

Pain Management // Overview of Capabilities

Given BBK's wide-ranging experience in this category, we are keenly aware of the current environment for pain management: due to the limited availability of certain drugs, and the side-effect profiles of others, patients are rarely satisfied with their current treatment. BBK's campaigns empathize with these issues, offering clinical trial participation as an option for pain management.



RHEUMATOID ARTHRITIS STUDY

// Rheumatoid Arthritis (RA)

The use of clear, simple, explanatory language has been the key to BBK's successful support of multinational RA studies – which have often involved multiple complex protocols. It has also been crucial to the 95 percent approved-with-no-edits rate that BBK's materials have achieved with local ethics committees for these studies.



Pain Management Study

For people with pain due to cancer

// Cancer Pain

BBK's carefully crafted messages – and our proven assurance that those messages and the protocols are 100% consistent – have re-energized enrollment and site performance for numerous multinational, multi-protocol cancer pain studies. Our success at providing these services is clear across our range of experience with studies of cancer pain management.



OASIS STUDY

OSTEOARTHRITIS SELECTIVE INHIBITOR STUDIES

// Osteoarthritis Pain

Since the withdrawal of Vioxx®, BBK has been part of the multinational effort to determine the future of COX-2 inhibitors. BBK has conducted in-depth interviews, convened focus groups, and tested concepts online to gauge patient and physician interest around the world. BBK has used findings from this research to develop culturally adapted communications materials with global impact.



**A study for people
with debilitating back pain**

// Vertebral Compression Fractures (VCFs)

While patients with vertebral compression fractures (VCF) need a remedy for the chronic pain that those fractures cause, they also need treatment options directed toward a solution for the cause of that pain. The messaging in BBK's VCF campaigns has always kept this dual concern at the forefront, maximizing its impact on prospective study participants.

Rheumatoid Arthritis *in MTX-naïve patients*

// Ankylosing Spondylitis

Patients with ankylosing spondylitis face an uncertain diagnosis clouded by many related rheumatoid conditions – so it's often been up to BBK's precision screening, messaging, and referral capabilities to ensure that the right patients were made aware of clinical trial participation as a potentially appropriate treatment option.

MIGRAINE

// Migraine Pain

Efforts to introduce new migraine treatments are challenged by the ongoing need to legitimize migraine as a bona fide illness. BBK has met and overcome this challenge in many ways, raising public awareness of the condition and helping migraine sufferers seek treatment using innovative outreach methods like traveling art exhibits.

Phase III Study // Cancer Pain Management



Customized Consultation // For a study with extremely narrow inclusion criteria, our country-by-country analysis and customized plans pinpointed specific recruitment barriers, which, along with coaching, enabled country managers and monitors to motivate sites struggling with slow study start-up issues.

OUR INVOLVEMENT

After First-Patient-In Date

REGIONS

North America, South America
Western Europe, Eastern Europe

31 Total Countries

AUDIENCES

Patients
Investigators
Monitors
Country Study Managers

Most Challenging to Motivate

KEYS TO ENROLLMENT

Study Messaging
Monitor Coaching

31

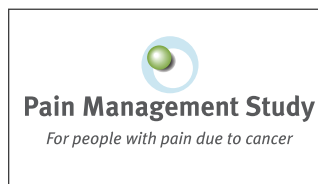
Number That Counts // For every country, a tailored plan. Whether the barriers were drug import, patient ignorance of pain as a by-product of cancer, or site frustration, BBK collaborated with country study managers and monitors to identify the most pressing issues, then coached them in overcoming the issues with clearly messaged campaign materials.

Objective // Enroll 1146 patients into two cancer pain protocols.

Challenges // Complex protocol with narrow inclusion criteria; slow country and site start-up affecting site motivation; patient attitudes toward cancer pain.

Results // Customized plans and coaching empowered country managers and monitors to effectively support sites with lagging motivation and increase enrollment rates.

