

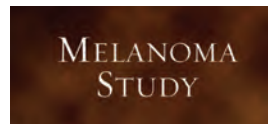
## Oncology // Overview of Capabilities

BBK has recruited global oncology studies spanning a wide range of specific cancers and stages – from prevention and screening to the diagnosis and treatment of primary, recurrent, and metastatic cancers. Our in-depth knowledge of the key target audiences – patients, their family members, and the physicians who care for these patients – provides the solid foundation on which we build our enrollment campaigns.



### // Breast Cancer

BBK has enrolled numerous breast cancer studies, including studies of what is now the leading first-line therapy for early-stage breast cancer. Our key to recruitment success has been facilitating the discussion of study participation between physician and patient, at the moment when doctors are often disinclined to bring up clinical studies.



### // Melanoma

BBK has conducted U.S.- and global-based patient recruitment and retention campaigns, as well as enrollment feasibility analyses and site selections for all phases of melanoma studies. Leveraging our expertise in educating patients, our campaigns inform patient audiences about this disease while positioning the study as an option worthy of consideration.



### // Colorectal Cancer

Clinical studies of colorectal cancer are best served by BBK's comprehensive advertising and public relations initiatives. These tactics are an invaluable means of conveying a balance of empathetic images and disarming messages – a balance that drives study participation and encourage preventative care, especially among older patients.



### // Prostate Cancer

BBK has extensive experience supporting prostate cancer studies in all phases and throughout the world. From detection to end-stage diagnoses, BBK has created empathetic, straightforward patient materials, engaging physician-to-physician tactics, and a customized level of site support to ensure on-time study enrollment.



### HEAD + NECK

### // Head and Neck Cancers

Because of the extremely low incidence of head and neck cancers, international studies face significant enrollment challenges. When this has occurred, BBK's physician referral programs have provided breakthrough combinations of well-planned, country-by-country implementations, and highly differentiating study brands.



### // Early Breast Cancer

Powerful messages of encouragement can be the key to coaching women with early breast cancer to aggressively pursue all treatment options – including study participation. The value of deploying these pragmatic messages is evident in the overwhelming success of BBK enrolling these types of studies and in the branding of approved treatments.

## Phase III Study // Early-Stage Breast Cancer



**Beating (Up) Breast Cancer** // BBK's bold campaign created discussion opportunities between physicians and patients who were interested, yet hesitant to broach clinical study participation. An empowering message to "Come Out Fighting" coached aggressive pursuit of all treatment options, including this study.

### OUR INVOLVEMENT

After First-Patient-In Date

### COUNTRY

United States

40 Total Sites

### AUDIENCES

Patients

Oncologists

Study Coordinators

Family Members

Most Challenging to Engage

### KEYS TO ENROLLMENT

Study Branding

Patient Materials

# 60

**Number That Counts** // BBK's dynamic campaign reignited a lagging clinical study by getting physicians and patients to talk, ultimately enrolling all 420 patients in only 10 months. BBK's approach got results with two months to spare – bringing medicine 60 days closer to finding the cure.

**Objective** // Within 12 months, enroll 420 patients into a study of an investigational treatment for breast cancer in post-menopausal women

**Challenge** // Rescue mission: study had been under way for one year, but had achieved only 25 percent enrollment

**Result** // Enrollment completed two months ahead of revised schedule, with BBK contracted to support only 50 percent of sites

## Expert Analysis



Often, responding quickly and proactively to a diagnosis of breast cancer can make all the difference in the success of a treatment. Although this study had been under way for some time before BBK came on board, enrollment was staggeringly low. BBK's campaign sought to empower these women to

fight back by aggressively seeking information about all treatment options, including clinical study participation.

The central motif, female boxing, helped open patient-physician discussions by communicating empathy while boldly urging action. Response was so positive that recruitment finished two months ahead of the revised schedule.

