

## Cardiology // Overview of Capabilities

We have conducted numerous recruitment campaigns for a variety of cardiovascular drugs, devices, and treatments, and have marketed medical devices and launched new therapies across a wide range of cardiovascular conditions. Our approaches achieve results quickly, educating patients about their condition – and their treatment options – in a manner that engages them in their care, rather than allowing them to be passive participants.



### // Chronic Heart Failure (CHF)

When site initiations are delayed, enrollment rates at each initiated site inevitably need to be increased. When delays occur in studies involving patients with this chronic cardiovascular condition, BBK's efforts help maximize enrollment by facilitating sites' efforts to mine patient panels and to reach out to referring physicians.



### // Cholesterol and Blood Pressure

Studies that require cardiology patients with comorbidities often face the dual enrollment challenge of locating patients not only with a specific combination of heart-related conditions, but with a specific severity of each. In such cases, BBK outreach campaigns have boosted enrollment by drawing in the right patients through highly targeted messaging.



### // Obesity and Atherosclerosis

When enrollment for studies of diabetes-related heart conditions become crippled by the studies' lifestyle adjustment demands, BBK has encouraged patients by helping them focus on incremental visit-by-visit goals – instead of sometimes daunting overall study goals. This approach has enabled patients to take a comfortable “step-by-step” view of study participation.



### // Diabetic Hypertension

For cardiology studies under strict time and cost constraints, one-on-one patient education has provided an invaluable enrollment boost. BBK's ambassador programs have demonstrated this numerous times: on-site diabetes educators can easily identify patients, discuss the study with them directly, and use the interaction to revitalize enrollment.



### // Congestive Heart Failure

BBK's fresh, eye-catching direct-to-patient outreach campaigns have helped support the enrollment of studies in this area by reaching out not only to congestive heart failure patients, but also to their caregivers – an untapped target audience that is heavily involved in the decision to participate.



### // Cardiomyopathy

Heart disease has become a high-profile public health issue. BBK often leverages the significant public consciousness of cardiovascular health, including conditions like cardiomyopathy, in order to propel our efforts to raise awareness of clinical studies, public health initiatives, and fund-raising efforts in this area.

## Global Retention // Atherosclerosis



**Step by Step //** When enrollment for this diabetes clinical trial was jeopardized by the study's lifestyle adjustment demands and extensive length of participation, BBK encouraged patients by helping them focus on incremental visit-by-visit goals – instead of daunting overall study goals. This approach enabled patients to take a comfortable “step-by-step” view of study participation.

<b>OUR INVOLVEMENT</b>	Global Retention
<b>COUNTRIES</b>	Canada, France, Netherlands Spain, United Kingdom, United States
<b>AUDIENCES</b>	Principal Investigators Site Staff Patients
<b>KEYS TO ENROLLMENT</b>	Physician Retention Toolkit Extension of Care Items

64 Total Sites

Most Important for Success

# 6

**Number That Counts //** Six bi-monthly newsletters were created to provide patients with information about the study procedures, helpful tips as they progressed through the study, and lifestyle changes that could help reduce the risk of heart attack and stroke.

**Objectives //** Raise awareness of the importance of retention efforts; reinvigorate commitment to the study by leveraging tools and training with principal investigators and site staff throughout the world

**Challenges //** Long study duration; placebo-controlled; medication available off-label

**Result //** Dramatically reduced patient discontinuation

## Expert Analysis



Initially scheduled to last up to 26 months, this study was extended by nine months to accommodate the need for further data. The sponsor became concerned that this additional commitment had the potential to negatively affect patient participation and compliance. BBK implemented an aggressive retention campaign built around the development of bi-monthly newsletters that focused on the simple step-by-step goals that patients could reach with regard to healthy eating and living, and reminded patients of the importance of attending all study and follow-up visits. BBK also provided patients with study-branded extension of care items – water bottles, pedometers, stress balls, etc. – to assist patients with study compliance and with the ultimate aim of improving heart health beyond study participation.

## Phase III Study // Chronic Heart Failure



**A Community Effort** // BBK was tasked with overcoming two key enrollment barriers: site initiation delays and projected enrollment shortfalls. As a result of BBK's efforts, sites were prepared to "hit the ground running" once they became active, and were bolstered by campaign materials that provided site staff with ways to effectively communicate the study opportunity.

<b>OUR INVOLVEMENT</b>	Before First-Patient-In Date
<b>COUNTRY</b>	United States } 40 Total Sites
<b>AUDIENCES</b>	Patients
	Referring Physicians
	Site Staff } Most Difficult to Motivate
<b>KEYS TO ENROLLMENT</b>	Rapid Development
	Rapid Deployment

# 360

**Number That Counts** // Recruiting 360 patients for this heart failure study didn't seem daunting with a full roster of sites; however, initiation delays at some sites posed a huge threat to achieving on-time enrollment. BBK's campaign materials, training, and support enabled all sites to maximize their enrollment potential as they became active.

**Objective** // Recruit 360 patients within nine months into a heart failure study

**Challenge** // Majority of sites not activated by first-patient-in date

**Results** // Maximized enrollment at initiated sites; enrollment achieved on time

### Expert Analysis



This study was in danger of failing to enroll on time when BBK was asked to intervene. A number of sites had not yet been initiated due to contracting issues, so the enrollment potential of initiated sites would have to increase significantly to meet study goals on time. Just before the first-patient-in date, BBK was able to project the study's enrollment shortfall and develop a campaign to maximize sites' enrollment from their own databases and to increase referrals. With customized site support, BBK positioned the study for success by preparing uninitiated sites to rapidly enroll their patient panels once they were up and running.

