

Pediatrics // Overview of Capabilities

By their very nature, studies involving children are often difficult to enroll. When a protocol design poses additional recruitment barriers, it's that much more important that all recruitment efforts be carefully planned and conducted, and driven by clear and concise messaging that speaks to physicians and parents, as well to young patients. Through the right combination of tactics, BBK has successfully achieved enrollment for many pediatric studies in the U.S. and throughout the world.



// Type II Diabetes

To effectively reach out to parents of children with type 2 diabetes, BBK has crafted several engaging national and global awareness campaigns. These campaigns educate parents about their child's condition, empower them to proactively screen their child for the disease, and encourage them to consider study participation as a viable option for care.



// Epilepsy

Competing with a wide range of treatment options for epilepsy, BBK regularly assists study sites in carefully mining their patient panels to identify ideal candidates for study participation. Combined with effective national press campaigns, BBK has provided sites with a steady and reliable method for funneling potential participants into these studies.



// 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 clinical study opportunities.



// Attention Deficit Hyperactivity Disorder

With ADHD, it's important to focus attention on the condition itself – not the child. BBK has conducted aggressive physician referral campaigns to define what sets our particular studies apart from other available treatment options. Along with an effective mix of TV and radio advertisement, BBK-supported studies have again and again met with enrollment success.



The Young Adult and Pediatric Bipolar Study

// Bipolar I Disorder

BBK has extensive global experience in developing and customizing site tools and outreach materials that engage and motivate parents, their children, and physicians to action. In addition, BBK is well-versed in the coordination and placement of all traditional (print, radio, TV) and online (sponsored links, banner advertisements) media for any given market.

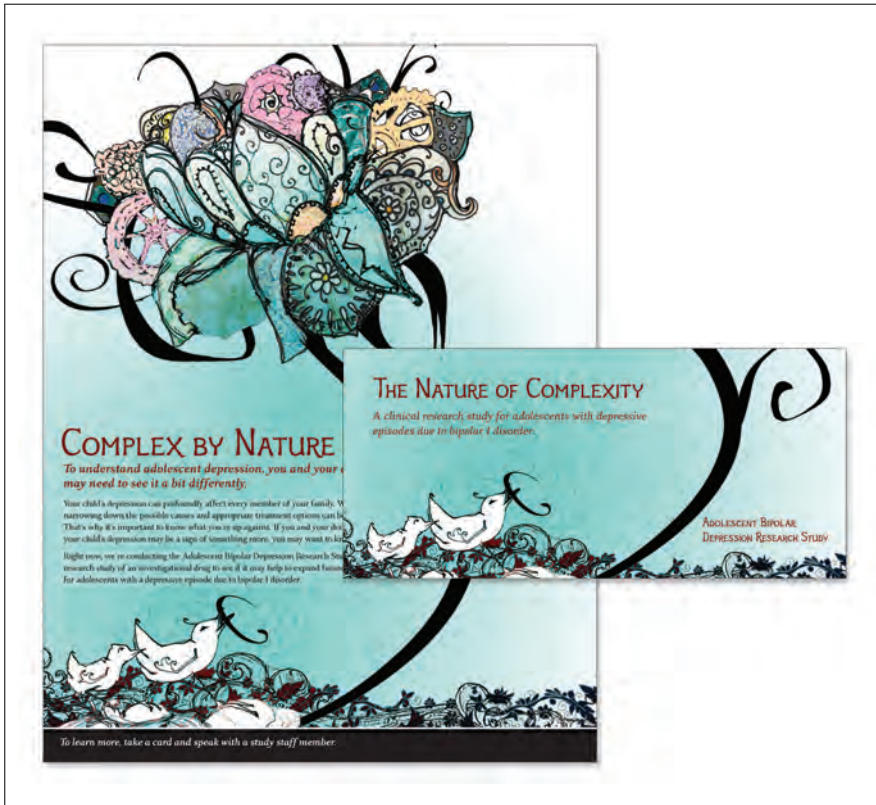


PEDIATRIC CONSTIPATION STUDY

// Idiopathic Constipation

For this type of sensitive condition, BBK has developed point-of-care informational materials and carefully placed print ads, as well as online advertising. These proven strategies have consistently driven parents to speak with investigating pediatricians to learn more about their child's potential treatment options.

