

Autoimmune Disorders // Overview of Capabilities

Treatments for autoimmune disorders can be elusive, often leaving patients feeling vulnerable. BBK has a wide range of experience with supporting the enrollment of autoimmune studies. Our campaigns enable patients to recognize clinical research study participation as an option worthy of consideration and, accordingly, one that may possibly help them find a better means of managing their condition.

B-CELL THERAPY RESEARCH

// Rheumatoid Arthritis (RA)

BBK has helped many RA studies to successfully enroll on time. Our campaigns have spanned the gamut of offerings, including centralized outreach efforts and site-based recruitment programs, site support and training, study planning and recruitment feasibility, and country and site selection.



psoriasis RESEARCH STUDY

// Psoriasis

For studies seeking to enroll psoriasis patients, BBK has designed highly differentiating campaigns that convey empathetic messages of hope. Television, direct mail, public relations, Internet advertising, and study Web sites have shown to be effective ways to get these targeted messages to the right audience to draw the necessary patient response.

TYPE 1 Diabetes

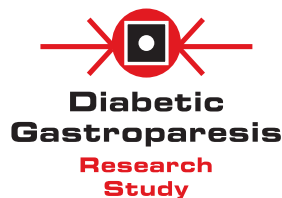
// Type 1 Diabetes

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.

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 help patients to consider a study as part of their treatment plan.



// Diabetic Gastroparesis

By helping type 1 diabetics identify their symptoms more accurately and seek care more confidently, BBK's campaigns for diabetic gastroparesis studies have enabled sites to achieve target enrollment for studies that are often thought to be un-enrollable.



Crohn's Disease

// Crohn's Disease

Studies of Crohn's Disease medications often have significant disincentives to participation. Consequently, BBK has often targeted patients and physicians who are particularly devoted to helping advance medicine. While this approach has reduced the number of prospective patients, BBK has also shown that it cuts quickly through informational clutter to engage and motivate.

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 | Most Important to Motivate |
| Site Staff | |
| 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

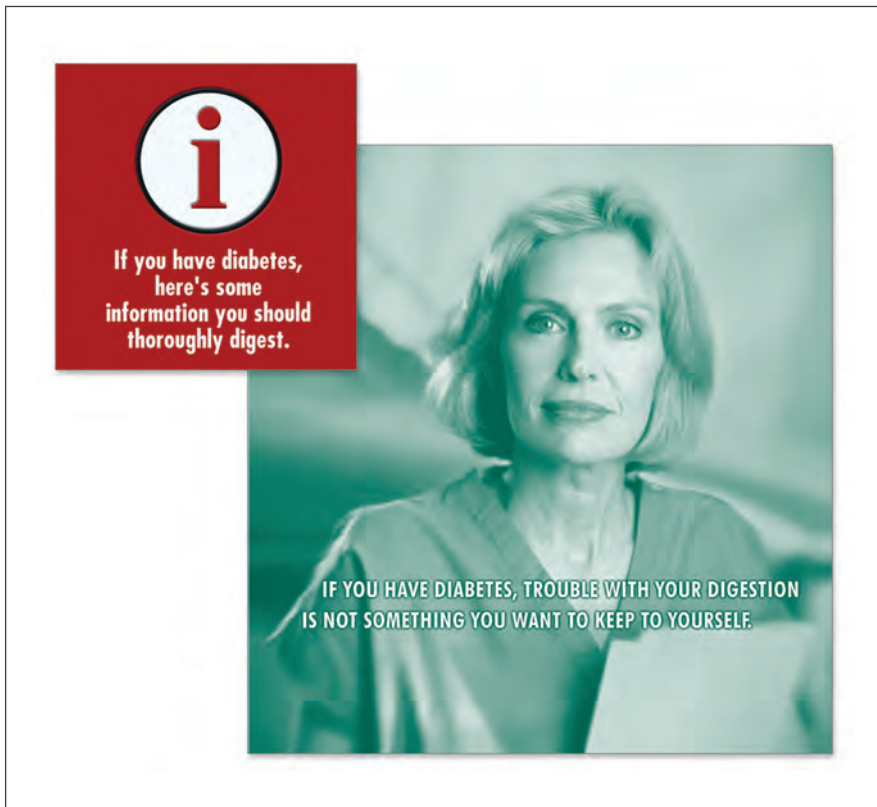
Result // Enrollment goal of 220 patients achieved on time

