

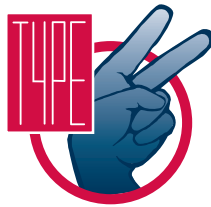
Endocrinology // Overview of Capabilities

It's information overload: People managing these conditions are often bombarded every day with conflicting data. To help patients make sense of the many new discoveries, shifting treatment options, and contradictory research results – and to help them see study participation as a real option – BBK recruitment materials include education and patient support. Our campaigns also help site staff clearly communicate the benefits of a particular study.



// Type 2 Diabetes

BBK has extensive experience enrolling small- and large-scale studies in type 2 diabetes and related diseases. Our success in this area is directly related to TrialCentralNetSM technology that tracks ethics review of materials, return on investment for recruitment tactics, and sites' ability to process patient referrals.



// Pediatric Type 2 Diabetes

To effectively reach out to parents of children with type 2 diabetes, BBK has crafted several engaging national and global awareness campaigns. These campaigns educate parents about their child's condition, empower them to proactively screen their child for the disease, and encourage them to consider study participation as a viable option for care.

TYPE 1 Diabetes

// Type 1 Diabetes

BBK has consulted on and devised recruitment support for a variety of type 1 diabetes studies. Solutions for these studies are frequently contingent on the idiosyncrasies of the study design – especially when participants are insulin-dependent – to avoid the perception of the study as an added medical burden.



// Female Hormone Health

Women reaching menopause are heir to a wide range of complex health concerns and often need extra support to understand and accept their condition. BBK has supported numerous studies in this area, with empathetic materials that encouraged patients to discuss potentially embarrassing – yet treatable – medical conditions.



// Male Hormonal Health

BBK has recruited numerous U.S. and global men's health studies, from sexual disorders to late-stage prostate cancer. Besides targeting patients, messaging is also directed toward those female caregivers who help their partners or family members make important health decisions, and is reflected in both media placement and patient communication materials.



// 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.

Multiple Studies // Potential Participant Online Communities



Member Benefits // Membership Web sites and accompanying retention programs champion the ideals of regularly educating one's self about health matters, and inspire members to regularly update their health status and contact information as a means of facilitating invitations to participate in specific clinical studies.

OUR INVOLVEMENT

Before First-Patient-In Dates

COUNTRIES

Canada
United States

Select Patient Populations

AUDIENCES

First-Time Visitors
Returning Members

KEY TO ENROLLMENT

Membership Retention Programs

11

Number That Counts // By inspiring members to update their health and contact information, BBK has helped sponsors enroll 11 subsequent studies using the ready pool of participants our online communities have generated. BBK has thus multiplied the return on investment for each sponsors' initial recruitment outreach effort.

Objective // Develop a means of applying the response to one study's recruitment outreach to multiple future studies

Challenge // Overcome the intrinsic fact that the desire to participate in a given clinical study is a reaction to a concern that patients have about their condition at a specific moment in time

Result // Membership helped populate 11 subsequent studies

Expert Analysis



Knowing that they would be conducting multiple studies for the same condition, and that enrolling each study would require direct-to-patient outreach, the sponsor asked BBK to develop a means of retaining inquiries about the initial studies in a manner that could be easily applied to future studies. BBK's

solution was to invite patients who screen-failed for the first study to become members of an online service that would notify them of future clinical trial opportunities for which they might qualify. To ensure that registrants' information remained up-to-date, a retention program periodically provided items related to health education in exchange for confirmation of current disease status and contact information.

