

Psychopharmacology // Overview of Capabilities

Whether neurological or psychological in nature, conditions that affect mood and behavior often carry a stigma that can be just as emotionally taxing as the illness. At BBK, we prime our campaigns with information that elevates the discussion of the condition, dispels fears, and empowers patients to take action to improve their health, while providing study staff with the means to maximize referral conversion to enrollment.



// Bipolar Disorder

BBK has enrolled studies of pediatric and adult bipolar disorder across the globe. As these studies can be very hard to enroll – patients are often treatment-resistant or non-compliant – BBK’s campaigns have focused on investigator-patient relationships, and on ensuring that each campaign is targeted to the right national and cultural audience.



DEPRESSION OVER 65

// Depression in the Elderly

In the elderly, the symptoms of depression can be very different and very difficult to recognize. BBK’s outreach to seniors with depression has always been mindful of this, presenting each study opportunity as a sensitive and viable treatment option that these elderly patients may want to consider.



// Major Depressive Disorder (MDD)

While there are many effective treatments available for MDD, as many as 30 percent of patients are either treatment-resistant or experience significant side effects. Our extensive experience recruiting MDD studies gives us the insight needed to both reach out to and drive response from these hard-to-motivate patients.



// Bipolar Depression

Patients experiencing bipolar depression can be particularly difficult to recruit. They are often resistant to their treatment or ambivalent about it, and are exceptionally hard to motivate. BBK recruitment programs for bipolar depression studies have thus focused on the investigator-patient relationship that is crucial to enrollment success.

FOCUSING ON
a clinical research study



// Attention Deficit Hyperactivity Disorder

Coping with this condition is difficult enough, but asking parents to consider study participation – either for themselves or for a child – can be a daunting request. In BBK’s experience, campaigns that express the empathy and commitment of the physician are the most successful in capturing patients’ and parents’ interest in study participation.



// Alcohol Dependence

BBK has enrolled a variety of alcohol dependence studies, and has found the key to success is two fold: leverage well-defined key messages in both outreach and study materials, and ensure superior site selection, assessments, and individualized recruitment plans are part of the campaign. BBK knows these are the essential elements of on-time enrollment.

Phase IV Study // Adolescent Bipolar Depression



Straight Talk // BBK created a recruitment strategy that provided a strong but sensitive call to action. Site training and consultation enabled study staff to communicate effectively with adolescent patients and concerned parents, as well as referring physicians and media outlets, to generate patient referrals.

OUR INVOLVEMENT	
Before First-Patient-In Date	
COUNTRIES	
United States (including Puerto Rico)	} 35 Total Sites
Mexico	
Russia	
Turkey	
AUDIENCES	
Adolescent Patients	} Most Critical to Engage
Parents	
Physicians	
KEYS TO ENROLLMENT	
Media Outreach	
Study Messaging	

2

Number That Counts // Empathetic messaging was critical to generate interest in study participation. BBK created targeted recruitment materials that provided concerned parents with a greater understanding of the nature of their child's depression, and acknowledged the significant impact that pediatric bipolar depression can have on the family as a whole.

Objective // Support the recruitment of 300 adolescent patients with bipolar I disorder for a multinational study evaluating the effects of treating this population's major depressive episodes with an FDA-approved drug for adults with bipolar depression

Challenges // Parents cautious about psychiatric meds; study drug side effects, including significant weight gain; no placebo control arm in majority of competing research studies

Results // Significant increase in prequalified referrals; study projected to enroll in significantly less time than allotted based on screening rates

Expert Analysis

ADOLESCENT BIPOLAR DEPRESSION RESEARCH STUDY

Brought in to help study sites jump-start their recruitment efforts, BBK created a culturally adaptable recruitment toolkit for all 35 sites worldwide. By devising a balance between creative appeal and practical information, the patient materials simultaneously engaged adolescents as the target audience and parents as the key decision-makers. A media assessment survey of U.S. sites generated the findings BBK used to help site staff implement a localized media campaign of print, Web, radio, and television – all of which drove highly qualified referrals to study sites and increased top-of-mind awareness among site staff. The result: screening rates increased significantly and the study was projected to enroll well ahead of schedule.