Expert Analysis



Not only does cancer pain often go unrecognized by patients, in some countries, pain is considered something merely to be borne, not treated. As well, oncologists are not always focused on pain symptoms and treatment. To overcome these attitudinal issues, BBK created and localized a communications program with patient-facing materials to help investigators and coordinators bring up the topic, to establish the importance of and their interest in treating these symptoms, and to introduce the study. The messaging brought pain to the forefront of the conversation between investigator and patient, and encouraged the patient to consider a clinical study.

Global Market Research for Phase III Study // COX-2 Inhibitor



Dual Purpose Global Research // Would patients and physicians embrace a COX-2 inhibitor study so soon after a highly publicized safety recall of a COX-2 drug? BBK's extensive research gave the sponsor the tools to make a sound decision on study initiation, while also creating a solid foundation for the immediate launch of the study.

OUR INVOLVEMENT

Feasibility Planning

REGIONS

Europe, Africa, East Asia,
South and North America, Australia

AUDIENCES

Patients
Physicians

} Most Crucial
Buy-In

KEYS TO ENROLLMENT

In-Depth Interviews
Message Testing

25,000

Number That Counts // BBK's job was to determine the feasibility of a multinational, COX-2 inhibitor study. With an expected enrollment goal of 25,000 patients, the first task was to conduct country-by-country research to determine which optimal countries were capable of yielding high numbers of patients.

Objective // Conduct global market research to determine the feasibility of a COX-2 inhibitor study with an enrollment goal of 25,000 patients.

Challenge // Determine whether patients and physicians would be receptive to COX-2 inhibitors so soon after a significant safety recall.

Results // BBK armed the sponsor with the tools to make a sound decision about study initiation, and also provided potential messaging strategies for recruitment.

Expert Analysis



BBK conducted global market research to determine feasibility of an impending Phase III medical outcomes study of a new COX-2 inhibitor after a popular COX-2 inhibitor was withdrawn from the worldwide market in well-publicized safety recall. Strategic country selection included all five major global regions, while a global survey determined patient demographic breakdowns. In-depth patient and physician interviews and focus groups in 16 countries answered key issues facing the study. Overall, BBK's research gave the sponsor the tools to make a sound decision on study initiation, and provided a study launch pad by uncovering potential recruitment messaging strategies.

Phase III Study // Diabetic Neuropathy



Small Budget, Big Results // BBK used low-cost, kraft-style cardboard and paper as the stock for the brochures and other print collateral, leveraging its tactile nature as a way of making patients more aware of the value of their sense of touch. This stand-out approach differentiated the study and helped achieve enrollment more quickly.

OUR INVOLVEMENT

After First-Patient-In Date

COUNTRY

United States

} 41 Total Sites

AUDIENCES

Patients

News Media

Site Staff

Referring Physicians

} Most Difficult to Motivate

KEY TO ENROLLMENT

Targeted Integrated Marketing

9

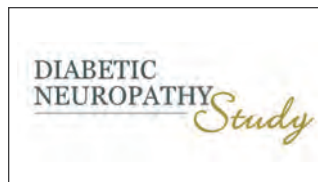
Number That Counts // Despite a study condition that was unfamiliar to patients and narrow inclusion and exclusion criteria, BBK's highly targeted campaign enrolled all 1,160 patients within the aggressive nine-month time frame. What's more, study goals were exceeded on a remarkably small production budget.

Objective // Enroll a total of 1,160 patients within nine months; the study had been under way for more than one year

Challenges // Narrow inclusion and exclusion criteria; lack of awareness of the condition among patients; many competing studies

Results // BBK exceeded enrollment: 4,372 referrals generated; 1,350 patients enrolled. BBK was asked to implement a retention campaign for the study's two-year duration

Expert Analysis



This study was under way for more than one year and in jeopardy of failing to enroll when BBK was asked to step in. The protocol's narrow inclusion and exclusion criteria were to blame, along with a general lack of awareness about diabetic neuropathy. In fact, patient awareness of the condition was so low, by the time patients were diagnosed with diabetic neuropathy, they typically did not meet the criteria for participation in this study. After creating a highly targeted recruitment strategy and evocative and eye-opening messaging, the campaign leveraged local public relations, along with a variety of advertising media, as well as patient and physician outreach, to garner big results. Thousands of inquiries were generated and enrollment exceeded study goals.

