

Infectious Disease // Overview of Capabilities

Our experience in this therapeutic category spans a wide range of conditions – and a wide range of solutions. Perhaps more than any other field, the recruitment barriers faced by studies of treatments for infectious disease are often contingent on the current progress of the clinical R&D marketplace. However, devising unique solutions for unique recruitment conundrums is where BBK excels.



// Human Immunodeficiency Virus (HIV)

If there's any good news about fighting HIV, it's that sponsors are working hard to rapidly increase the arsenal of treatment options. The bad news is that as a result, the HIV clinical study marketplace is very crowded. BBK has responded by creating campaigns for HIV studies that cut through clutter while being culturally adaptable.



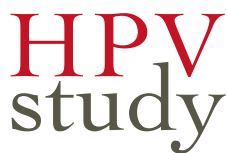
// Hepatitis C

When facing a knowledgeable patient population that is constantly searching for the latest treatment information on hepatitis C, the key has been to be as up front and direct as possible. By creating detailed-yet-accessible recruitment and retention materials, BBK has provided support, empathy, and care to participants struggling with this disease.



// Nosocomial Pneumonia

To meet the challenges of recruiting studies for nosocomial pneumonia, BBK has worked closely with physicians and site staff to develop site-specific recruitment plans. Based on each site's needs, BBK created customized recruitment and/or retention toolkits that help facilitate on-time enrollment.



// Human Papillomavirus (HPV)

Because people with HPV are often asymptomatic, BBK's public relations team has frequently worked with infectious disease centers and dedicated study sites to promote HPV-related clinical trials using intra-institutional press releases and educational forums. Our methods have encouraged discussion about the disease, best practices, and the latest in research.



chronic
bronchitis
study

// Chronic Bronchitis

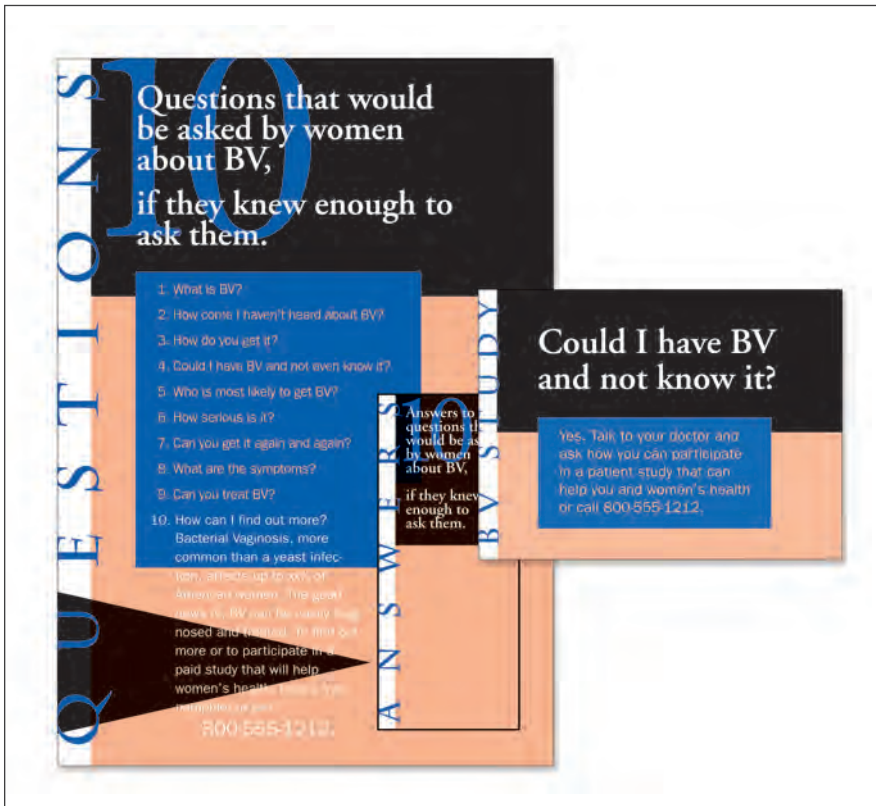
For campaigns involving seasonal infections, BBK generally faces one of two challenges: enrolling a study months before a condition typically presents itself, or towards the end of a given season when disease cases are on the decline. In either case, BBK has created radio and TV ads that have consistently generated the right type of patient referrals.



