

## Musculoskeletal // Overview of Capabilities

The strength in our muscles and bones is essential to a high quality of life. Our experience in this category spans all age groups and has often leveraged the importance of prevention and treatment for these conditions. From public health campaigns to medical device and pharmaceutical clinical studies, BBK's work reflects a commitment to education and motivating patient audiences, as we support this most basic framework of the human form.



### // Osteoporosis

BBK has recruited clinical studies of treatments for osteoporosis throughout the world. A common barrier is the fact that this condition is asymptomatic, which requires compelling messages around education as well as the study opportunity. Our campaigns have succeeded by creating the right balance between the two.



### // Sarcopenia

The key to enrolling patients with sarcopenia is often educating patients about problems caused by age-related muscle loss, as BBK has shown in numerous studies. This is particularly true of menopausal women – who BBK has successfully motivated by leveraging the fact that maintaining muscle mass can also mean maintaining independence.



A study for people with debilitating back pain

### // Vertebral Compression Fractures (VCFs)

While patients with vertebral compression fractures 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 always keeps this dual concern at the forefront, maximizing its impact on prospective study participants.



### // 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% approved-with-no-edits rate that BBK's materials have achieved with local ethics committees for these studies.



OSTEOARTHRITIS  
STUDY

### // Osteoarthritis Pain

BBK's work for this condition has included domestic and global clinical trials, as well as market research. As most of these studies have centered on addressing osteoarthritis pain, it's been necessary to first assess the global attitude surrounding current treatment options. Once completed, BBK effectively leverages the potential benefits of study participation.



### // Orthopedics

BBK has worked with medical device companies to foster better relationships through physician practice building. To help streamline the process, BBK has created practical templates and improved ordering spreadsheets that enable sales teams to easily provide their physician network with customized collateral in a more cost-effective manner.

## 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 II Study // Osteoporosis



**Screening Success //** BBK's breakthrough solution for driving highly qualified referrals was to offer free osteoporosis screening to the public, and then introduce the study opportunity to those women whose results showed they had a bone mass that prequalified them for study participation. Sites achieved their enrollment goals on time.

OUR INVOLVEMENT	
After First-Patient-In Date	
COUNTRIES	
Canada	} 37 Total Sites
United States	
AUDIENCES	
Postmenopausal Women	} Most Challenging to Engage
Site Staff	
KEY TO ENROLLMENT	
Prescreening Program	

# 72

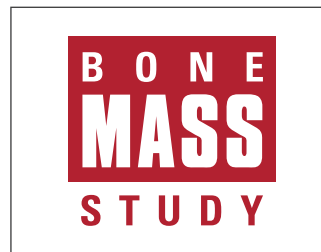
**Number That Counts //** Because of a well-orchestrated recruitment campaign and site support program, BBK over-enrolled by 72 patients in only four months what appeared to be an all-but-unenrollable study. Our success so impressed the sponsor that BBK was asked to recruit for the global phase III study and a second phase III study of a different indication for the same compound.

**Objective //** Enable 37 sites to enroll 340 postmenopausal women with osteopenia within four months

**Challenges //** Symptomless condition; high screen-failure rate; remaining enrollment period coincided with holiday season

**Result //** Enrollment target exceeded by 72 patients

### Expert Analysis



Before BBK was approached for recruitment help, projections showed that study enrollment would be achieved a year late. And because sites lacked adequate prescreening equipment, staff were sending potential participants for time-intensive DXA scans and experiencing a tremendous screen-fail rate. To turn things around, BBK created and placed a compelling TV and direct mail campaign, sending women who responded to locations where they could get a free, quick screening of their bone mass using heel-scan technology. Women with an appropriate bone mineral density were then introduced to the study opportunity and scheduled for their first study visit as highly qualified referrals.

## Phase III Study // Osteoporosis



**Customized Site Support //** BBK launched global outreach to successfully enroll this study with a customized recruitment toolkit. Culturally adapted and translated for each of the 28 countries involved, patient materials targeted postmenopausal women with osteoporosis. The study of 7,200 women enrolled on time.

### OUR INVOLVEMENT

Before First-Patient-In Date

### REGIONS

Eastern & Western Europe

North America

Oceania

200 Total Sites  
in 28 Countries

### AUDIENCES

Postmenopausal Women

Site Staff

Most Challenging  
to Engage

### KEYS TO ENROLLMENT

Customized Patient Outreach

Cultural Adaptation

# 200

**Number That Counts //** Based on BBK-generated forecasts of recruitment needs within the 28 countries involved, each of the 200 study sites worldwide received customized recruitment support to meet their enrollment goals. In many regions, it was local media advertisements that helped generate the prequalified referrals needed for sites to achieve their recruitment levels.