Phase IV Study // Adolescent Bipolar Depression



Straight Talk // BBK created a recruitment strategy that provided a strong but sensitive call to action. Site training and consultation enabled study staff to communicate effectively with adolescent patients and concerned parents, as well as referring physicians and media outlets, to generate patient referrals.

OUR INVOLVEMENT	
Before First-Patient-In Date	
COUNTRIES	
United States (including Puerto Rico)	} 35 Total Sites
Mexico	
Russia	
Turkey	
AUDIENCES	
Adolescent Patients	} Most Critical to Engage
Parents	
Physicians	
KEYS TO ENROLLMENT	
Media Outreach	
Study Messaging	

2

Number That Counts // Empathetic messaging was critical to generate interest in study participation. BBK created targeted recruitment materials that provided concerned parents with a greater understanding of the nature of their child's depression, and acknowledged the significant impact that pediatric bipolar depression can have on the family as a whole.

Objective // Support the recruitment of 300 adolescent patients with bipolar I disorder for a multinational study evaluating the effects of treating this population's major depressive episodes with an FDA-approved drug for adults with bipolar depression

Challenges // Parents cautious about psychiatric meds; study drug side effects, including significant weight gain; no placebo control arm in majority of competing research studies

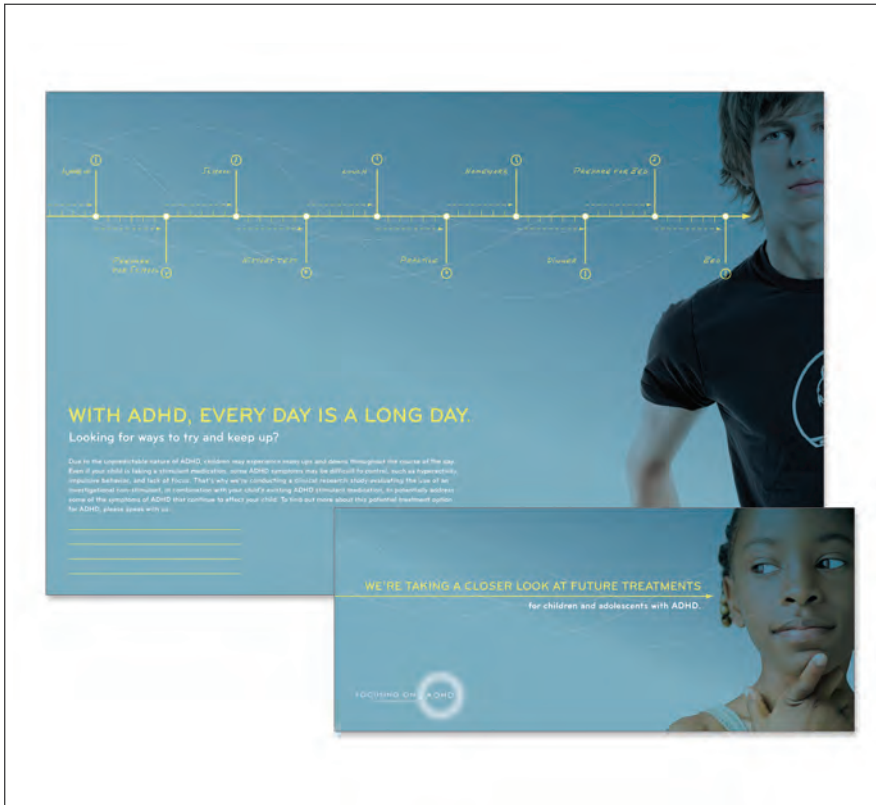
Results // Significant increase in prequalified referrals; study projected to enroll in significantly less time than allotted based on screening rates