## Psycho-Social Study // Breast Cancer



**Virtual Study Community** // By designing an online system that met the needs of the users – namely, allowing breast cancer patients to complete the study's lengthy survey over a series of sessions, rather than one – expressed caring for the participants, which they repaid in-turn by completing their participation.

### OUR INVOLVEMENT

Before First-Patient-In Date

### COUNTRY

United States

Nationwide Participation

### AUDIENCES

Patients

Caregivers

Family and Friends

Most Difficult to Motivate

### KEY TO ENROLLMENT

Understanding the Participant

# 1

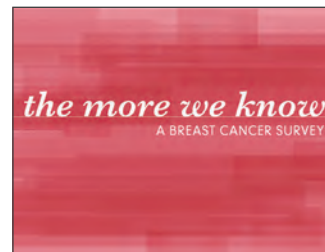
**Number That Counts** // Recruitment, enrollment, and retention for this campaign was achieved quickly and cost-effectively using only a single medium: the Internet. Direct e-mail, banner ads, and sponsored links on search engines drove inquiries, and the Web site was so comprehensive that less than 30 out of the 500 survey participants called the toll-free help line provided, and 95 percent completed the survey.

**Objective** // Create a vehicle to recruit, enroll, and retain 500 women being treated for early, estrogen receptor-positive breast cancer to participate in a psychosocial study

**Challenges** // Length of survey a challenge for participants, who are typically very fatigued from treatment; address sponsor's requirements for data management, security, user interface, and reporting

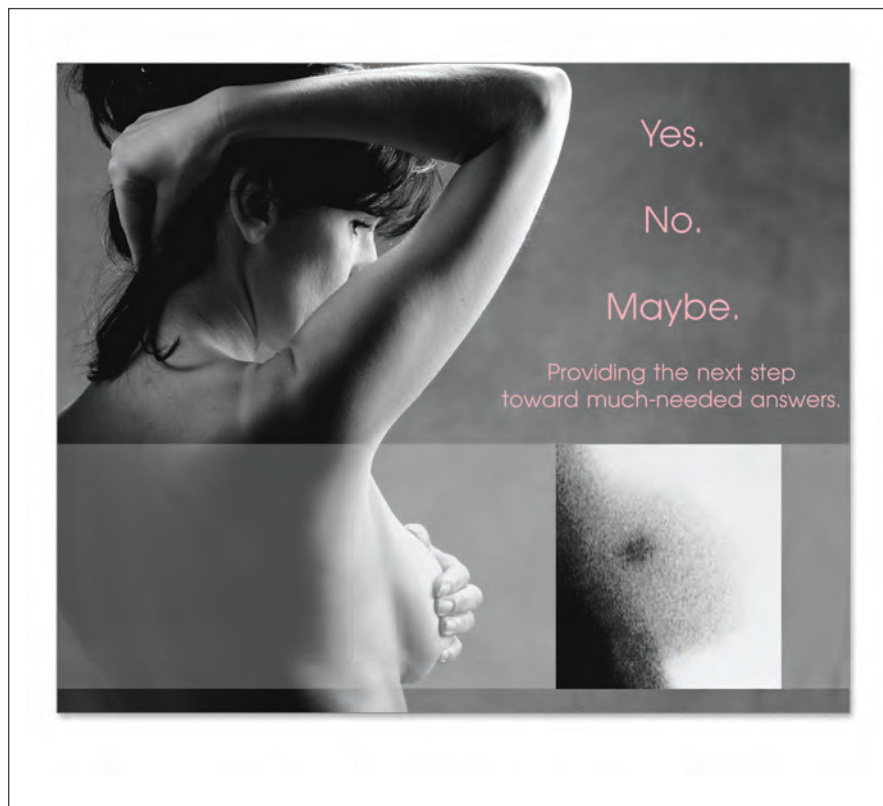
**Result** // Study completed within three weeks

## Expert Analysis



BBK was faced with the challenge of recruiting, consenting, and retaining 500 women for a survey study to determine how women who are being treated for early, estrogen receptor-positive breast cancer make decisions about taking hormonal therapy. Study participation was challenging because patients' ongoing cancer treatments typically left them severely fatigued. BBK's solution was to conduct both recruitment and the study itself completely online, using a Web site that contained the survey, and that allowed patients to complete it at their own pace, in as many sessions as they needed. More than 95 percent of women who consented to participate completed the survey and the study was finalized within three weeks.