**Objective //** Recruit 7,200 postmenopausal women within 12 months for a global osteoporosis study

**Challenges //** Symptomless condition; cultural adaptation for 28 countries

**Result //** Global enrollment achieved on time

## Expert Analysis



Direct-to-patient outreach was critical to the successful enrollment of this global study of 7,200 postmenopausal women with osteoporosis. Unaccustomed to this type of outreach,

European study monitors were initially resistant to these support efforts, including the placement of patient recruitment advertisements in local media. But the targeted outreach generated an influx of prequalified referrals, enabling sites in those regions to meet their enrollment goals. Cultural adaptation of all patient materials for each of the 28 participating countries also contributed to on-time enrollment.

## Phase II Study Retention // Osteoporosis



**Relationships That Last** // Our success enrolling this protocol won BBK the job of retention to ensure that a majority of participants completed the two-year study. The bold logo created to brand the study was carried through to patient reminders and appreciation items, creating a consistent study identity that fostered investment in participation.

### OUR INVOLVEMENT

Before First-Patient-In Date

### COUNTRIES

Canada  
United States

37 Total Sites

### AUDIENCES

Postmenopausal Women  
Site Staff

Most Challenging to Engage

### KEY TO ENROLLMENT

Relationship Building

# 92

**Number That Counts** // With BBK support, more than 92 percent of participants were retained for the two-year study duration, well above client expectations. The key to success was relationship building between site staffs and patients that created a sense of connection to and investment in the study.

**Objectives** // Maintain retention above 85 percent; increase the number of substudy participants

**Challenges** // Lengthy study period of two years; invasive substudy procedures

**Results** // Retention remained over 92 percent; on-time enrollment of the substudy

## Expert Analysis

**BONE  
MASS  
STUDY**

BBK's successful recruitment of this osteoporosis study set the stage for BBK retention efforts. The goal was to retain at least 85 percent of participants for the two-year study while simultaneously enrolling a substudy. Thanks to the relationships built between site staffs and patients

during the recruitment phase, BBK further cultivated these alliances, recognizing that patients needed to be related to if they were going to make a commitment to long-term participation. Retention materials, including patient reminders and appreciation items, bolstered the enthusiasm of both study staffs and patients. Bottom line: enrollment remained above 92 percent and, at the same time, BBK was able to recruit more than 110 new patients for the substudy.

## Phase III Study // Osteoporosis Prevention



**Collaboration Counts //** With competing studies at 12 of the U.S. sites challenging recruitment efforts, BBK leveraged site support relationships established during successful phase II enrollment. The collaboration between BBK site specialists and study coordinators kept this study top of mind and enrollment was completed six weeks early.

<b>OUR INVOLVEMENT</b>	Before First-Patient-In Date
<b>COUNTRIES</b>	Canada United States
<b>AUDIENCES</b>	Postmenopausal Women Site Staff
<b>KEYS TO ENROLLMENT</b>	Patient Outreach Site Support Relationships

22 Total Sites

Most Challenging to Engage

# 300

**Number That Counts //** The target audience for this osteoporosis prevention research study were postmenopausal women. The protocol included two arms with an enrollment goal of 150 for each arm or 300 total patients overall. BBK's effective recruitment tactics supported ahead-of-schedule enrollment that surpassed the sponsor's expectations.

**Objective //** Randomize 300 postmenopausal women within seven months

**Challenges //** Multiple competing studies; study required recruitment for two arms and two categories within each arm

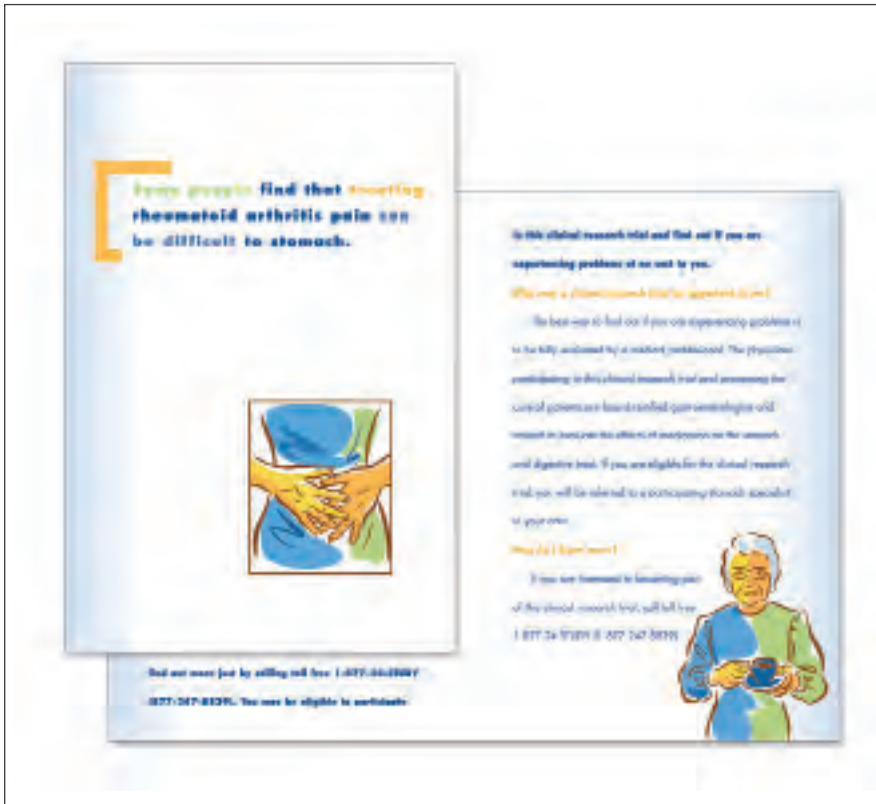
**Result //** Enrollment goal met six weeks ahead of schedule