Phase II Study // Alcohol Dependence



Whose Terms Are Best? // This study was evaluating an agent intended to help alcohol-dependent individuals moderate their drinking – a design that challenged many assumed principles of substance abuse management. BBK was tasked with developing a creative campaign that carefully but confidently inserted this study into the sensitive discussion of how to succeed in a struggle with alcohol.

OUR INVOLVEMENT

After First-Patient-In Date

COUNTRY

United States

20 sites

AUDIENCES

Patients

Support Community

Most Difficult to Engage

KEY TO ENROLLMENT

Messaging

2

Number That Counts // The media campaign BBK developed served 2 critical audiences: patients searching for different ways to address their alcohol dependence, and the many entrenched advocates of an “all-or-nothing” abstinence approach to managing this condition.

Objectives // Support the recruitment, consent, and randomization of nearly 400 patients in a year

Challenges // Study’s goal was at odds with many common disease management paradigms; placebo arm

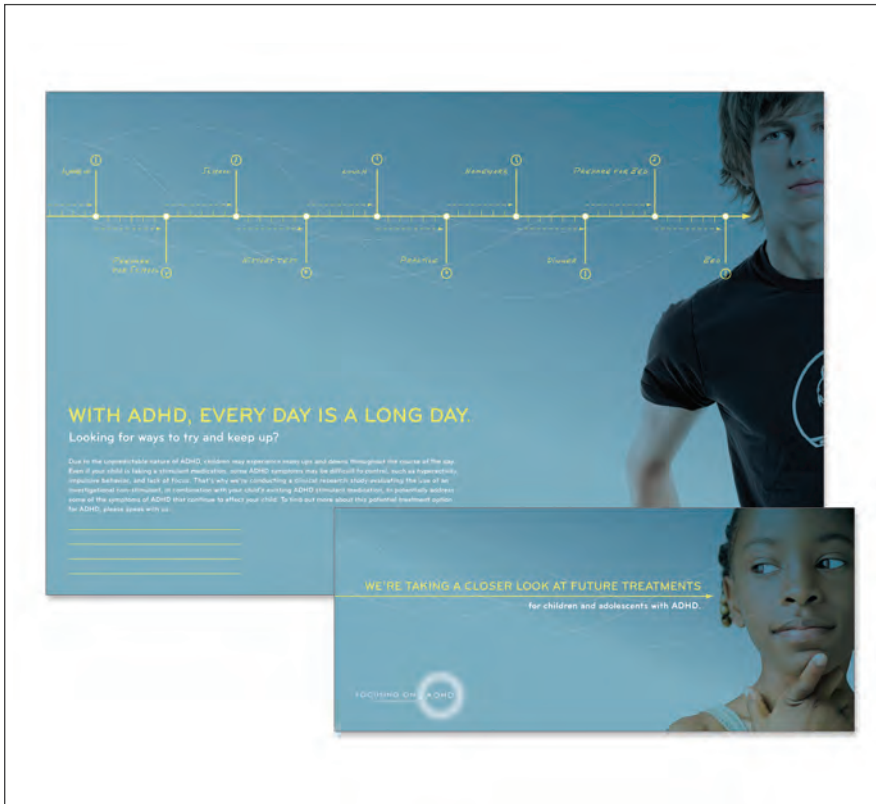
Results // Rapid recruitment and enrollment achieved well ahead of schedule

Expert Analysis



Pharmacological methods of treating substance abuse are a relatively new phenomenon – and many vested interests are still sensitive to the idea of using one drug to help manage dependence on another. To recruit patients for this study, BBK had to deploy creative that effectively negotiated with the many prominent voices that declare “cold turkey” the only way to successfully treat alcohol dependence. The campaign BBK launched did just that: it spoke to patients’ need for approachable, less daunting treatment options, while also acknowledging that the best “terms” to set for patients’ treatment are the ones the patients negotiated themselves. This sympathetic but straightforward message was delivered through a robust, multipronged media effort that included TV, radio, print, and online tactics. Full enrollment was achieved well ahead of schedule.