Expert Analysis

ADOLESCENT BIPOLAR DEPRESSION RESEARCH STUDY

Brought in to help study sites jump-start their recruitment efforts, BBK created a culturally adaptable recruitment toolkit for all 35 sites worldwide. By devising a balance between creative appeal and practical information, the patient materials simultaneously engaged adolescents as the target audience and parents as the key decision-makers. A media assessment survey of U.S. sites generated the findings BBK used to help site staff implement a localized media campaign of print, Web, radio, and television – all of which drove highly qualified referrals to study sites and increased top-of-mind awareness among site staff. The result: screening rates increased significantly and the study was projected to enroll well ahead of schedule.

Phase III Study // Attention-Deficit Hyperactivity Disorder (ADHD)



Back on Track // On-time enrollment of this ADHD study was unlikely before BBK took over recruitment. With the launch of a multifaceted outreach campaign, patient referrals picked up exponentially, and increased screening and enrollment enabled reinvigorated study sites to achieve their recruitment goals.

OUR INVOLVEMENT	After First-Patient-In Date
COUNTRY	United States } 54 Total Sites
AUDIENCES	Pediatric Patients Parents } Most Critical to Engage
KEYS TO ENROLLMENT	Multipronged Outreach Site Support Consultation

4

Number That Counts // An effective mix of print, broadcast, and online media bolstered recruitment of this study in the last four months of the year-long enrollment period. Along with site support consultation, site and CRA coaching, and referral management, BBK's efforts accomplished what was thought to be impossible: full enrollment with more than four weeks to spare.

Objective // Drive a high volume of prequalified referrals to meet last-patient-in (LPI) date

Challenges // Psychostimulant requirement; placebo arm; weight and BMI eligibility criteria; seasonal recruitment issues

Result // Study enrolled a month ahead of schedule due to steady volume of referrals and significant increases in sites' screening and enrollment activities

Expert Analysis



Seven educational forums, two phases of centralized print and radio advertising, and three months of Web-based outreach helped BBK revitalize this ADHD pediatric study.

Before BBK stepped in, sites had enrolled in eight months only 40 percent of the required 441 patients. In four short months, BBK's comprehensive outreach campaign generated parents' interest in study participation for their children in impressive numbers: sites increased screening activity by 86 percent and enrollment activity by 133 percent. BBK's Web-based patient recruitment management system, TrialCentralNetSM, helped keep track of recruitment efforts, ROI, and resource redeployment needs. End result: study screening and randomization goals were met more than a month ahead of schedule.

Phase III Study // Attention-Deficit Hyperactivity Disorder (ADHD)



Cost-Effective Global Recruitment // This study had the ambitious plan of testing a new investigational combination of ADHD medications in pediatric patients with vastly different treatment histories. BBK’s ability to field multiple outreach tactics and coordinate complementary messages provided the recruitment support the sponsor needed.

OUR INVOLVEMENT	
After First-Patient-In Date	
COUNTRIES	
United States	} 38 Total Sites
Canada	
Mexico	
Taiwan	
AUDIENCES	
Pediatric Patients	} Most Critical to Engage
Parents	
KEYS TO ENROLLMENT	
Multichannel Outreach	
Community Advocacy	

2

Number That Counts // This study needed to identify and recruit two completely different sets of pediatric patients: children who had already been treated with a specific ADHD medication, and children who had never taken this drug. BBK’s creative and media experts designed a multi-layered campaign which achieved that challenging feat with time to spare.

