

Gastroenterology // Overview of Capabilities

BBK has a wide range of experience supporting the enrollment of gastroenterology studies. Our campaigns successfully drive response by defining the danger signs, and by creating a moment of self-recognition in patients that leads them to seek diagnosis and treatment options – including clinical research study participation. BBK also provides the infrastructure necessary to handle the resulting influx of calls and referrals.



// Bowel Dysfunction

BBK has enrolled a variety of studies of investigational treatments for both opioid-induced and idiopathic bowel dysfunction in adults and children. When outreach is necessary, BBK knows how to overcome patient inhibitions and drive inquiries. When referrals are key, BBK knows how to gain the interest and support of physicians.



// Ulcer

The standard methods of diagnosing ulcers are often invasive – so it's no wonder that BBK's efforts to introduce alternative, noninvasive methods of diagnosing this condition have met with resounding success. That success has included not only full study enrollment, but also the creation of formidable brands that out-position competing diagnostic methods.



// Gastroesophageal Reflux Disease (GERD)

Many people mistake gastroesophageal reflux disease for common stomach indigestion. Consequently, BBK has implemented outreach for studies of this condition that emphasized GERD's intense symptoms, and that included empathetic messaging carried through targeted media such as television and direct mail.



// Diabetic Gastroparesis

By helping people with type 1 diabetes identify their symptoms more accurately, and by encouraging those patients to seek care more confidently, BBK's campaigns for diabetic gastroparesis studies have enabled sites to achieve their target enrollment – even though these studies were often thought to be un-enrollable.



Crohn's Disease

// Crohn's Disease

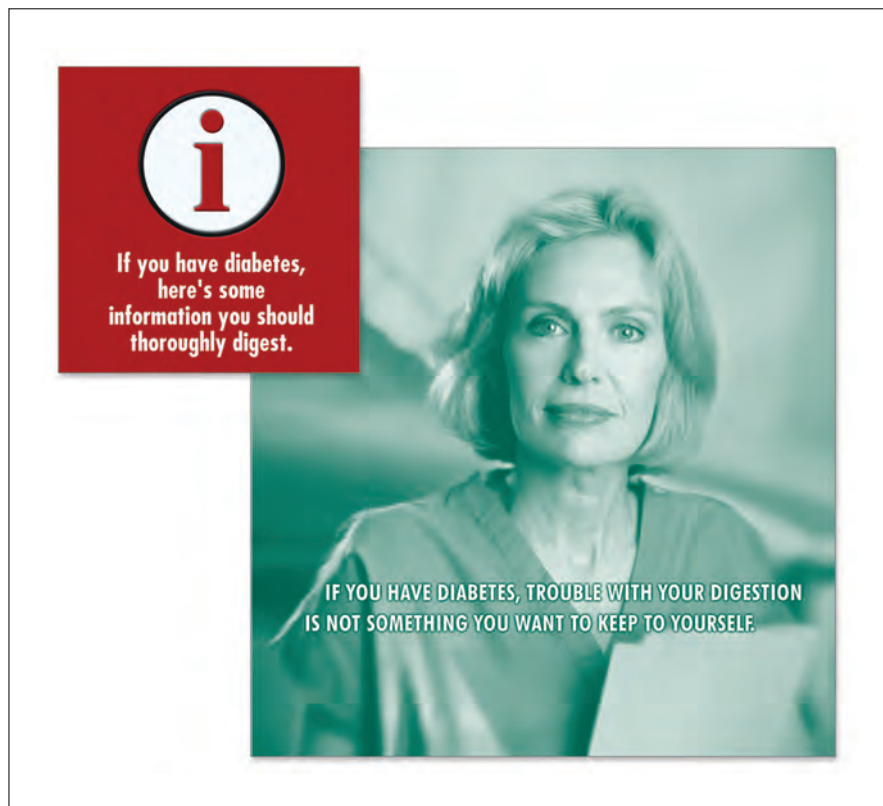
Studies of Crohn's Disease medications often have significant disincentives to participation. Consequently, BBK has often targeted patients and physicians who are particularly devoted to helping advance medicine. While this approach has reduced the number of prospective patients, BBK has also shown that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



// Ulcerative Colitis

Intensive market research and focus group testing have both driven the development of the creative materials and advertising that BBK has used to support the enrollment of studies of investigational drugs for ulcerative colitis. In each campaign, BBK's outreach was effectively backed by our referral tracking system TrialCentralNetSM.

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

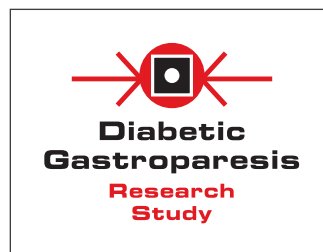
Number That Counts // Diabetic gastroparesis is rare, with only 20 percent of people with type 1 diabetes developing it. Prevalence is even lower in type 2 patients. Nevertheless, BBK's recruitment campaign exceeded projections, generating thousands of inquiries, resulting in 474 patient referrals to 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 II Study // Gastroesophageal Reflux Disease (GERD)

Early Planning Pays Off // Because the sponsor engaged BBK for the planning and development of a recruitment campaign well before the first-patient-in date, BBK was able to cost-effectively reach out to enough patients within the first few weeks to enroll this study months ahead of schedule.