Phase III Study // Attention-Deficit Hyperactivity Disorder (ADHD)



Back on Track // On-time enrollment of this ADHD study was unlikely before BBK took over recruitment. With the launch of a multifaceted outreach campaign, patient referrals picked up exponentially, and increased screening and enrollment enabled reinvigorated study sites to achieve their recruitment goals.

OUR INVOLVEMENT	After First-Patient-In Date
COUNTRY	United States } 54 Total Sites
AUDIENCES	Pediatric Patients Parents } Most Critical to Engage
KEYS TO ENROLLMENT	Multipronged Outreach Site Support Consultation

4

Number That Counts // An effective mix of print, broadcast, and online media bolstered recruitment of this study in the last four months of the year-long enrollment period. Along with site support consultation, site and CRA coaching, and referral management, BBK's efforts accomplished what was thought to be impossible: full enrollment with more than four weeks to spare.

Objective // Drive a high volume of prequalified referrals to meet last-patient-in (LPI) date

Challenges // Psychostimulant requirement; placebo arm; weight and BMI eligibility criteria; seasonal recruitment issues

Result // Study enrolled a month ahead of schedule due to steady volume of referrals and significant increases in sites' screening and enrollment activities

Expert Analysis



Seven educational forums, two phases of centralized print and radio advertising, and three months of Web-based outreach helped BBK revitalize this ADHD pediatric study.

Before BBK stepped in, sites had enrolled in eight months only 40 percent of the required 441 patients. In four short months, BBK's comprehensive outreach campaign generated parents' interest in study participation for their children in impressive numbers: sites increased screening activity by 86 percent and enrollment activity by 133 percent. BBK's Web-based patient recruitment management system, TrialCentralNetSM, helped keep track of recruitment efforts, ROI, and resource redeployment needs. End result: study screening and randomization goals were met more than a month ahead of schedule.

Phase III Study // Bipolar I Depression



Supporting the Sites // BBK's successful recruitment strategy and tactics offered both a strong and sensitive call to action, and the training and support necessary for sites to communicate effectively with local media outlets, caregivers, and patients themselves.

OUR INVOLVEMENT	
Before First-Patient-In Date	
COUNTRIES	
Australia	} 76 Total Sites
India	
United States	
AUDIENCES	
Patients	} Most Difficult to Motivate
Caregivers	
Site Staff	
KEY TO ENROLLMENT	
Site Support	

3

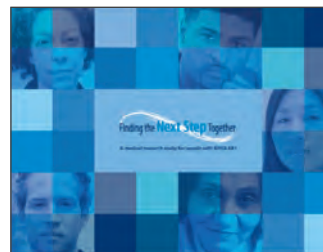
Number That Counts // BBK's campaign helped enroll the 282 patients required for this study in less than eight months – about three months ahead of the sponsor's scheduled end date. A full array of tactics, including materials directed at patients and caregivers, supported sites in effectively communicating with prospective participants about the study opportunity.

Objective // Enroll 282 patients in a bipolar 1 depression study within 11 months

Challenge // Successfully motivate a difficult-to-engage audience

Result // Enrolled the study three months ahead of schedule

Expert Analysis



Motivating patients with bipolar 1 depression to respond to this clinical study opportunity required the right tactics and messaging, as this audience has a particularly hard time concentrating its energy and taking action. Motivating sites to effectively disseminate information was equally

important. BBK's site support services consulted with site staffs, encouraging them to run campaign media and offering guidance on using collateral effectively. In the end, it was this high level of site support that enabled the study to enroll three months ahead of schedule.