// Molluscum Contagiosum

Warts can be an embarrassing condition. Faced with this challenge of competing with over-the-counter medications, BBK reached out to referring physicians directly to obtain pediatric referrals necessary for enrollment. Furthermore, BBK's toolkits have been effective in dispelling myths surrounding both the origin and treatment of this stubborn virus.

Phase IV Study // Bacterial Vaginosis



Breaking Taboo // By referring to an embarrassing condition, bacterial vaginosis, as “BV”, BBK made a taboo topic something easily talked about. An aggressive direct advertising and public relations campaign helped this study exceed enrollment goals.

OUR INVOLVEMENT	Before First-Patient-In Date	
COUNTRY	United States	65 Total Sites
AUDIENCES	Female College Students Local Broadcast News Media Local Print News Media	Champions of the Message
KEYS TO ENROLLMENT	Publicity Targeted Message	

10

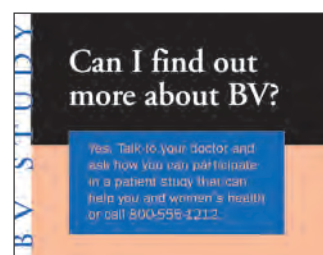
Number That Counts // By framing information about the condition in the familiar format of “10 Questions and Answers”, the campaign quickly and effectively engaged both women and the media. This campaign targeted young women who did not have a relationship with a physician, and leveraged a well-publicized event (the release of the first over-the-counter yeast infection treatment) to help generate interest.

Objective // Recruit 320 patients within four months for a bacterial vaginosis study

Challenges // Open a dialogue about a taboo subject; educate women and the media about an often undetected, misunderstood, sensitive condition

Results // Campaign generated over 7 million print and broadcast impressions. Enrollment exceeded target ahead of schedule

Expert Analysis



The topic was taboo. The task was crystal clear: create an open dialogue about a subject that no one wanted to talk about. Although it affects millions, bacterial vaginosis is a condition that women either don't know exists or are too embarrassed about to discuss.

The focus was on bacterial vaginosis as a common, treatable medical condition that is often undetected or erroneously self-diagnosed as a yeast infection. BBK mounted an aggressive, integrated advertising and public relations campaign that generated more than 7 million print and broadcast impressions. Enrollment exceeded target and concluded ahead of schedule.

Phase III Study // Chronic Bronchitis



Message Delivery // Little headway was being made to enroll this study before BBK was brought in to rejuvenate site staffs and their recruitment efforts. BBK created a comprehensive local media campaign that delivered the study message to the target population at the height of the flu season, when patients are most vulnerable to chronic bronchitis flare-ups.

OUR INVOLVEMENT	
After First-Patient-In Date	
COUNTRY	
United States	54 Total Sites
AUDIENCE	
Patients	
KEY TO ENROLLMENT	
Targeted Media	

6

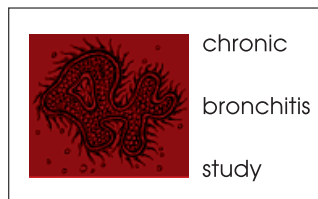
Number That Counts // Six weeks. That's all the time it took for BBK's media campaign to generate some 30 million impressions from targeted outreach in 35 local media markets. Public service announcements, TV, radio, and print advertising complemented a public relations push to generate more than 1,400 qualified referrals.

Objectives // Reinvigorate patient recruitment and support sites in enrolling 400 patients within 6 months

Challenges // Seasonal condition; narrow study eligibility criteria

Result // Enrollment achieved two months ahead of schedule

Expert Analysis



BBK's support and consultation helped site staff get enrollment back on track for this study of a new indication for an approved drug designed to treat acute exacerbations of chronic bronchitis. The media tactics employed by BBK ensured the study message

reached – and motivated – potential participants through TV, radio, print, and public service announcements. Using seasonal flu tracking data, BBK launched the media campaign in 35 local media markets across the U.S. to coincide with the peak of the cold and flu season in each market – the season when people with chronic bronchitis are at increased risk of flare-up, a criteria for study participation.

Phase II Study // Hepatitis C



Listening In // Incorporating feedback from focus groups helped BBK create a global brand for this study of a novel therapy to treat hepatitis C. And an informed patient population was receptive to messaging that presented study participation as a possible alternative to standard of care medications and the side effects that come with them.

