

Respiratory // Overview of Capabilities

Imagine the desperation that comes from being unable to breathe easily. When it comes to respiratory studies, BBK works to provide patients with information as well as empathy. With experience that spans surgical procedures, medical devices, antibiotics, and pharmacotherapies, our messaging and materials help to educate patients about their condition, and work to present clinical research studies as viable treatment options worthy of consideration.

Asthma Clinical Trials

// Asthma

BBK has supported numerous asthma studies for many pharmacological and medical device innovations – inhalers, capsules, injections, and more. The one common denominator: patients want to participate in daily activities with a minimum of management. With this in mind, BBK’s campaigns have helped patients to consider a study as part of their treatment plan.



// Mild Allergic Asthma

To identify specific patient populations with seasonal allergies, BBK relies on GeoPopulation AnalyzerSM: our state-of-the-art, proprietary technology that helps drive our country, site location, and recruitment outreach media selections. This resource allows BBK to efficiently implement custom media plans on a site-by-site basis to drive enrollment.



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.



// Chronic Obstructive Pulmonary Disorder

To improve the current treatments for COPD, BBK has targeted patients and physicians who are particularly interested in advancing future remedies. This approach allows us to quickly cut through informational clutter to engage and motivate participants as well as to generate high-quality referrals.



// Emphysema

Patients with emphysema are desperate to find a treatment that meets their unique needs. Using intense nationwide advertising and public relations, BBK has been able to introduce clinical studies as a viable treatment option for those looking to maintain a level of independence in their lives, as well as offering a proactive way to manage their health.

Phase II Study // Asthma



Right on Target // BBK determined that enrollment success would hinge on helping sites maximize their databases as well as communicating to patients an understanding of their condition. Using bright colors, empathetic images, and the words of asthma sufferers, campaign materials conveyed hope for alternative treatments and the opportunity to take control through study participation.

OUR INVOLVEMENT	Before First-Patient-In Date
COUNTRY	United States } 41 Total Sites
AUDIENCES	Patients Site Staff } Most Important to Motivate
KEYS TO ENROLLMENT	Database Mining Campaign Outreach

220

Number That Counts // Research conducted by BBK revealed that study-specific messaging would be the key to motivating patients to consider this clinical research study opportunity. That message reached patients mined from sites' databases with the help of BBK's Web-based tools, and brought in all 220 patients needed to enroll the study.

Objective // Enroll 220 patients for a phase II asthma study

Challenges // Competing studies; narrow eligibility criteria; placebo

Result // Enrollment goal of 220 patients achieved on time

Expert Analysis



In a marketplace of products that address mainly the symptoms and not the causes of asthma, this sponsor was evaluating an investigational new drug for its ability to reduce the frequency and intensity of asthmatic reactions. BBK developed campaign materials that acknowledged potential study participants feeling "sidelined" from life, while working with sites to help them mine their patient databases. With the help of TrialCentralNetSM, BBK's patient recruitment management system, sites optimized the use of targeted outreach materials and maximized their databases to achieve targets.

Phase III Study // Chronic Asthma



Technology Works // This study demonstrated the exceptional capabilities of BBK's proprietary technology in accomplishing the sponsor's immediate and long-term patient recruitment goals. By equipping study staffs with the appropriate Web-based tools to reach, prescreen, and consent potential participants, study enrollment was achieved on time worldwide.

OUR INVOLVEMENT	
Before First-Patient-In Date	
COUNTRIES	
Australia, Canada, Chile, Columbia	} 54 Total Sites
Guatemala, India, Japan	
Malaysia, Mexico, New Zealand	
Peru, United Kingdom, United States	
AUDIENCES	
Patients	} Most Important to Engage
Site Staff	
KEY TO ENROLLMENT	
Multi-Tiered Outreach	

2

Number That Counts // BBK determined that a comprehensive multitiered outreach effort was needed to meet this sponsor's two goals. BBK combined technology with compelling creative concepts to succeed on both counts, successfully enrolling a multicountry asthma study and creating a pool of patients potentially eligible for future studies.

- Objectives** // Support enrollment of a 13-country, 54-site asthma study; create online database of prescreened patients for future asthma-related protocols
- Challenges** // Customized patient recruitment materials required for multiple countries; investigational drug offered no major benefit above current treatments; placebo arm
- Results** // Outreach activities enrolled study on time; Web-based asthma study community / database created for future worldwide protocols

Expert Analysis



BBK built a Web-based solution using TCN e-Systems™, enabling data collection, analyzing, and sharing for the sites and sponsor, and providing an educational resource for some 4,000 prescreened patients. Through outreach activities that included print, radio, and online advertising, potential participants were directed to a study-specific Web site to be prescreened; ineligible patients were directed to a public Web site where they were consented to receive information about future protocols. A relationship management program engaged and retained patients who joined the online community.

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

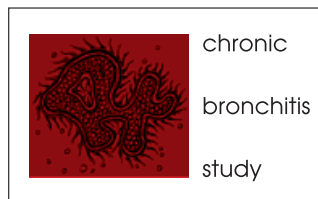
Number That Counts // Six weeks. That's all the time it took for BBK's media campaign to generate some 30 million impressions from targeted outreach in 35 local media markets. Public service announcements, TV, radio, and print advertising complemented a public relations push to generate more than 1,400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

ACCLAIM
Forest Research Laboratories and Almirall Prodesfarma

Eligibility includes: COPD symptoms
1-866-877-6037

Technology Saves the Sites // With two months to recruit 200 patients, BBK deployed key e-recruitment technologies to 1) precisely target media buys, and 2) track site progress to gauge needs for support. These actions kept lagging U.S. sites competitive in this global study.