## Expert Analysis



BBK was asked to recruit this study based on our recruitment success of phase II. The study was stratified into two arms, each with two categories that had specific enrollment goals depending on the patient's time since menopause. Once a category met its quota, it was closed to enrollment. BBK addressed stratification requirements by directing recruitment outreach to those audiences that were enrolling at a slower pace. To avoid the approaching holiday season, BBK expedited the launch of patient outreach efforts, including television advertising, generating nearly 1,000 inquiries and resulting in 398 referrals to complete enrollment six weeks ahead of the deadline.

## 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

RA Community

Most Difficult to Engage

#### 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 // Sarcopenia



**Delivering the Message //** An comprehensive educational direct-mail brochure served as the cornerstone of this campaign – supported by radio, print, and public relations – and effectively drove enrollment by positioning the study as a means of possibly making a proactive difference in the maintenance of muscle mass for health.

### OUR INVOLVEMENT

After First-Patient-In Date

### COUNTRY

United States

35 Total Sites

### AUDIENCES

Patients

Site Staff

Local News Media

Most Difficult to Motivate

### KEY TO ENROLLMENT

Study Positioning

# 4

**Number That Counts //** After eight of the 12 months of the enrollment period had elapsed, yielding only 24 of the required 135 patients, the sponsor turned to BBK for help with what it thought was an unenrollable study. But in just four months, and primarily through direct mail to seniors within a 10-minute driving distance to the sites, BBK achieved enrollment with two weeks to spare.

**Objective //** Enroll 135 participants in four months for a study evaluating an investigational drug for sarcopenia

**Challenges //** Participants had to be generally healthy seniors without symptoms of sarcopenia; participants had to commit to maintaining their current diet and exercise regimens during the study

**Result //** Enrollment was achieved ahead of schedule

## Expert Analysis

**muscle mass**  
STUDY

How do you get people in good health to participate in a clinical study of a compound that's designed to treat a condition with no symptoms? That's the question the sponsor asked BBK

two-thirds of the way through the enrollment period of this study of an investigational drug for sarcopenia (age-related muscle loss). BBK's answer: educate seniors that maintaining muscle mass to avoid injury is as important to maintaining independence and mobility as retaining bone density is to fighting osteoporosis. With a campaign well-positioned, outreach tactics appropriately targeted, and sites trained and equipped with materials, inquiry and screening rates rose rapidly and enrollment was achieved ahead of schedule.

## Prospective Studies // Vertebral Compression Fracture (VCF) Repair



**Concentrating on Motivations** // BBK increased the enrollment of three studies of an approved VCF repair device by discerning the specific motivations for physicians to refer patients to, and for patients to participate in, each of the studies; implementing compelling programs and materials leveraged these insights.

OUR INVOLVEMENT	
After First-Patient-In Date	
COUNTRY	
United States	Three Studies
AUDIENCES	
Patients	Most Important to Motivate
Referring Physicians	
Investigators	
Site Staff	
KEYS TO ENROLLMENT	
Study Positioning	
Study Messaging	

# 3

**Number That Counts** // The campaigns for these three studies each followed a basic, three-step process to achieve rapid results. First, identify the barriers to enrollment. Second, determine the positioning and messaging to overcome the given barrier. Third, develop programs and materials that quickly and insightfully present the messages that will garner both attention and response.

**Objectives** // Develop recruitment programs and materials for three clinical studies of an approved VCF repair device

**Challenges** // Studies were behind in enrollment; study treatment already approved and readily performed

**Results** // BBK quickly identified the motivations to refer/participate for each of the three studies, and developed study-specific materials that helped get enrollment back on track

## Expert Analysis



For varying reasons, three separate studies of an approved VCF repair device were experiencing enrollment rates far lower than anticipated. To help increase the numbers of eligible patients seen by each site, BBK quickly determined the enrollment barriers that faced each of the studies and then

crafted the means to overcome these obstacles. For example, for the study examining the medical device for the repair of VCFs associated with cancer treatment, potential referring oncologists typically were unaware that the intensity of the pain experienced by patients often left them bedridden. By positioning study participation as a means of helping to ensure patients could attend their chemotherapy sessions, BBK generated an influx of referrals.