Phase III Study // Diabetic Neuropathy – Retention



Small Budget, Big Results // The success of this campaign hinged not so much on the materials themselves, but on the interactions they facilitated between patient and staff. By fostering this important bond, BBK kept compliance and retention at remarkably high levels, despite the low number of study visits.

OUR INVOLVEMENT	After First-Patient-In Date
COUNTRY	United States } 41 Total Sites
AUDIENCES	Patients } Most Difficult to Motivate
	Site Staff
KEY TO ENROLLMENT	Fostering Relationships

2

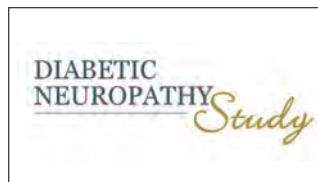
Number That Counts // The two-year participation – a major barrier for any study – was exacerbated by the low number of study visits – especially considering that patients were typically confused and frightened by the implications neuropathy had on health. BBK reduced these dual threats by providing educational information and maximizing the opportunity for patients to speak with the site staff during visits.

Objectives // Implement a retention campaign to facilitate patient compliance and completion of the two-year participation period

Challenges // Long time period between study visits; four day-long and intensive study visits at the end of both years one and two

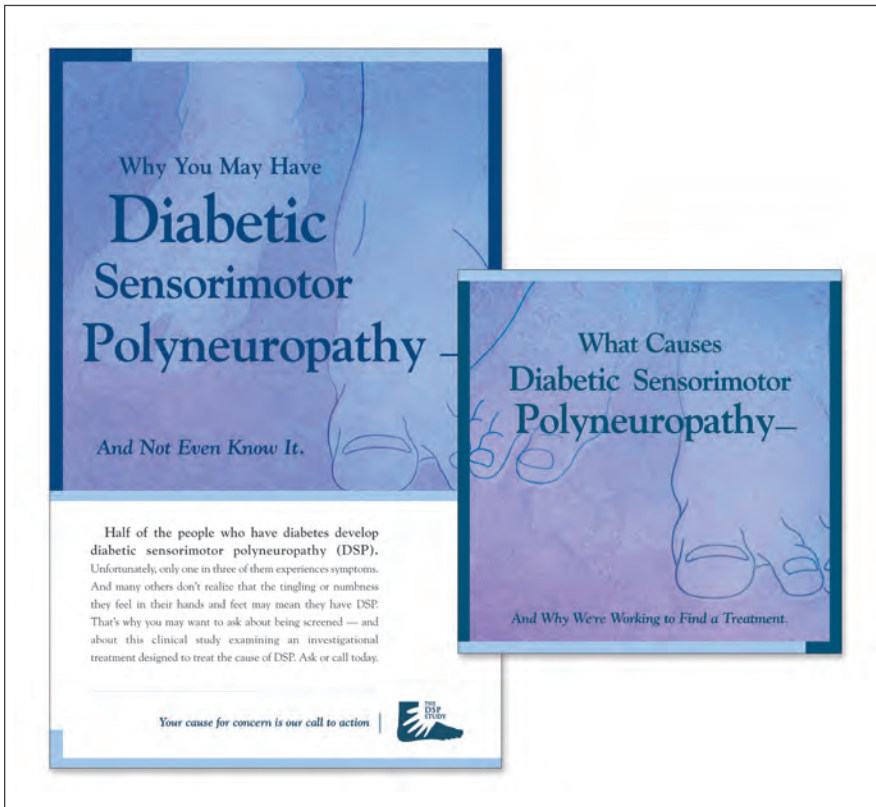
Results // Target number of patients completed enrollment, allowing sufficient data to be gathered and submitted to the FDA on time

