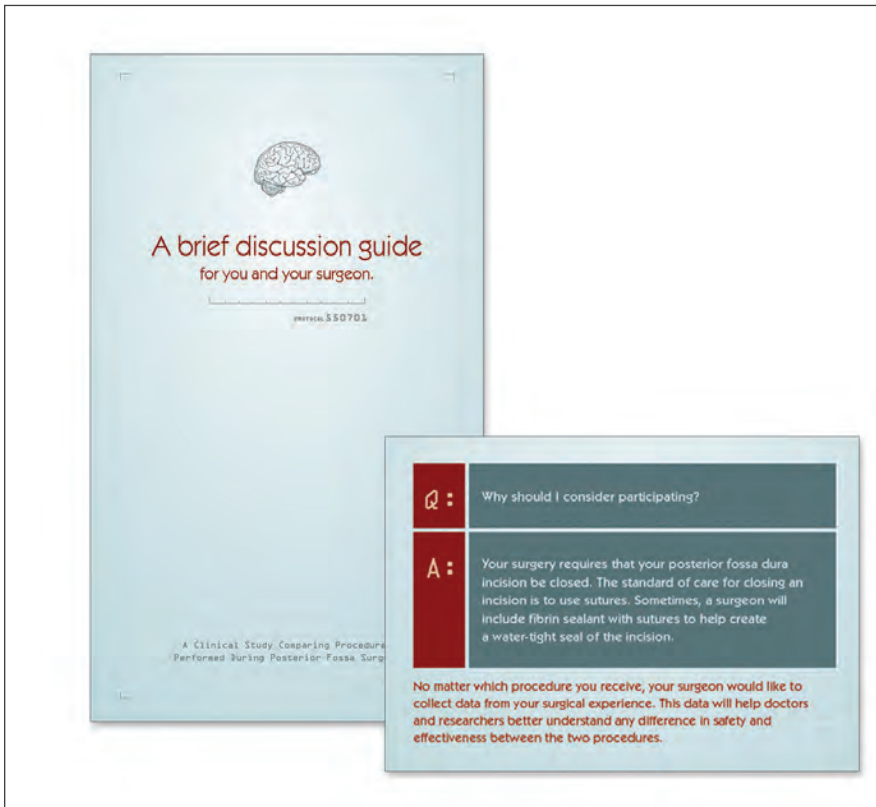
Expert Analysis



The Young Adult and Pediatric Bipolar Study

Although there was no drug approved specifically for pediatric patients at the time, this multinational study faced significant recruitment challenges. Most diagnosed patients were likely to be receiving drug off-label and would be unwilling to wash off; parents of undiagnosed patients were wary of psychiatric medications given recent reports of a rash of children on adult antidepressants attempting suicide; and, in Latin America, cultural mores impeded discussions of psychiatric problems, even with physicians. BBK's solution focused on the undiagnosed or newly diagnosed, accurately and respectfully expressing empathy for both parents and patients and leveraging the personal care offered through the study. In the end, the study enrolled early.

Exploratory Phase II Study // Posterior Fossa Surgery



Identifying and Motivating Investigators // Facing major delays in site initiation, this study sought 15 new sites to increase enrollment rates. BBK's site selection provided 40 highly qualified sites and our creative campaign helped investigators overcome the challenge of explaining a complex randomization process. BBK significantly increased the enrollment rate.

OUR INVOLVEMENT	After First-Patient-In Date
COUNTRY	United States
AUDIENCES	Patients
	Investigators
KEY TO ENROLLMENT	Understanding Motivations

19 Sites, Seeking 15 More

Most Difficult to Motivate

2

Number That Counts // BBK brought to bear the two-fold solution of 1) site selection to boost site initiation rates; and 2) creative materials to facilitate informed consent rates. Helping patients know their options, and inspiring physicians to approach and consent more study candidates led to success. A thorough knowledge of the audiences and how to motivate them made the difference.

Objectives // Increase enrollment rates; identify 15 new sites.

Challenges // Fewer than half of all sites were activated; explaining study randomization kept surgeons from introducing the study to and discussing it with eligible patients.

Results // BBK provided 40 top-ranked sites, tools to support investigator approach and consent rates, and ultimately increased enrollment rates.