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

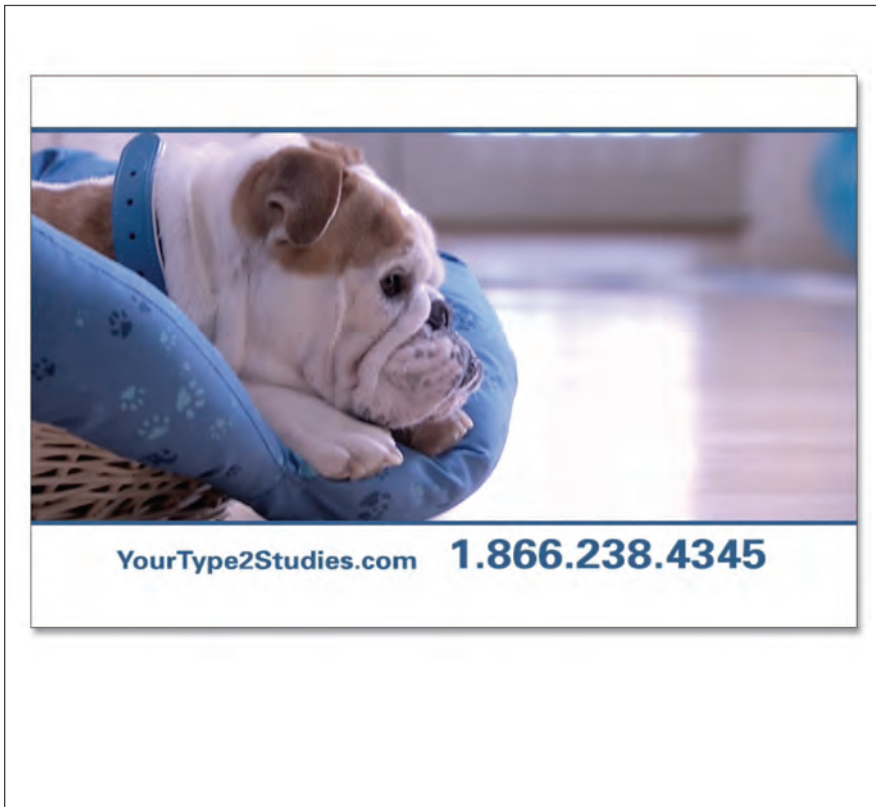
Expert Analysis

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.

Phase III Study Franchise // Type II Diabetes



The Right Training // BBK's multimedia recruitment campaign for this suite of type 2 diabetes studies was a remarkable success. It featured a direct response television advertisement, print and radio ads, and Web outreach – and took just a month to attract all the patients needed for study participation in the U.S. BBK immediately repeated that achievement in the ensuing international rollout of the campaign.

OUR INVOLVEMENT

Before First-Patient-In Date

COUNTRIES

Australia, Brazil

Canada, New Zealand

United States

} 90 Total Sites

AUDIENCES

Patients

Site Staff

Country Study Managers

} Most Critical to Engage

KEY TO ENROLLMENT

International Media Campaign

4

Number That Counts // The generation of enough referrals to enroll 500 patients in the U.S. was just the start of BBK's success in recruiting for these studies. It set the tone for the multinational media effort that followed. Patients with type 2 diabetes on four continents responded to and were motivated by BBK's media campaign, leading to successful enrollment at sites around the world.

Objectives // Recruit nearly 500 patients for U.S. sites in 12 months; re-launch campaign internationally to provide franchise-level support across multiple countries and protocols

Challenges // Overcrowded marketplace; messaging had to be precise but still "generic" enough to cross protocols

Results // Enrollment in the U.S. completed in only a month; culturally adapted campaigns took a few more months to do the same at ROW sites

Expert Analysis



The sponsor initially contacted BBK to support U.S. sites for a single type 2 diabetes protocol. The response to the campaign launched to enroll that study was overwhelming, and BBK was then contracted to support the sponsor's global franchise of type 2 diabetes studies. After using a wide range of

channels to enroll a single study in one country, BBK then iterated each element of the campaign – TV, radio, print, and Web ads – for multiple studies and multiple countries. The result was a media masterstroke. The international campaign featured crafted messages that supported either individual protocols or the franchise as a whole depending on the needs of the ROW sites, and the entire effort was delivered through precision multinational media buys.

Phase III Study // Type 2 Diabetes



Thorough Global Insight // With extensive country planning, shrewd positioning and messaging, and highly effective media planning and buying, BBK’s campaign achieved on-time enrollment – almost in spite of the fact that the study designs for each of these five protocols offered no significant motivation to participate.

OUR INVOLVEMENT	Before First-Patient-In Date
REGIONS	North America, South America, Europe, Asia-Pacific
AUDIENCES	Patients, Country Study Managers, Site Staff, Referring Physicians
KEYS TO ENROLLMENT	Campaign Planning & Design, Cultural Adaptation

47 Total Countries

Most Challenging to Motivate

47

Number That Counts // Before they could be culturally adapted into 75 languages, more than 20 versions of the materials had to be crafted to accommodate an equal number of country-specific protocol revisions. Turning this into an opportunity, BBK leveraged its understanding of the patients and healthcare systems in each of the 47 countries to create materials that were highly tailored, rather than merely translated.

Objective // Recruit a total of 3,400 patients for a suite of five type 2 diabetes protocols

Challenges // Complex logistics of communicating the study opportunity in 47 countries and 75 languages; varying protocol revisions in 20 countries; study designs did not offer compelling motivation to participate

Results // All five protocols enrolled ahead of schedule, with two protocols enrolling three months ahead of their scheduled end dates

Expert Analysis



The very size of the task alone would make it difficult to recruit this study: 3,400 patients were needed from 47 countries for a suite of five type 2 diabetes protocols. Complicating matters was the fact that neither study designs nor the investigational drug offered any significant potential advantage over available treatments, thus leaving little incentive to participate. The centerpiece of the campaign was a 60-second TV spot that could be easily edited to facilitate use in many countries. Additional mass media outreach included print and radio, as well as direct e-mail. By developing a well-crafted, easily customized campaign, BBK not only achieved enrollment for all five protocols, but also significantly contained production costs without compromising efficacy.