## Branding // Breast Imaging



**Emotional Connection //** BBK's breakthrough campaign introduced this client's nuclear medicine test for breast imaging to the trade market by creating advertisements that told the story of women who had benefited from this product. By establishing an emotional connection, BBK helped this brand introduction gain maximum impact.

<b>OUR INVOLVEMENT</b>	Product Brand Launch
<b>COUNTRY</b>	United States
<b>AUDIENCES</b>	National press Trade media Patients
<b>KEY TO ENROLLMENT</b>	Establish brand awareness

Brand awareness was crucial

# 74

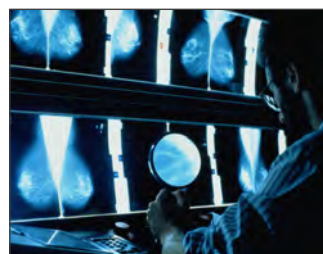
**Number That Counts //** BBK's advertisements told the stories of women who had benefited from this client's breast imaging product. The ads used a frank and emotional tone that differentiated the company's brand from its competitors, and generated more than 74 million impressions in national and trade media.

**Objectives //** Introduce client's breast imaging product to the market, and establish a brand presence for the product

**Challenges //** Product differentiation through the right combination of an impacting, targeted brand and the right choice of audiences

**Results //** 74 million+ impressions achieved in national and trade media, moving the client's product and its brand to the forefront of industry awareness

### Expert Analysis



To introduce this client's product, the first-ever nuclear medicine test for breast imaging, BBK launched a provocative campaign that targeted patients directly. Highlighting the product as a viable follow-up test for women with abnormal mammograms, BBK told the story through the voices of patients who had benefited from the breakthrough. The ads' forthright and empathetic tone established an emotional connection and differentiated the company from the competition. More than 74 million impressions were achieved in national and trade media.

## 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

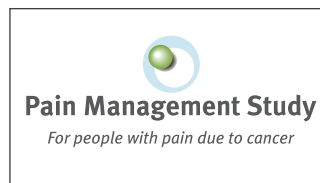
**Number That Counts** // For every country, a tailored plan. Whether the barriers were drug import, patient ignorance of pain as a by-product of cancer, or site frustration, BBK collaborated with country study managers and monitors to identify the most pressing issues, then coached them in overcoming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

## Diagnostic Assay Test Study // Colorectal Cancer



**Making the Case** // BBK's messaging broke down patient resistance to colonoscopy with humor, and leveraged the fact that study participation provided a means of both receiving a definitive bill of colorectal health, and of helping patients' children and grandchildren – and potentially themselves; should the new test prove effective, it might eliminate the need for colonoscopies.

OUR INVOLVEMENT	
Study Planning	
COUNTRY	
United States	76 Total Sites
AUDIENCES	
Patients	Most Difficult to Motivate
News Media	
Site Staff	
KEYS TO ENROLLMENT	
Focus Group Testing	
Study Messaging	

# 5

**Number That Counts** // People 65 and older are at highest risk for colorectal cancer, so it is recommended that they be screened every five years via colonoscopy. Should the investigational test prove effective, it had the potential to reduce – or even eliminate – the need for colonoscopy within the study participant's lifetime. Highlighting this potentiality proved to be a major “deal closer” in the recruitment materials.