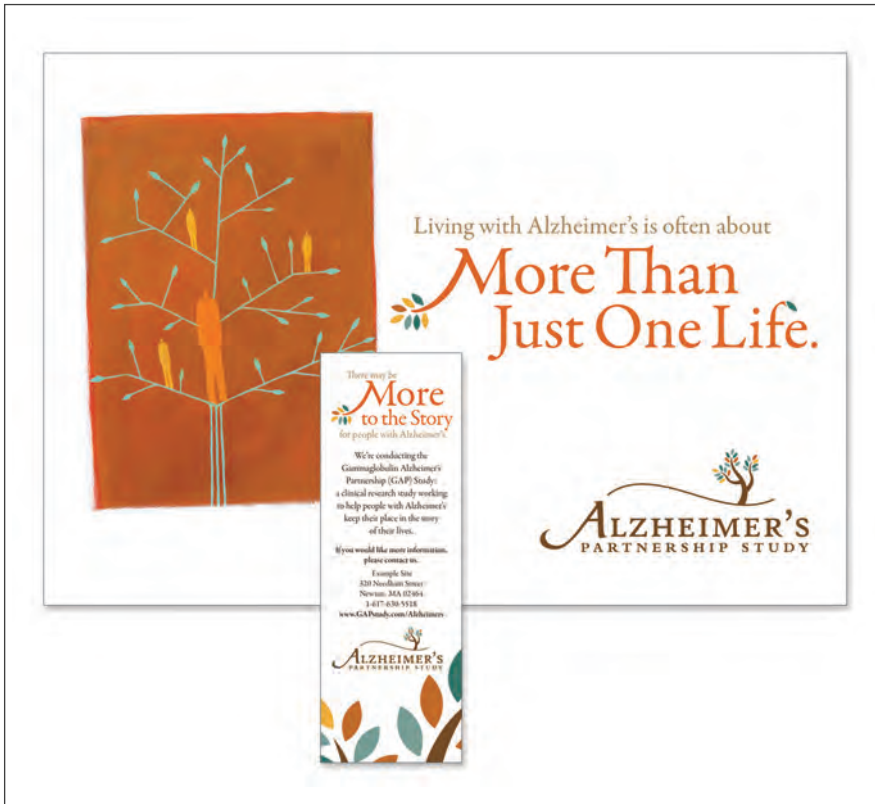
Expert Analysis



Physicians hesitated to bring up study participation due to a concern that patients would doubt their technical abilities when they explained the randomization design – to either wound sealant or surgical technique. BBK's solution was to provide investigators with a more accurate positioning – that

they would make the best decision for patient care at the moment of surgery, even if it meant removing patients from the study. This messaging was embedded in the materials, making it easy for both patients and investigators to communicate. To further inspire surgeons, BBK produced a newsletter that ranked investigators by enrollment numbers, thus subtly appealing to their competitive natures. Enrollment rates increased significantly.

Phase III Study // Mild to Moderate Alzheimer's Disease



It Takes Two // As with many Alzheimer's studies, this one needed to enroll patients who relied on a dedicated caregiver. Consequently, this sponsor needed not one but two informed consents for every randomized patient: one from the patient, and another from his or her caregiver. BBK was brought on to provide the expert messaging needed to overcome this enrollment challenge.

OUR INVOLVEMENT	After First-Patient-In Date	
COUNTRY	United States	} 360 Patient / Caregiver Teams Needed
AUDIENCES	Caregivers Patients	
KEY TO ENROLLMENT	Multi-Audience Messaging	} Crucial Facilitators

2

Number That Counts // In order to enroll one patient into the study, two people needed to be approached, informed, and consented. It took BBK's messaging savvy to speak both to patients' current needs and to caregivers' long-term concerns about their own future with this condition and its treatment.

Objective // Enroll 360 patients and their caregivers within a year

Challenge // Communicate this study opportunity to two related audiences with different perspectives on the condition

Results // A recruitment campaign comprised of educational, outreach, and retention materials that spoke to patients and caregivers, and fully explained the study's current and future implications for all participants

Expert Analysis



BBK's insight helped the sponsor address a key messaging question: how can recruitment materials not only motivate patients, but also address caregivers about the future of Alzheimer's treatment both for the patient and potentially for the caregivers themselves? BBK responded

with a campaign that spoke compellingly to a full spectrum of practical and emotional concerns for both caregivers and patients. This included everything from the time investment of each study visit to the importance of contributing to potential future treatment options for the next generation of patients with Alzheimer's.