Phase III Study // Bipolar I & II Disorders



Frank Talk About Manic Depression // When this campaign was launched, materials addressing manic depression tended to be dry, impersonal, strictly informational, or overly solicitous. BBK's standout campaign used an empathetic tone that objectified the condition of bipolar disorder rather than the patient, and inspired action rather than apathy.

OUR INVOLVEMENT	After First-Patient-In Date
COUNTRY	United States } 120 Total Sites
AUDIENCES	Family and Friends
	Patients } Most Difficult to Motivate
	Site Staff
	Referring Physicians
KEY TO ENROLLMENT	Audience Analysis

6

Number That Counts // The sponsor was concerned with enrolling not one but actually six separate protocols – some targeting bipolar I patients and some targeting bipolar II. What at first appeared to be an enrollment problem, BBK soon recognized as an opportunity: namely, drive inquiries under a single study brand, and then triage accordingly to sites that were conducting the study appropriate for that patient.

Objective // Within seven months, enroll 1,500 patients across six different protocols

Challenge // Wide range of eligibility criteria from protocol to protocol

Results // Family members were empowered to inquire and thereby assist patients in seeking care, helping to achieve on-time enrollment of the studies

Expert Analysis



Enrolling the six protocols evaluating this investigational drug meant targeting a wide range of both bipolar I and II patients. Plus, when in a manic phase, patients are less likely to seek care. To simplify recruitment for these studies, BBK chose to target the families and

friends of sufferers rather than the patients themselves. The standout campaign did anything but shy away from the subject matter. In an emotive and empathetic way, materials depicted the effects of this condition as encountered by those close to patients and moved the discussion from the stigma of manic depression to that of a medical condition called bipolar disorder. The direct tone empowered members of the target audience, inspiring them to take action.

Phase II Study // Bipolar II Depression



Media that Delivers // Patients with bipolar II disorder are faced with controlling severe mood swings while coping with the mood that impacts them most – depression. BBK’s messaging focused on the fact that treatment for bipolar depression was tantamount in importance to that of bipolar disorder, a message that resonated with potential participants.

OUR INVOLVEMENT

After First-Patient-In Date

COUNTRY

United States

} 30 Total Sites

AUDIENCES

Patients and Their Caregivers

Psychiatrists

Site Staff

} Most Challenging to Engage

KEY TO ENROLLMENT

Targeted Media

103

Number That Counts // BBK launched an aggressive media campaign that generated 103 randomized patients in the first two months of the six-month enrollment period. By targeting print and radio advertising to within 50 miles of each of the 30 sites, the campaign reached interested psychiatrists who referred patients and put the study on-track to enroll early.

Objective // Support enrollment across 30 sites of 180 adult patients diagnosed with bipolar II disorder who were experiencing depression symptoms

Challenges // Investigational drug with ambiguous side effects; placebo-controlled study did not offer compelling motivation to participate; multiple study visits

Result // Recruitment materials supported the randomization of 103 patients in two short months

Expert Analysis



BBK created a media campaign that spoke directly to patients and psychiatrists, combining “push” media tactics to generate study awareness and “pull” media tactics to reach those seeking information on bipolar treatment. Advertisements in weekly newspapers and a 60-second radio

spot generated frequency of message to targeted audiences while the interest of psychiatrists was leveraged with a recruitment toolkit that focused on the investigational drug and its novel way of working.

Phase II Study // Depression in People Over 65



Seeing the Unspoken // The symptoms of depression evolve as a person ages, so they're harder to recognize. Seniors with depression may also feel their symptoms are just part of aging, and may not feel comfortable discussing them even with a doctor. Consequently, many patients eligible for this study were living silently with their condition. BBK helped individuals see the true cause of their symptoms – and consider this study as a possible treatment option.