**Objective** // Recruit 100 patients 65 years and older within eight months for a study investigating a new, noninvasive, DNA-based diagnostic method for colorectal cancer

**Challenges** // Public avoidance of regular screening via colonoscopy; unpleasant procedure and participation requirements

**Result** // Enrollment was achieved on time

## Expert Analysis



This study was investigating a noninvasive screening method; however, patients would still have to undergo a colonoscopy as part of the study. And while national awareness of the need for colorectal cancer screening was good, many older Americans commonly avoid being screened. This recruitment challenge was compounded by the fact that participants had to collect and transport a stool sample to their site. Concept testing with the target audience revealed the answer: use humor to combat inhibition, and the hard facts to make the case. Combining sobering occurrence and treatment statistics with a pleasantly wry humor, BBK's campaign made the need for screening inarguable, helping sites to achieve their targets.

## Phase III Study // Gastric Cancer



**Helping Those Who Help the Patient //** In addition to creating recruitment tools, BBK worked to keep sites focused on the study. A series of newsletters was translated into the language that was most comfortable for the site staff; this positioned the sponsor as concerned about site workloads, and helped make the study a priority.

- OUR INVOLVEMENT**  
After First-Patient-In Date
- REGIONS**  
North America, Australia  
Eastern and Western Europe
- AUDIENCES**  
Referring Physicians  
Investigators  
Site Staff  
Patients
- KEY TO ENROLLMENT**  
Patient Interviews

125 Total Sites

Most Difficult to Motivate

# 17

**Number That Counts //** Cancer patients are often interested in learning about clinical study opportunities, even if they decide not to participate. This campaign was a demonstration of this truism – and it holds sway worldwide. In 17 countries, the materials enabled sites to identify those patients who were most likely to be interested, as it offered a means of continuing their fight with end-stage cancer.

**Objective //** Help facilitate enrollment of 425 patients in six months across 125 sites in 17 countries in North America, Europe, and Australia

**Challenges //** Physician reluctance to initiate discussions about clinical study participation; 12 months of an 18-month enrollment period had passed, with only 35 patients enrolled

**Result //** Study enrolled three weeks past last-patient-in date, much sooner than expected

### Expert Analysis



Investigators were reluctant to ask patients to participate, believing that patients – who had a life expectancy of only a few months – would be unwilling to undergo the frequent barrage of tests that study participation required. Conversely BBK discovered, certain patients – those with a “fight ‘til the end” attitude – were very interested in hearing about all their options, including clinical studies, if there was even a remote chance of extending their time. By providing tools that enabled site staffs and referring physicians both to pre-identify patients who would be most likely to participate, and to bring those patients to the attention of investigators, BBK was able to significantly increase sites’ enrollment rates.

## Phase II Study // Stage III or IV Malignant Melanoma



**Fighting Melanoma with Compassion //** With hundreds of competing studies and only six months to fulfill enrollment goals, BBK's focus was to differentiate this melanoma study in the minds of both patients and physicians. Success came with finding the right investigators and refining campaign messaging to take a more compassionate and empathetic approach.

OUR INVOLVEMENT	
After First-Patient-In Date	
COUNTRIES	
Canada	} 25 Total Sites
United States	
AUDIENCES	
Patients	} Most Difficult to Engage
Investigators	
Site Staff	
Referring Physicians	
KEYS TO ENROLLMENT	
Study Messaging	
Site Selection	

# 10

**Number That Counts //** This protocol was competing with 200+ studies, 55 of which were enrolling patients with stage III or IV melanoma, specifically. BBK found the shortest distance to full enrollment was to create a standout recruitment campaign and add 10 new sites with investigators who specialized in melanoma, but were not involved in competing studies.

