

Immunology // Overview of Capabilities

When the body's immune system doesn't function properly, the break down can result in a variety of diseases. For clinical research trials evaluating potential treatment options for allergies, bacterial diseases, and bronchitis – among others – BBK creates recruitment campaigns to educate patients about their condition, and uses the opportunity to also inform them about clinical study participation as a potential treatment option.



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.



// Grass Pollen Allergies

BBK has extensive experience supporting studies designed to reduce the effects of grass pollen in children and adults. Intensive market research and focus-group testing have both driven the development of creative materials and advertising that BBK has used to support the enrollment of studies of investigational drugs for grass pollen allergies.



// 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.



// Clostridium Difficile

Enrollment feasibility and site selection are often the key to successfully recruiting participants who may be in hospitals or long-term care facilities for research studies of bacterial diseases. BBK's patient recruitment-focused approach can help identify not only the best-equipped sites, but which medical specialty would provide the most ideal investigator on a region-by-region basis.



The Asthma Study

// Chronic Asthma

When recruitment campaigns generate more patient referrals than are needed, BBK sees it as an opportunity to develop online communities. These Web-based registries allow interested patients to receive information about the sponsor's upcoming clinical trials, while also providing the sponsor with interested potential participants to support additional protocol enrollment on a franchise level.



// Peanut Allergy

Through the use of BBK-developed broadcast, print, and online media designed to position sites as centers of excellence and education for children's allergies, BBK has helped to raise public discussion surrounding allergy treatments, and has driven parents to increasingly speak with investigating pediatricians about enrolling their child in a clinical research study.

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

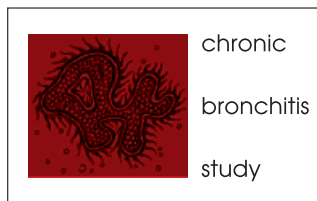
Number That Counts // Six weeks. That's all the time it took for BBK's media campaign to generate some 30 million impressions from targeted outreach in 35 local media markets. Public service announcements, TV, radio, and print advertising complemented a public relations push to generate more than 1,400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

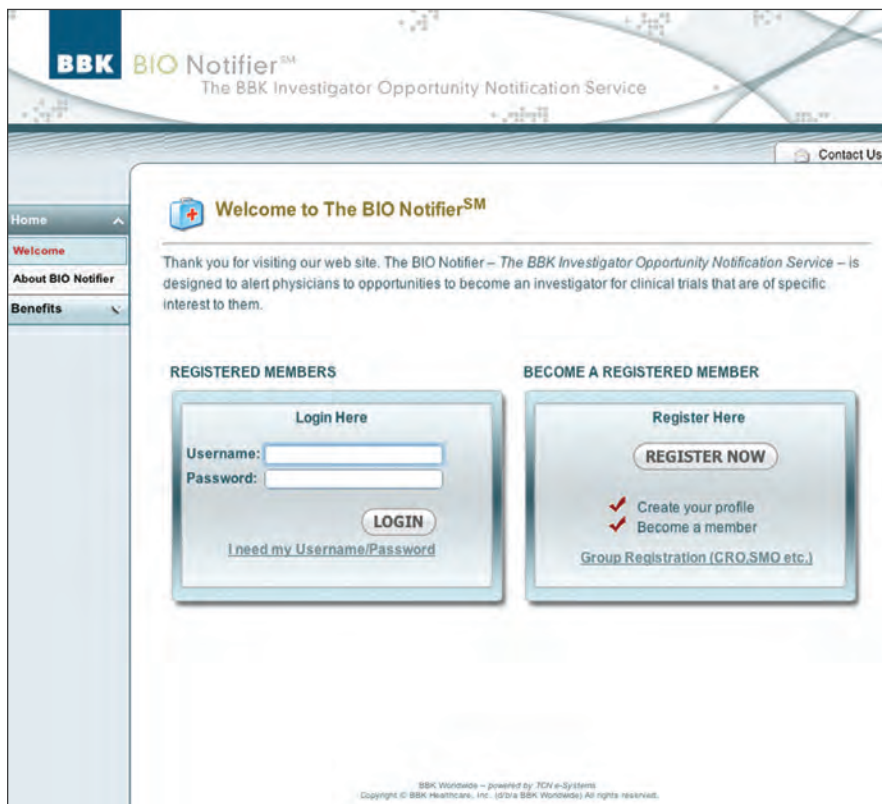
Expert Analysis



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 // Clostridium Difficile Infection Vaccine



A Proven Approach // BBK exceeded the goals for this project ahead of schedule by leveraging its proprietary approach to site selection via The BIO Notifier™, producing an insightful analysis of study and sponsor needs, an objective outreach plan, and an online survey that cleverly promoted the study to prospective investigators.