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 II Study // Diabetic Gastroparesis



Good Timing // The study sponsor brought BBK in for recruitment planning before study initiation, providing ample time to develop and implement a recruitment strategy capable of generating sufficient inquiries to result in the identification and enrollment of more than the target 250 patients needed.

| OUR INVOLVEMENT | |
|------------------------------|----------------------------|
| Before First-Patient-In Date | |
| COUNTRY | |
| United States | 40 Total Sites |
| AUDIENCES | |
| Patients | Most Difficult to Motivate |
| Investigators | |
| Site Staff | |
| Advocacy Groups | |
| KEYS TO ENROLLMENT | |
| Study Planning | |
| Study Positioning | |

474

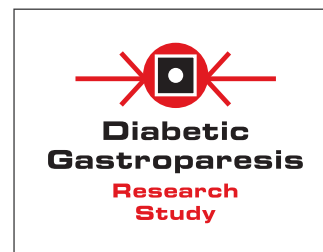
Number That Counts // Diabetic gastroparesis is rare, with only 20 percent of people with type 1 diabetes developing it. Prevalence is even lower in type 2 patients. Nevertheless, BBK's recruitment campaign exceeded projections, generating thousands of inquiries, resulting in 474 patient referrals to participating sites, which enabled sites to complete enrollment.

Objective // Enroll 250 patients within nine months for a diabetic gastroparesis study

Challenges // Low awareness and prevalence of the condition; protocol included a placebo arm; two invasive procedures were required

Results // The campaign exceeded projections, generating 2,127 inquiries, resulting in 474 patient referrals to participating sites

Expert Analysis



Low prevalence of diabetic gastroparesis had this sponsor expecting recruitment challenges, so BBK became involved prior to study initiation to strategize and implement a recruitment plan. While the protocol presented a number of barriers to enrollment – including a placebo arm and two invasive screening and monitoring procedures – BBK recognized that the procedures also offered a de facto screening for the condition. By educating patients about the little-known condition and leveraging study participation as an opportunity for a definitive diagnosis, the potential participant pool increased significantly, and enrollment was achieved on time.

Phase III Study // Multiple Sclerosis (MS)



A Proven Approach // Well-trained site staff armed with strategic recruitment tools and tactics made the difference in enrolling this MS study on time. With BBK's support and consultation, rejuvenated study staff built effective relationships with both potential participants and referring physicians that bolstered qualified referrals.

OUR INVOLVEMENT

After First-Patient-In Date

COUNTRY

United States

100 Total Sites

AUDIENCES

Patients

Caregivers

Site Staff

Most Critical to Engage

KEY TO ENROLLMENT

Study Messaging

1

Number That Counts // Messaging that resonated with the MS patient population was one of the key tactics BBK developed to get enrollment back on the right track. "What if you could take one pill a day to treat your RRMS?" was the question that sparked interest in the study opportunity and prompted potential participants to learn more about a novel oral treatment option.

Objective // Reinvigorate patient recruitment and retention to achieve on-time study enrollment

Challenges // Placebo arm; wash off requirement

Results // BBK support helped sites get back on track to achieve on-time enrollment; raised awareness about a first-of-a-kind investigational oral drug

Expert Analysis



BBK conducted site assessments and discovered that site staff were enthusiastic and dedicated to enrolling the protocol, but lacked the resources to do so. BBK developed a comprehensive recruitment toolkit, providing study staff with proven tools and techniques to successfully enhance recruitment. By clearly positioning

the study as a worthy treatment option for MS patients experiencing intolerable side effects from standard of care injections, BBK was able to address concerns about the placebo control arm – an obstacle that otherwise was likely to deter physicians from referring their patients. To address compliance and retention issues, BBK developed and trained site staff on effective relationship-building strategies to keep patients motivated to complete their study participation.

Phase III Study // Psoriasis



Distinct Messaging // After analyzing the formidable recruitment challenges threatening this study's enrollment, BBK knew that success would depend on distinguishing this study opportunity from other studies and treatments. The campaign positioned participation as access to the latest science – which resonated with patients who had little success with other treatments.