OUR INVOLVEMENT	
After First-Patient-In Date	
REGIONS	
North America	} 130+ sites
Europe	
AUDIENCES	
Patients	} Most Difficult to Engage
Caregivers	
Referring Physicians	
KEY TO ENROLLMENT	
Direct Response TV	
Radio / Internet Ads	

30

Number That Counts // BBK carefully distilled the message that reached target patients into just 30 seconds of TV footage. This direct response advertisement served as the cornerstone of national- and local-level outreach campaigns – campaigns that put words to many patients' mute suffering, and put this study's enrollment back on schedule in just a few months.

Objective // Enroll 200 elderly patients who suffer from depression in six months

Challenge // Many target patients didn't recognize their symptoms as those of depression

Result // Lagging enrollment rates returned to normal within a few months

Expert Analysis 6



This sponsor had only been trying to enroll this study for three months before deciding to consult with BBK. BBK identified the crux of the problem – the difficulty of clearly identifying and engaging seniors with depression – and responded with an elegant centralized media campaign. The campaign spoke directly to patients, addressing them as individuals experiencing unspoken but recognizable symptoms – and highlighted the study as an important medical recourse. Increased recognition of the condition among the target audience quickly caused a substantial spike in enrollment rates.

Phase II/III Study // Major Depressive Disorder (MDD)



Supporting the Patient – and the Site // To help motivate this difficult-to-engage patient audience, BBK developed a compelling and empathetic call to action for patient recruitment materials. Equally important to patient messaging was providing site staff the training and support necessary to communicate effectively with both local media outlets and potential study participants.

OUR INVOLVEMENT	Before First-Patient-In Date
COUNTRIES	Argentina, Finland, Poland, Russia, United States
AUDIENCES	Patients, Investigators, Referring Physicians, Site Staff
KEYS TO ENROLLMENT	Study Messaging, Site Support

43 Total Sites (linked to Countries)

Most Difficult to Motivate (linked to Audiences)

2

Number That Counts // Site support and patient messaging were the two key elements of this multi-country recruitment campaign. BBK developed a compelling call to action designed to empathize with patients who were less than satisfied with their current medication. BBK site support guided inexperienced study sites through media placement and boosted enrollment.

Objective // Within 14 months, enroll 478 patients with MDD who were not receiving adequate relief or were experiencing significant side effects from their current medication

Challenges // Motivate a difficult-to-engage patient audience to participate in a placebo-controlled study and, in certain cases, to leave their current physician for the care of the study doctor

Result // Enrollment achieved ahead of schedule

Expert Analysis



In addition to the basic fact that people with major depressive disorder (MDD) often can be difficult to motivate, a critical challenge for this study was the fact that patients had to be dissatisfied with their current treatment. This meant that because the sites did not have sufficient numbers of patients in their panels to achieve the enrollment target, the campaign would have to motivate patients who were already under the care of a physician to actually self-refer to the study doctor, thereby leaving the care of their current provider. Positioning the study sites as particularly sensitive to the needs of people with MDD, and committed to helping find better treatment options, BBK's campaign achieved enrollment in the United States within a few short months, and global enrollment well ahead of schedule.

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	} 40 Total Sites
Mexico	
United States	
AUDIENCES	
Parents	} Most Difficult to Engage and Motivate
Children and Adolescent Patients	
Study Investigators	
Referring Physicians	
KEYS TO ENROLLMENT	
Creative Concept	
Study Messaging	

3

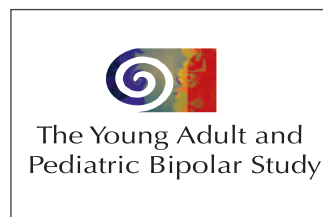
Number That Counts // BBK's creative campaign successfully engaged the three key target audiences: 1) for parents, it presented a portrait of their child that motivated them to seek help; 2) for patients, it expressed what they were feeling; and 3) for physicians, who were enthusiastic about the materials,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



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.