OUR INVOLVEMENT	Site Selection	
COUNTRY	United States	} 40 Sites Needed; 118 Identified
POTENTIAL INVESTIGATORS	Infectious Disease Specialists Gastroenterologists Internists	
KEY TO SUCCESS	The BIO Notifier™	} Key Specialists to Identify

118

Number That Counts // While the sponsor only required 40 U.S. sites at which to conduct the study, BBK identified 118 highly qualified sites. The remarkable response to BBK's survey not only provided the sponsor with the necessary sites, but also with a significant number of highly qualified investigators for subsequent studies, including a pediatric study of the investigational vaccine.

Objective // Obtain 120 completed surveys of potential investigators to result in selection of 40 sites.

Challenge // With the study behind in enrollment in other countries, BBK had to identify sites in the U.S. in a remarkably condensed time frame.

Results // From more than 300 surveys, BBK identified 118 highly qualified sites, providing the sponsor with highly qualified investigators for both this study and related studies.

Expert Analysis



After successfully completing site selection for the sponsor on a previous study, BBK was called upon to help identify sites with a high percentage of patients who had been treated for Clostridium difficile infection. BBK's proprietary approach to site selection using the BBK Investigator Opportunity Notification Service (The BIO Notifier) provides objective and insightful evaluation of potential investigators, reaching far more physicians than typically can be expected from CROs or SMOs. With the target of receiving 120 completed surveys, BBK actually garnered more than 300 completed surveys, resulting in 118 physicians who not only were interested in becoming investigators, but also who met the criteria to qualify as an ideal investigator.

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

Referring Physicians

Site Staff

Most Critical to Engage

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.

Phase II Study // Peanut Allergy



Establishing Patient Trust // All pediatric studies have to work to win patient and parental confidence, but for a study where peanut allergy patients would be required to ingest the substance known to be life-threatening, establishing trust was the key issue. The solution was positioning principal investigators as leading experts committed to finding a cure for peanut allergy, resulting in a six-fold increase in study enrollment.

OUR INVOLVEMENT	
After First-Patient-In Date	
COUNTRY	
United States	38 Total Sites
AUDIENCES	
Parents	Most Difficult to Motivate
Patients	
Physicians	
Sites	
KEY TO ENROLLMENT	
Study Positioning	

66

Number That Counts // BBK's campaign brought this failing study back to life. A combination of public relations, physician and patient outreach, Internet outreach, and site support garnered significant referrals – enough to enroll 66 new patients and to allow submission of study results to the FDA.

Objective // Enroll 84 pediatric patients in a peanut allergy study in less than one year (11 patients enrolled prior to BBK involvement)

Challenge // Patients as young as 12 years old were required to ingest peanut protein

Result // In less than one year, BBK enrolled six times the number of patients that the sponsor had recruited on its own

Expert Analysis



Having achieved just 10 percent of target during the first year, and with only months left in the enrollment period, the sponsor turned to BBK for assistance. The key was to establish patient and parent trust. BBK achieved this by positioning investigators as leading experts committed to finding a cure, and providing parents with materials that fully and empathetically articulated the safeguards in place for study participants. As a result, BBK enrolled six times the number of patients than the sponsor had recruited on its own – enough to allow submission of study results to the FDA.

Phase III Study // Pediatric Grass Pollen Allergy



'Twas the Season // To get parents thinking about their child's grass pollen allergy in the dead of winter, BBK's campaign leveraged how quickly holidays seem to come around – from Thanksgiving, Christmas, and New Year's to Valentine's Day and Easter. This approach brought parents around – and at rates greater than expected.

OUR INVOLVEMENT

After First-Patient-In Date

COUNTRIES

Canada
United States

77 Total Sites

AUDIENCES

Parents of Pediatric Patients
Site Staff
Investigators
Referring Physicians

Most Difficult to Engage

KEYS TO ENROLLMENT

Study Messaging
Media Planning

3

Number That Counts // Despite the fact that the study had been open for enrollment for more than a year, BBK had only three months in which to enroll more than 252 pediatric patients. The time frame was actually even shorter for TV, which only ran for one month, due to budget limitations and a start date after New Year's. Nonetheless, within six weeks of January 1, the study had enrolled the majority of its patients.

Objective // Enroll 252 patients within three months

Challenges // Remaining enrollment period coincided with holiday season; parents typically not thinking about grass pollen allergy during winter months; limited budget

Result // On the last day of the enrollment period, BBK had enrolled 254 patients – two more than were actually required

Expert Analysis



With more than a year elapsed, and only 48 of the 300 required pediatric participants enrolled, this study faced a staggering recruitment challenge: the remaining 252 patients would have to be enrolled during the holiday season, and during a time of year in which parents are more concerned with their child's cold or flu than they are with the upcoming grass pollen allergy season. To meet the challenge, BBK implemented a campaign of TV, radio, print, and direct e-mail that creatively positioned the holidays and winter as, ironically, the best time to be thinking about grass pollen allergy treatment. By seeding the market in December, and running heavy media in January, BBK was able to enroll the study by the deadline – the last day of February.