Expert Analysis



Once enrolled in the study, participants were as much in danger of being non-compliant and dropping out of the study as they had been for developing neuropathy – that is to say, they had little information and opportunity to focus on their study participation, as study visits were mainly short, few, and far between. To help patients feel more connected – and thereby committed – to the study, BBK developed a complete study compliance program, the keystone of which was a participant Web site that featured regularly updated information about living with diabetic neuropathy, and reminders about study participation in simple, easy-to-understand language and format. Materials were also created for each study visit to build the relationship between site staff and participant.

Phase III Study // Diabetic Sensorimotor Polyneuropathy



Identifying Patients Before They're Excluded //

To surmount the barrier of highly exclusive criteria, BBK created a de facto screening program for all the sites' diabetes patients. Posters and brochures prompted patients to ask about study participation, and BBK's training re-energized site staff with quick and easy tasks for identifying and consenting potential participants.

OUR INVOLVEMENT

After First-Patient-In Date

COUNTRY

United States

} 27 Total Sites

AUDIENCES

Patients

Site Staff

Investigators

} Most Challenging to Motivate

KEY TO ENROLLMENT

Study Positioning

1

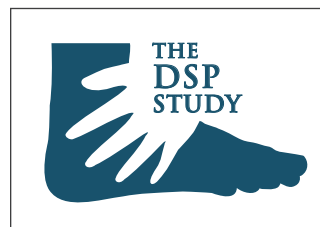
Number That Counts // While the list of exclusion criteria was the one major barrier to enrollment, it was sites' weariness – brought on by the high screen-fail rate – that was the one major barrier to identification of participants. BBK's singular solution was to reposition the study in the minds of the site staff as a chance to rule out neuropathy in their diabetes patients, and to provide the tools necessary to make this easy.

Objective // Enroll 480 patients within six months

Challenges // Lack of patient awareness of the condition; waning site enthusiasm; limited sponsor budget for recruitment

Results // Enrollment was achieved on time; BBK was subsequently contracted to develop and implement a campaign to ensure 80 percent of the enrolled patients completed their two-year-long study participation

Expert Analysis



A primary concern for people with diabetes should be the development of neuropathy and the limitations it can place on their lives – but many patients are not even aware of the condition and its symptoms. This lack of awareness also often meant they

would be ineligible for participation in this study, as the protocol design excluded patients with anything more than indications of the initial onset of the condition. With half the enrollment period elapsed, the majority of patients still to enroll, waning site interest in the study, and a tight budget, the sponsor turned to BBK for support. Luckily, BBK's expert site training and recruitment materials were enough to complete enrollment within days of the last-patient-in date.

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

Untreated Headache Sufferers

Key Demographic

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.

Branding Campaign // Migraine



Media Does It // Although well-established, this client’s drug had never been promoted before and was prescribed only in the most difficult of migraine cases. With no real breaking clinical news to promote, BBK leveraged a competitor’s announcement to gain media attention for our client. An aggressive publicity campaign resulted in high-impact exposure.

OUR INVOLVEMENT

Branding

COUNTRY

United States

AUDIENCES

Media

Public

Medical Community

Migraine Specialists

KEY TO ENROLLMENT

Public Relations

50

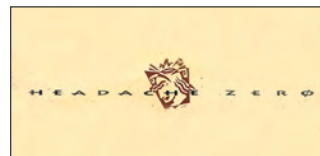
Number That Counts // BBK drove more widespread use of the client’s 50-year-old niche drug by positioning the client’s treatment as a firmly established migraine therapy. The campaign was so successful that in the early months of BBK’s all-out media blitz, the client’s product sales jumped at least 25 percent ahead of projection.