Objective // Use a multipronged outreach campaign to enroll nearly 300 pediatric patients before a rapidly approaching last-patient-in date

Challenges // Study needed to enroll both treatment-experienced and treatment-naïve children; placebo arm

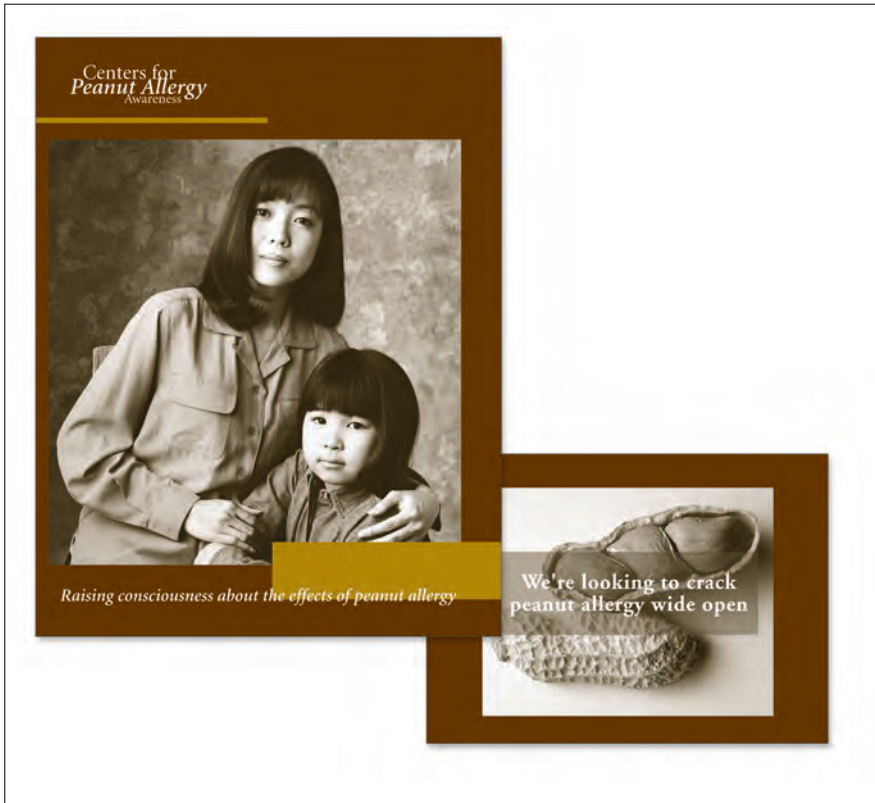
Result // Recruitment and enrollment completed

Expert Analysis



Tasked with rapidly recruiting a paradoxical set of patients, BBK quickly realized the situation called for a particularly intricate patient recruitment campaign. It would take very different messages to speak to each critical audience – treatment-naïve patients, treatment-experienced patients, and the parents of both groups – and a carefully coordinated fleet of media tactics to effectively deliver those messages. BBK orchestrated this complex effort with only a few months left in the enrollment period – the final campaign used multiple combinations of radio, print, online, social media, and community-based tactics to engage each audience. As enrollment progressed, BBK strategically iterated the campaign’s media deployments until both patient groups were completely enrolled.

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

Patients

Physicians

Sites

Most Difficult to Motivate

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 Bipolar I Disorder



Distinctive Campaign // Not only did BBK's distinctive campaign garner significant response, but it did so with only a small budget. This was because the central visual concept accurately and artistically expressed the condition in a manner that successfully crossed cultures, thereby simplifying and streamlining cultural adaptation.

OUR INVOLVEMENT	
Before First-Patient-In Date	
COUNTRIES	
Argentina	} 40 Total Sites
Mexico	
United States	
AUDIENCES	
Parents	} Most Difficult to Engage and Motivate
Children and Adolescent Patients	
Study Investigators	
Referring Physicians	
KEYS TO ENROLLMENT	
Creative Concept	
Study Messaging	

3

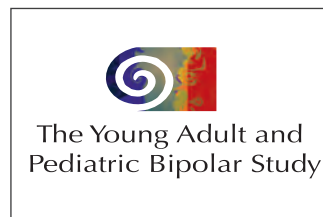
Number That Counts // BBK's creative campaign successfully engaged the three key target audiences: 1) for parents, it presented a portrait of their child that motivated them to seek help; 2) for patients, it expressed what they were feeling; and 3) for physicians, who were enthusiastic about the materials, it energized their efforts. Ultimately motivating all three audiences was the key to enrollment.