OUR INVOLVEMENT	
After First-Patient-In Date	
COUNTRY	
United States	75 Total Sites
AUDIENCES	
Patients	Most Challenging to Engage
Investigators	
Study Coordinators	
Study Team	
KEYS TO ENROLLMENT	
Television Outreach	
Referral Management	TrialCENTRALNet SM

2,500

Number That Counts // Targeted television media buys were guided by BBK's GeoPopulation AnalyzerSM, which calculates conditional prevalence for the areas surrounding sites. Those ads were responsible for 2,500 inquiries through a call center and a Web site, leading to enough qualified referrals to put this study back on schedule.

Objective // Enroll 200 patients within two months in this Phase III COPD study of an investigational bronchodilator

Challenges // Reaching adequate numbers of potential participants in the brief time frame available

Results // More than 1,800 calls and 700 Web inquiries produced more than 400 qualified referrals

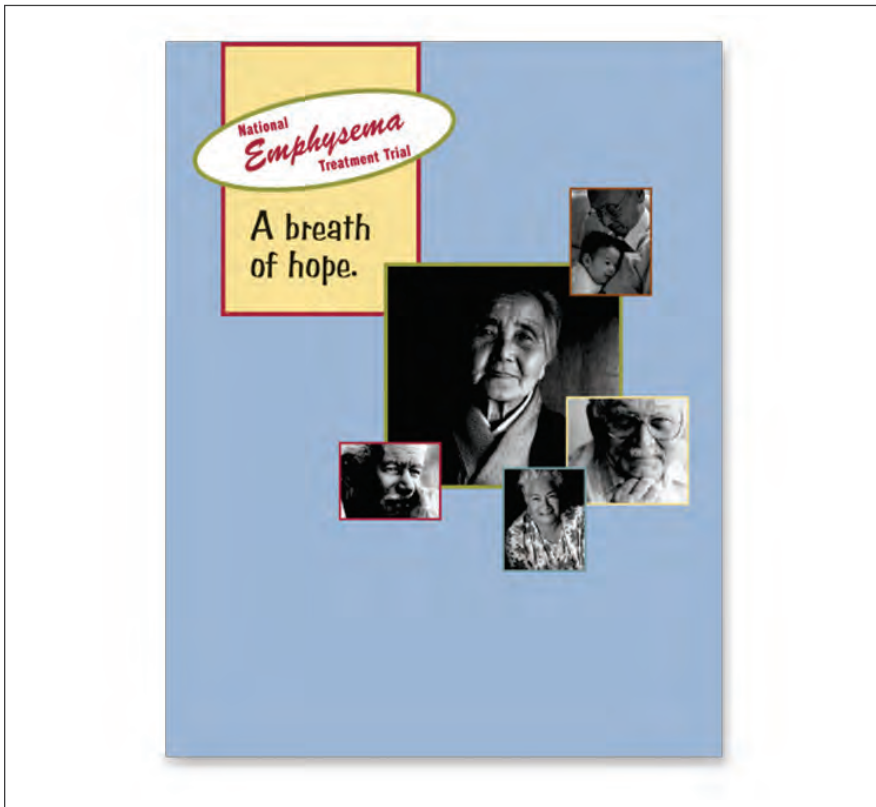
Expert Analysis



After a year, this COPD study's enrollment lagged so far behind in the U.S. that sites were in danger of having their patient quotas reassigned to high-enrolling European partners. BBK responded by launching a television campaign targeting the best geographic distribution of placement

to support sites in 21 separate markets (guided by our GeoPopulation Analyzer technology). Using BBK's patient recruitment management system, TrialCENTRALNet, the sponsor tracked patient statuses in real time, allowing timely enrollment assistance to troubled sites. With such precision, the campaign produced significant referrals, putting the study back on track.

Phase III // Emphysema



Clearing the Air // Recruiting this government-sponsored trial meant fulfilling diversity requirements and working within strict communications limitations. Nevertheless, BBK launched a bold awareness campaign that included public relations and advertising, generating an overwhelming response from a wide range of ethnic audiences.

OUR INVOLVEMENT

After First-Patient-In Date

COUNTRY

United States

17 Total Sites

AUDIENCES

Patients

Health & Regulatory Authorities

KEYS TO ENROLLMENT

Public Relations

Mass Media

30

Number That Counts // BBK's campaign included intensive public relations and television advertising – key tactics for producing the 30 million impressions that facilitate enrollment. The bold approach helped recruit 2,500 ex-smokers for this national study by empowering them to seek help.

Objective // Generate awareness to recruit 2,500 ex-smokers (533 enrolled prior to BBK's involvement) for an emphysema trial

Challenges // Diversity requirements and the large number of patients needed; limitations on government-sponsored communications regarding smoking-related matters

Results // Campaign produced 30 million impressions, 14,000 inquiries, and 2,600 referrals to facilitate study enrollment

Expert Analysis



This government-funded trial was investigating the merits of lung volume reduction surgery (LVRS) with the goal of using the data to petition Medicare for coverage of the procedure. With

thousands of participants still needed and diversity requirements to meet, study enrollment had stalled. Despite having to work within strict limitations on government-sponsored communications regarding smoking, BBK's intensive campaign drew an overwhelming response. In a few months, the campaign generated enough referrals to facilitate study enrollment. Results revealed that LVRS reduced mortality for certain emphysema patients and Medicare ultimately announced it would cover LVRS for appropriate candidates.

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.