**Objectives //** Select additional investigative sites and design a recruitment campaign capable of enrolling 53 patients within six months

**Challenge //** 200+ competing studies (55 recruiting for stage III or IV melanoma)

**Result //** The study enrolled six weeks ahead of schedule

## Expert Analysis



This study was lagging due to both poor site performance and a staggeringly high number of studies competing for melanoma patients. To meet the study enrollment goals in the waning enrollment period, BBK identified 10 new sites with investigators who specialized in melanoma, were not conducting competing studies, and who had significant referral networks. The creative campaign differentiated this study in the minds of patients and physicians, leveraging the theme of compassion – compassion for late-stage melanoma patients, the compassionate use provision of the protocol, and empathy for the lack of a standard of care. In the end, enrollment was achieved ahead of schedule.

## Phase III Study // Metastatic, Hormone-Refractory Prostate Cancer



**Call To Action //** The campaign's call to action – *It's about fighting advanced prostate cancer, cell-by-cell* – was included in all of the patient and site support materials. Illustrations suggested the investigational vaccine doing battle with cancer cells, establishing intrigue about advanced medical science at work.

<b>OUR INVOLVEMENT</b>	After First-Patient-In Date
<b>COUNTRY</b>	United States } 135 Total Sites
<b>AUDIENCES</b>	Patients Investigators Site Staff Referring Physicians } Most Challenging to Motivate
<b>KEYS TO ENROLLMENT</b>	Study Messaging Call to Action

# 9

**Number That Counts //** BBK presented nine interactive recruitment Webinars to energize sites in using the recruitment materials – coaching them in the key messages that would excite patients about the study's novel approach to their rapidly advancing disease. High performing sites shared successful techniques and others aired concerns to garner helpful suggestions.

**Objective //** Within 12 months, enroll 600 patients into a Phase III metastatic, hormone-refractory prostate cancer study

**Challenges //** Patients had only nine to 12 months of life left; broaching the topic of study participation was difficult for investigators

**Results //** BBK revitalized recruitment, communicating a worthy study opportunity; and the client continued to reorder materials long after BBK's involvement ended

## Expert Analysis



The most crucial method of recruiting a cancer trial – the discussion between patient and physician – may sometimes be the most difficult to initiate. To give investigators a more comfortable, objective approach, BBK reframed this campaign to present the unique molecular science behind this promising vaccine. Recruitment materials included talking guides for site staffs and provided clear information about the study's purpose and potential. Ultimately, BBK rallied investigative teams and patients to a worthy study opportunity and helped move medical science a step closer to winning the fight against prostate cancer.

## Phase III Study // Non-Small Cell Lung Cancer (NSCLC)



**Regulatory Complexity** // For this major global study, BBK's strategy involved grouping sites with similar regulatory parameters and customizing materials for each group to reduce versioning time. Ultimately, this approach helped gain quick approval for all recruitment materials and led to an accelerated enrollment rate.

OUR INVOLVEMENT	
Before Last-Patient-In Date	
REGIONS	
North & South America	} 33 Total Countries
Eastern & Western Europe, Asia	
AUDIENCES	
Patients	} Crucial to Success
Investigators	
Study Staff	
Ethics Committees	
KEY TO ENROLLMENT	
Cultural Adaptation	

# 33

**Number That Counts** // Despite a very limited budget, BBK executed and adapted an effective patient recruitment campaign into 33 languages, with messaging that resonated deeply with patients throughout the world.

**Objective** // Develop materials to help recruit 800 patients with NSCLC within seven months – the last months of a three-year enrollment period

**Challenges** // Adapt materials for widely varying cultures and regulatory requirements with a very limited production budget

**Results** // All materials approved by numerous ethics committees with little or no edits; project completed on time

### Expert Analysis



BBK was asked to develop materials for recruitment in more than 30 countries with widely differing cultural and regulatory environments – but without an adequate production budget to support advanced customization.

To maximize the sponsor's investment, BBK expanded upon the client's creative into targeted outreach materials that achieved maximum impact by speaking effectively to all audiences. All materials were quickly approved by numerous ethics committees with few or no edits, which facilitated rapid deployment of tailored materials and kept the project on schedule.