Objectives // Give an established but obscure migraine drug a fresh identity and the means to compete with an emerging breakthrough drug

Challenge // With only an incremental improvement to the product – moving from an injectable to a nasal form – there was no real “breaking news” to convey to the public

Results // The campaign precipitated rediscovery of the product; sales jumped 25 percent ahead of projection

Expert Analysis



The impending announcement of clinical results for a competitor’s emerging “breakthrough” migraine drug threatened to relegate the client’s existing migraine treatment

to further obscurity. But the drug needed a fresh identity to compete. BBK cleverly perceived the competition’s announcement as an opportunity to drive more widespread use of the client’s 50-year-old niche drug, positioning the competition as a newcomer that was joining already established migraine therapies. An aggressive publicity campaign precipitated a national rediscovery of the client’s migraine therapy, and product sales jumped at least 25 percent ahead of projection.

Phase III Study // Rheumatoid Arthritis



Understanding Patients, Outrunning the Competition //

BBK recruited this rheumatoid arthritis (RA) study in just six months by continually monitoring and adjusting recruitment tactics. With messaging that empathized with the daily disruptions caused by RA, BBK was able to differentiate this study from other competing trials.

OUR INVOLVEMENT	
Before First-Patient-In	
COUNTRY	
United States	28 Sites
AUDIENCES	
Patients	
Investigators	
Site Staff	Most Difficult to Engage
RA Community	
KEY TO ENROLLMENT	
Study Positioning	
Study Messaging	

220

Number That Counts // With an enrollment timeline of only six months, BBK helped this sponsor enroll all 220 patients before competing treatment options were brought to market.

Objective // Enroll 220 patients at 28 sites within six months.

Challenges // Condensed enrollment timeline; competing RA clinical studies; multiple invasive procedures required.

Result // On-time study enrollment achieved.

Expert Analysis



Patients with RA were in desperate need of better treatments, particularly those with fewer side effects. With competing treatment options soon coming to market at the time of this study, the sponsor hoped to outrun the competition by accelerating the enrollment timeline. BBK's campaign materials answered the challenge, emphasizing the search for cutting-edge medicines and offering the clinical study as a treatment option. As a result of these efforts, BBK helped sites meet the enrollment deadline.

Phase II Study // Vaginal Atrophy



Creativity with Sensitivity // Facing the challenge of enrolling patients who may not recognize their condition, never mind want to talk about it, study recruitment had stalled. BBK designed an outreach and site communication program that tactfully conveyed an invitation to discuss the condition, speeding study enrollment.

OUR INVOLVEMENT	
After First-Patient-In Date	
COUNTRIES	
United States	} 5 BBK-Supported Sites, 15 Total
Canada	
AUDIENCES	
Patients	} Most Important to Motivate
Site Staff	
Investigators	
KEYS TO ENROLLMENT	
Creative Concept	
Study Messaging	

5

Number That Counts // Within five months, BBK helped the five most-enrollment-challenged sites achieve their targets, using several key tactics: radio advertising, direct mail, direct e-mail, a study discussion brochure, and a study participation guide.

Objective // Increase enrollment at five sponsor-selected sites within five months

Challenges // Patients were embarrassed to bring up the condition; five supported sites were the slowest enrollers; two-thirds of the enrollment period had elapsed

Result // The five BBK-supported sites enrolled twice as many patients as the 10 unsupported sites combined, helping to achieve enrollment only one month beyond schedule

Expert Analysis



Given the personal nature of the subject matter, it's understandable that vaginal dryness and atrophy, common symptoms of menopause, typically go untreated. As such, sites seeking postmenopausal women for a clinical

study of an investigational treatment had quickly tapped out their patient panels of the few women who complained of the problem. And the time to meet enrollment was running out. BBK launched a program of public outreach, utilizing educational materials and site support to generate referrals and maximize enrollment for the five most lagging sites. By the enrollment deadline, BBK had generated twice as many enrolled patients at the five supported sites as 10 unsupported sites had produced on their own.