OUR INVOLVEMENT

Before First-Patient-In Date

REGIONS

Asia, Middle East

North America

Pacific Rim, Western Europe

42 Total Sites in
16 Countries

AUDIENCES

Patients

Physicians

Most Critical
to Engage

KEYS TO ENROLLMENT

Focus Groups

Cultural Adaptation

6

Number That Counts // Six focus groups in 6 different parts of the world provided BBK with the feedback that was critical to determine the messaging and creative concepts that would resonate with and draw the interest of patients with hepatitis C across the globe.

Objective // Recruit 150 patients in 6 months for a 16-country clinical research study

Challenges // Placebo arm; multiple study visits

Result // On-time global enrollment achieved

Expert Analysis



BBK was asked by this sponsor to create recruitment and retention materials to educate potential participants throughout the world about an oral investigational drug with a new approach to fighting the hepatitis C virus. Feedback from numerous focus groups as well as country site managers helped drive the creation of patient materials and their cultural adaptation. Equipped with a comprehensive campaign toolkit, BBK supported and consulted study sites to help them achieve on-time enrollment for this 16-country research study within the 6 months allotted.

Phase III Study // Hepatitis C



Study Advancement // Retention is often the real challenge of a hepatitis C study. The goal for this protocol was to retain 90 percent of all participants. BBK collaborated with study site monitors, motivating this key audience to ensure that patients made an informed decision about participation, and a conscious commitment to remain in the study throughout lengthy treatment and follow-up.

OUR INVOLVEMENT	After First-Patient-In Date
COUNTRIES	Argentina, Australia, Austria, Canada, France, Germany, Israel, Italy, Poland, Spain, U.K., U.S.
AUDIENCES	Patients Site Staff
KEY TO RETENTION	Relationship Building

125 Total Sites

Most Important to Engage

90

Number That Counts // People with hepatitis C who had never received treatment for the virus were the target population for this study. With participation potentially lasting up to two years, 90 percent of the 1,050 randomized patients were retained, due in large part to the strong relationships built between study coordinators and patients with the support of BBK retention specialists.

Objective // Retain 90 percent of the 1,050 enrolled patients

Challenges // Six months of follow-up after treatment was completed, despite placebo arm; translation/customization in 11 languages

Result // Enrollment remained above 90 percent

Expert Analysis



Hepatitis C patients are well-educated healthcare consumers, and readily consider clinical study participation as a potential treatment option. The key to this study was to ensure that patients would complete the protocol,

despite the fact that it included a placebo arm and required patients to have blood tests for an additional six months after stopping treatment. To solidify buy-in at all levels, BBK created site materials that enabled study staff to educate patients and clearly communicate the formidable requirements which study participation entailed. Ultimately, enrollment for this protracted study remained above 90 percent.

Phase IIb Study // Human Immunodeficiency Virus (HIV)



Strategic Solutions // Overcoming the recruitment barriers faced by research studies of investigational treatments for infectious diseases is often a challenge. For this global HIV protocol, BBK created a culturally adaptable recruitment toolkit that site staff used to educate patients about the study opportunity and the potential benefits of study participation.

OUR INVOLVEMENT	Before First-Patient-In Date
COUNTRY	United States (including Puerto Rico) } 13 BBK-Supported Sites
AUDIENCES	Patients } Most Critical to Engage Referring Physicians Site Staff
KEYS TO ENROLLMENT	Site Consultation Study Messaging

2

Number That Counts // One-on-one site consultation and study messaging were the two key elements of this recruitment campaign. BBK site support guided study sites with patient outreach and media placement to motivate potential participants to learn more about the study opportunity.

Objective // Enroll 54 patients in the U.S. and Puerto Rico for an HIV research study with a total enrollment goal of 189 patients worldwide

Challenges // Extremely narrow eligibility criteria; high screen-failure rate; limited budget; competitive treatment landscape

Result // BBK-supported sites achieved a screening rate 16% higher than unsupported sites

Expert Analysis



BBK's proactive approach coupled with one-on-one consultation and training helped sites achieve a significantly higher screening rate in the U.S. and Puerto Rico for this hard-to-enroll global research study. BBK created a comprehensive recruitment toolkit with empathetic messaging that facilitated

the discussion between site staff and potential participants about the study opportunity. BBK support guided sites in placing local print and radio advertising that was complemented by a public relations campaign – all designed to get the study message before target audiences. And BBK created highly targeted banner ads on Facebook® to drive additional patient referrals to sites.