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OUR INVOLVEMENT	
Before First-Patient-In Date	
REGIONS	
Asia-Pacific, Europe, North America, South America	47 Total Countries
AUDIENCES	
Patients	
Country Study Managers	
Site Staff	Most Challenging to Motivate
Referring Physicians	
KEYS TO ENROLLMENT	
Campaign Planning & Design	
Cultural Adaptation	

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Phase III Study // Type 2 Diabetes in Children



Raising Awareness and Enrollment Rates // At the time, many parents were unaware of their overweight child's potential to develop type 2 diabetes. This fact, combined with narrow eligibility criteria, made identifying patients difficult. To achieve enrollment (and thereby help the sponsor win a patent extension for the study drug), BBK implemented a public awareness and recruitment campaign that supported selected, high-enrolling sites.

OUR INVOLVEMENT	
After First-Patient-In Date	
COUNTRY	
United States	67 Total Sites
AUDIENCES	
Parents and Patients	
News Media	
Advocacy Groups	
Alternative Referral Channels	Most Difficult to Engage
Site Staff	
KEY TO ENROLLMENT	
Targeted Site Support	

67

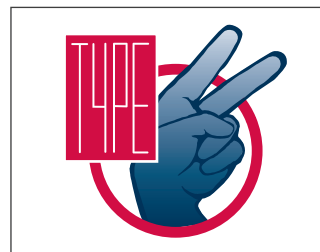
Number That Counts // With the sponsor only able to afford a third of the budget needed to achieve the estimated number of inquiries required to enable each site to meet its enrollment target, the decision was made to support only 67 high-performing sites. By focusing resources and enabling these sites to maximize their referral processing, the campaign's recruitment objectives were achieved.

Objective // Enroll 60 evaluable pediatric patients in order to fulfill an FDA requirement for patent extension of the study drug

Challenges // Restrictive eligibility criteria, placebo arm, low public awareness of pediatric type 2 diabetes, limited recruitment budget

Results // Enrollment rates for BBK-supported sites immediately and steadily increased throughout study; sponsor won study drug patent extension

Expert Analysis



BBK's analysis revealed the need for a sizeable campaign to drive the large number of inquiries needed to enroll 60 pediatric patients with HbA1c levels that fell within a narrow window – one that indicated early type 2 diabetes, but that didn't mandate immediate treatment with medication. To meet

the challenge, BBK conducted public relations and radio and TV advertising, as well as direct mail to homes, schools, and advocacy groups in communities surrounding sites. Efforts urged parents to consider screening for their children, and leveraged access to expert care through study participation. Referrals significantly increased for the BBK-supported sites. BBK's site support enabled sites to better process patient referrals.

Phase III Study // Type 2 Diabetes



Meeting the Challenge // Type 2 diabetes protocols have become increasingly difficult to enroll and this study was no exception. BBK developed an outreach strategy to reach the target audience through direct-to-patient communications; a well-placed TV spot maximized the outreach effort, generating an influx of inquiries from potential participants.

OUR INVOLVEMENT	
After First-Patient-In Date	
COUNTRY	
United States	68 Total Sites
AUDIENCES	
Patients	Most Challenging to Engage
Caregivers	
Site Staff	
KEYS TO ENROLLMENT	
Targeted Media	
Customized Outreach	

4

Number that Counts // BBK messaging presented participation in this clinical study as a treatment option for people at a crossroads in controlling their type 2 diabetes. Campaign materials educated patients about a new drug combination therapy to replace the one that was no longer working for them. The messaging resonated with the target audience and enrollment was met four weeks ahead of schedule.

Objective // Randomize an additional 800 patients across 68 sites

Challenges // Eligibility criteria limited pool of patients; multiple competing studies; placebo arm; condensed enrollment period

Results // Study achieved on-time enrollment of a total of 1,160 patients, 800 of whom were randomized with BBK campaign support a full month ahead of schedule

Expert Analysis



To get recruitment for this protocol back on track, BBK drew on its extensive experience supporting enrollment of type 2 diabetes studies. A year into recruitment, 590 patients were enrolled but an additional 800 were needed to achieve the recruitment goal of 1,160 participants. BBK created

a comprehensive recruitment strategy to reach out to patients and to request referrals from physicians and medical caregivers through personalized direct mail and e-mail. A 60-second TV spot targeted specific sites' markets identified by BBK as having a high prevalence of people with type 2 diabetes and generated additional inquiries to enable this study to enroll on time.

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
Canada

5 BBK-Supported Sites,
15 Total

AUDIENCES

Patients
Site Staff
Investigators

Most Important
to Motivate

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.