OUR INVOLVEMENT	Study Planning	
COUNTRY	United States	34 Total Sites
AUDIENCES	Undiagnosed Patients	Most Difficult to Motivate
	Diagnosed Patients	
	Site Staff	
KEY TO ENROLLMENT	Recruitment Planning	

250

Number That Counts // Although millions of people have GERD, most thought of it as chronic heartburn, rather than a medical condition that has serious health risks if left untreated, and so were not seeking care. By using public service-style messaging backed by eye-catching design, as well as an engaging TV spot, BBK drove enough inquiries to enroll the 250 needed patients well ahead of time.

Objective // Enable 40 sites to enroll 250 patients in six months for a GERD study

Challenges // Patient self-misdiagnosis; placebo arm; participation required two endoscopies; patients could not take other available treatment options

Result // Study enrollment for the required 250 patients was achieved within the first weeks of outreach – months ahead of schedule

Expert Analysis



Although millions suffer from GERD, this particular protocol had some restrictive eligibility criteria that threatened on-time enrollment. Luckily, the sponsor had anticipated patient recruitment problems and engaged BBK early in the planning process. With time to consult with the sponsor,

BBK implemented a recruitment campaign that maximized sites' existing patient panels, and that used TV and direct mail to patients within a reasonable driving distance to sites. This approach achieved study enrollment within the first few weeks of outreach, minimizing media costs. Moreover, concluding months ahead of schedule saved study site expenditures and significantly reduced the development cycle.

Phase III Study // Opioid-Induced Bowel Dysfunction



Managing Success // Once new sites were initiated, and the outreach campaign was under way, it was the referral tracking capabilities of BBK's recruitment management system, TrialCENTRALNet™ (TCN), that ensured ultimate enrollment success. By closely tracking each inquiry through to screening and randomization, TCN streamlined the enrollment process for all sites, maximizing site staff efforts and time.

OUR INVOLVEMENT	
After First-Patient-In Date	
COUNTRIES	
Canada	} 190 Total Sites
United States	
AUDIENCES	
Patients	} Most Difficult to Motivate
Physicians	
Referring Physicians	
KEYS TO ENROLLMENT	
Site Selection	
Referral Management	

40

Number That Counts // The sponsor sought up to 40 additional recruitment-ready sites (30 in the United States and 10 in Canada) to help reinvigorate the enrollment rate, which had fallen significantly. The ultimate goal was to randomize 760 patients across two parallel studies, and site staff capacities at existing sites were not sufficient for the necessary outreach that would get the study back on track.

Objectives // Assess sites in the United States and Canada; identify 40 additional sites that could manage the number of referrals from necessary outreach

Challenges // Narrow eligibility criteria; too few sites

Result // Enrollment was achieved ahead of schedule

Expert Analysis



This study of a promising treatment option was significantly behind in achieving enrollment – even despite the appealing fact that participation included an extension study offering additional treatment. After a rapid, in-depth assessment of the sites, it was quickly determined that the sponsor needed 40 new sites – and that these sites would need to have the capability of quickly processing the high number of inquiries they would receive from the direct-to-patient television, radio, and Web advertising campaign that would be needed to achieve on-time enrollment. Within a month and a half of the sponsor giving the green light, BBK had identified the sites and initiated a campaign that ultimately achieved enrollment before LPI.

Phase IV Study // Pediatric Idiopathic Constipation



Establishing Patient Trust // While BBK preserved the existing emoticon-inspired creative developed by the CRO, key messaging revisions and an enhanced design and layout were created to help the materials resonate with boys and girls of various ages – in part to help fill the four age-stratified arms of the study.

OUR INVOLVEMENT

After First-Patient-In Date

COUNTRY

United States

25 Total Sites

AUDIENCES

Parents

Patients

Physicians

Sites

Most Difficult to Motivate

KEYS TO ENROLLMENT

Advertising

Referral Management

120

Number That Counts // Less than half of the total 120 patients needed had been randomized when the sponsor contacted BBK. After an audit and revitalization of existing study materials, and a relaunch of the outreach effort, BBK implemented advertising and referral management support on a site-by-site basis to help get the message out and, ultimately, to enroll the study.

Objective // Jump-start enrollment for 25 sites to achieve the target 120 randomized patients

Challenges // Study medication frequently prescribed off-label; sites were having difficulty articulating the motivation to participate for parents and patients

Result // The revitalized campaign enabled the sites to achieve full enrollment ahead of schedule

Expert Analysis



Sites were having difficulty enrolling this study in large part because communicating about the study opportunity involved justifying why the child might participate when he or she could receive the study drug off-label. And, despite having implemented CRO-created materials, sites were frustrated by a lack of response, and enrollment had ground to a standstill. BBK revised the campaign messaging to clearly articulate the motivation to inquire and participate for parents of patients, and enhanced the design of the materials to better resonate with both audiences. Close site support provided the final push that helped the sites achieve full enrollment well ahead of the projected curve.

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