Objective // Recruit 190 patients for a multinational study seeking a pediatric indication for an approved treatment for bipolar I disorder

Challenges // Investigational drug commonly prescribed off-label; parents wary of psychiatric meds; modest budget

Results // BBK enabled the study sites to meet their individual targets and the study enrolled on time

Expert Analysis



Although there was no drug approved specifically for pediatric patients at the time, this multinational study faced significant recruitment challenges. Most diagnosed patients were likely to be receiving drug off-label and would be unwilling to wash off; parents of undiagnosed patients were wary of psychiatric medications given recent reports of a rash of children on adult antidepressants attempting suicide; and, in Latin America, cultural mores impeded discussions of psychiatric problems, even with physicians. BBK's solution focused on the undiagnosed or newly diagnosed, accurately and respectfully expressing empathy for both parents and patients and leveraging the personal care offered through the study. In the end, the study enrolled early.

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	} 77 Total Sites
United States	
AUDIENCES	
Parents of Pediatric Patients	} Most Difficult to Engage
Site Staff	
Investigators	
Referring Physicians	
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.

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	Most Difficult to Motivate
Patients	
Physicians	
Sites	
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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Nutritional Study // Pediatric Obesity and Type 2 Diabetes Prevention



Targeting Outreach to Reduce Risk // When Boston's prestigious Children's Hospital needed help enrolling its clinical study of a new dietary strategy for the treatment of obesity and the prevention of type 2 diabetes in children, hospital decision-makers turned to BBK. BBK responded with a cost-effective community outreach program that exceeded enrollment targets.

OUR INVOLVEMENT

After First-Patient-In Date

COUNTRY

United States

1 Site

AUDIENCES

Parents and Patients

Community News Media

Community Health Organizations

School Nurses

Most Difficult to Engage

KEY TO ENROLLMENT

Targeted Outreach Plan

3

Number That Counts // At the end of 15 months of this study's 18-month enrollment period, Children's Hospital had enrolled less than a quarter of their target number of parent/patient participant teams. Within three months – July, August, and September – and with a very limited budget, BBK's community outreach campaign exceeded the study's enrollment goal.

Objective // Enroll 40 of the required 50 parent/patient participant teams within three months

Challenges // Parents' lack of perceived health problems of asymptomatic obese children; parents' active participation in study with their child; limited recruitment budget

Results // Within 10 weeks of the campaign kickoff, Children's Hospital received inquiries sufficient to enroll a total of 54 parent/patient teams; enrollment closed two weeks early

Expert Analysis



As part of its effort to combat obesity and to prevent type 2 diabetes in children, Children's Hospital Boston was conducting a clinical study of a low glycemic index diet among children eight to 12 years of age. Because the hospital's own outreach efforts had enrolled only 10 of the required 50 parent/patient participant teams, BBK was tapped for expert assistance. To maximize a very limited recruitment budget, BBK conducted outreach in communities selected by their proximity to Children's Hospital and the number of outreach avenues they afforded – including radio and print advertising, numbers of new community outlets, community health-related organizations, and elementary schools. This approach jump-started enrollment and achieved the target two weeks early – even during the height of summer school vacation.

Phase I/II Study // Pompe Disease



Enrolling Pompe Early // A referral-request program marshaled the help of department heads, a compelling brochure alerted physicians to the rare disease and the study opportunity, and useful reminder items kept the study top-of-mind: this simple, well-executed campaign enrolled this challenging study ahead of schedule.