OUR INVOLVEMENT

Study Planning

COUNTRIES

Canada

Mexico

United States

74 Total Sites

AUDIENCES

Patients

Sites

Media

Most Difficult to Engage

KEY TO ENROLLMENT

Study Messaging

128

Number That Counts // BBK exceeded enrollment expectations by 128 patients and two months ahead of schedule. The well-orchestrated campaign had just the right mix of tactics, including TV and newspaper ads, media relations and advocacy outreach, direct mail to 15,000 psoriasis sufferers, a Web site, and patient education materials.

Objective // Enroll 800 patients within 10 months for three protocols

Challenges // Competing treatment options; competing clinical studies; placebo arm; long-duration study

Result // 928 patients were enrolled with two months to spare

Expert Analysis



With three protocols to enroll and considerable recruitment challenges, this client turned to BBK Worldwide. Not only did two of the protocols contain a placebo arm, but the third had a duration of more than a year – a commitment that could be daunting to potential participants. What's more,

competing treatment options and competing clinical studies warranted strategic patient recruitment help. BBK designed a distinctive campaign that positioned participation as access to the latest science, rather than the latest fad cure. The campaign drew an overwhelming response and helped the study exceed enrollment with two months to spare.

Phase III Study // Rheumatoid Arthritis



Understanding Patients, Outrunning the Competition //

BBK recruited this rheumatoid arthritis (RA) study in just six months by continually monitoring and adjusting recruitment tactics. With messaging that empathized with the daily disruptions caused by RA, BBK was able to differentiate this study from other competing trials.

OUR INVOLVEMENT

Before First-Patient-In

COUNTRY

United States

28 Sites

AUDIENCES

Patients

Investigators

Site Staff

RA Community

Most Difficult to Engage

KEY TO ENROLLMENT

Study Positioning

Study Messaging

220

Number That Counts // With an enrollment timeline of only six months, BBK helped this sponsor enroll all 220 patients before competing treatment options were brought to market.

Objective // Enroll 220 patients at 28 sites within six months.

Challenges // Condensed enrollment timeline; competing RA clinical studies; multiple invasive procedures required.

Result // On-time study enrollment achieved.

Expert Analysis



Patients with RA were in desperate need of better treatments, particularly those with fewer side effects. With competing treatment options soon coming to market at the time of this study, the sponsor hoped to outrun the

competition by accelerating the enrollment timeline. BBK's campaign materials answered the challenge, emphasizing the search for cutting-edge medicines and offering the clinical study as a treatment option. As a result of these efforts, BBK helped sites meet the enrollment deadline.

Phase III Study // Rheumatoid Arthritis



Suite Success // Customized recruitment tools and tactics, including culturally adapted patient materials, were the key to on-time enrollment of this three-protocol international rheumatoid arthritis (RA) study. Training by BBK on how best to use the tools motivated site staff and put this suite of studies top-of-mind.

OUR INVOLVEMENT

Before First-Patient-In Date

REGIONS

Europe
North America, South America

423 Total Sites in 28 Countries

AUDIENCES

Patients
Regional & Country Study Managers
Site Staff
Referring Physicians / Rheumatologists

Most Important to Motivate

KEYS TO ENROLLMENT

Recruitment Toolkit
Cultural Adaptation

3

Number That Counts // On-time recruitment was achieved in large part by distinguishing this suite of three RA studies from other available clinical study options. By leveraging the positive aspects shared by all three protocols, including active medication in all cohorts and a compassionate three-year open-label extension, patient materials carried a forceful message that resonated with all key audiences.

Objective // Enroll 1,805 patients for three international RA protocols in 28 countries

Challenges // Recruitment of two different patient populations; stringent eligibility criteria; competing RA treatments and global RA studies

Result // Customized recruitment materials supported the on-time randomization of 1,805 patients

Expert Analysis

B-CELL
THERAPY RESEARCH

Study managers and site staff across the globe tapped BBK's expertise to enroll this suite of three RA studies. A campaign toolkit included patient recruitment materials that were adapted by country to ensure messaging resonated with the many cultures involved in this 28-country protocol.

BBK training provided support to physicians and site staff, maximizing the efficacy of materials by helping study personnel communicate with patients about the study opportunity. TrialCentralNetSM, BBK's patient recruitment management system, kept track of sponsor and regulatory approvals for a coordinated effort that resulted in on-time recruitment.