## Disease Management Program // Congestive Heart Failure (CHF)



**Return on Investment //** BBK's pilot campaign highlighted the program feature benefit – receiving close monitoring and care at home – by playfully contrasting the comforts of home with the inconveniences of a hospital visit. Results proved the value of future spending for achieving the program's lofty enrollment goal.

<b>OUR INVOLVEMENT</b>	After First-Patient-In Date
<b>COUNTRY</b>	United States
<b>AUDIENCES</b>	Caregivers Patients
<b>KEY TO ENROLLMENT</b>	Understanding Target Audiences

Most Difficult to Motivate

# 2

**Number That Counts //** The key to success was to target both patients and their loved ones. By targeting the TV media buy specifically at times when caregivers as well as patients would be viewing (even though it meant airing the spot fewer times due to budget limitations), the campaign received a flood of responses, quickly demonstrating the value of investing in advertising beyond the pilot program.

**Objective //** Create and conduct a cost-effective pilot campaign to demonstrate significant return on investment (ROI) for future promotion of major disease management program

**Challenges //** Limited development and media budget

**Results //** Response rates from both TV and direct-mail outreach exceeded best expectations of the media plan and the client

## Expert Analysis



One of the country's largest managed healthcare plans was struggling to increase enrollment in its CHF disease management program. With BBK's help, the sponsor hoped to demonstrate ROI that would justify future promotional

spending towards the program's ultimate goal of enrolling 21,000 participants in California and Arizona. BBK developed a two-week pilot run of a direct-response television spot, supported by direct mail. The fresh campaign elicited a remarkable response rate from patients and caregivers, and BBK's detailed analyses indicated an exceptionally high response rate in additional media markets with only a modicum of investment.

## Phase IV Study // Hypertension

**Heart of the Matter //** Studies that require cardiology patients with comorbidities often face the dual enrollment challenge of locating patients not only with a specific combination of heart-related conditions, but with a specific severity of each. Using the right mix of print, electronic, and broadcast media, BBK was able to deliver a highly target message that drew in the right patients for enrollment.

<b>OUR INVOLVEMENT</b>	Before First-Patient-In Date
<b>COUNTRY</b>	United States
<b>AUDIENCES</b>	Patients Cardiologists Referring Physicians Site Staff
<b>KEYS TO ENROLLMENT</b>	Media Study Messaging

40 Sites

Most Critical to Engage

# 20

**Number That Counts //** After initial performance analysis of all sites, BBK reallocated resources to support only the top 20 performing sites, those responsible for the vast majority of patient referrals. Using five key metrics – prior performance, patients database, outreach results, length of time active, and responsiveness to consultation – BBK was able to reduce total costs and meet enrollment deadlines.

**Objectives //** Recruit a total of 260 patients in 12 months for a clinical trial comparing two strategies for the management of hypertension and mild dyslipidemia in patients with additional cardiovascular (CV) disease risk factors

**Challenges //** Patients with combination of comorbidities; narrow eligibility criteria; competing studies

**Result //** On-time study enrollment

## Expert Analysis



This research study was comparing two FDA-approved medications to determine which medication helped lower blood pressure and lower cholesterol levels – two important risk factors for heart disease and stroke. In addition to leveraging the potential benefits of the investigational medications, BBK's messaging and materials concentrated on the counseling sessions that patients would receive from dedicated cardiologists, as well additional information on how to make healthier lifestyle choices to help reduce their risk of heart disease and improve their quality of life moving forward. This information was easily distilled through the use of colorful and concise office brochures, posters, and flipbooks detailing the informed consent process, along with direct mail, and print, and radio advertisements.

## Phase II Study // Type 2 Diabetes and Hypertension



**Grassroots Recruitment //** Engaging such a specific segment of the diabetic population about a study for possibly preventing a condition they didn't know they were at risk for required an approach that was uniquely persuasive. By enlisting diabetes educators and arming them with a toolkit to engage physicians and patients, the campaign raised awareness and achieved enrollment.

OUR INVOLVEMENT	
Before First-Patient-In Date	
COUNTRY	
United States	53 Total Sites
AUDIENCES	
Patients	Most Difficult to Motivate
Diabetes Educators	
Referring Physicians	
Site Staff	
KEY TO ENROLLMENT	
Ambassador Program	

# 3

### Number That Counts //

To achieve study enrollment, BBK's "ambassadors" (diabetes educators) had the challenge of connecting the three dots between type 2 diabetes, hypertension, and kidney disease – two of which exhibit no symptoms, and about which patients typically know little. Using BBK's toolkit, however, the ambassadors were able to successfully engage patients and referring physicians.

**Objective //** Enroll a clinical study of a treatment to reduce the risk of progressive kidney disease in people with type 2 diabetes

**Challenges //** Engage patients about a condition patients were not aware of; limited recruitment budget

**Results //** BBK developed a uniquely persuasive campaign that reached patients in more than 35 markets and 53 sites nationwide to achieve enrollment on time

### Expert Analysis



People with type 2 diabetes and hypertension are instructed by their doctor to do everything they can to manage both their blood sugar and blood pressure on a daily basis. What many patients don't realize, though, is that both conditions put them at increased risk for kidney disease.

BBK's challenge was to promote a study of an investigational drug for reducing the risk of progressive kidney disease for these individuals. Given this complex rationale for considering study participation, BBK developed a grassroots ambassador program using diabetes educators. Armed with a toolkit of customizable communications, ambassadors reached out to referring physicians and patients in more than 35 markets and 53 sites nationwide.