OUR INVOLVEMENT

After First-Patient-In Date

COUNTRIES

France, Israel, Taiwan,
United Kingdom, United States

8 Total Sites

AUDIENCES

Parents
Heads of Pediatric Neurology Dept.
Neonatologists
Pediatricians

Most Critical to Motivate

KEYS TO ENROLLMENT

Department Heads' Endorsement
Global Referral Outreach

1

Number That Counts // Pompe is so rare that most neonatologists, neurologists, and pediatricians have never heard of it, and a pediatric neurology specialist may not see a single case in an entire career. But by asking physicians to rule it out first when a patient exhibits symptoms, BBK was able to enroll this landmark clinical trial – once thought by the sponsor to be “unenrollable” – ahead of schedule.

Objective // Enroll 50 patients with Pompe disease – a very rare condition occurring in approximately 70 newborns worldwide each year

Challenges // Hard-to-diagnose condition last to be considered by neurologists in diagnosing symptoms that are shared with more than 40 more common conditions; patients had to be enrolled soon after birth

Result // Enrollment achieved ahead of schedule

Expert Analysis

pompe STUDY

investigating enzyme replacement therapy for infants under six months with pompe disease

Study participation offered treatment for Pompe disease – an often fatal lysosomal storage disease typically found in newborns – where none existed. However, enrollment was exceptionally problematic because:

only about 70 cases throughout the world are diagnosed each year; the condition shares symptoms with other, more prevalent conditions and therefore is not first considered; and patients had to be enrolled within a short time following birth. BBK enrolled this global study ahead of schedule by initiating a global physician-outreach campaign that educated and marshaled the support of pediatric neurology department heads, their staff, and their referral networks in major medical centers throughout the world.

Phase III Study // Type 2 Diabetes in Children



Raising Awareness and Enrollment Rates // At the time, many parents were unaware of their overweight child's potential to develop type 2 diabetes. This fact, combined with narrow eligibility criteria, made identifying patients difficult. To achieve enrollment (and thereby help the sponsor win a patent extension for the study drug), BBK implemented a public awareness and recruitment campaign that supported selected, high-enrolling sites.

OUR INVOLVEMENT	
After First-Patient-In Date	
COUNTRY	
United States	67 Total Sites
AUDIENCES	
Parents and Patients	
News Media	
Advocacy Groups	
Alternative Referral Channels	Most Difficult to Engage
Site Staff	
KEY TO ENROLLMENT	
Targeted Site Support	

67

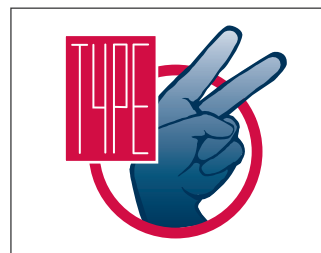
Number That Counts // With the sponsor only able to afford a third of the budget needed to achieve the estimated number of inquiries required to enable each site to meet its enrollment target, the decision was made to support only 67 high-performing sites. By focusing resources and enabling these sites to maximize their referral processing, the campaign's recruitment objectives were achieved.

Objective // Enroll 60 evaluable pediatric patients in order to fulfill an FDA requirement for patent extension of the study drug

Challenges // Restrictive eligibility criteria, placebo arm, low public awareness of pediatric type 2 diabetes, limited recruitment budget

Results // Enrollment rates for BBK-supported sites immediately and steadily increased throughout study; sponsor won study drug patent extension

Expert Analysis



BBK's analysis revealed the need for a sizeable campaign to drive the large number of inquiries needed to enroll 60 pediatric patients with HbA1c levels that fell within a narrow window – one that indicated early type 2 diabetes, but that didn't mandate immediate treatment with medication. To meet

the challenge, BBK conducted public relations and radio and TV advertising, as well as direct mail to homes, schools, and advocacy groups in communities surrounding sites. Efforts urged parents to consider screening for their children, and leveraged access to expert care through study participation. Referrals significantly increased for the BBK-supported sites. BBK's site support enabled sites to better process patient referrals.