

PROACTIVE TYPE 2 DIABETES RECRUITMENT PROGRAM

GOALS

- Accelerate recruitment for a fast-track Type 2 diabetes program spanning the United States and Canada
- > Rapidly deploy a full-service, centralized recruitment campaign following unsuccessful efforts by the sponsor to manage recruitment independently
- > Strengthen site relationships and provide site support
- > Facilitate the consent of 564 patients over a 5-month enrollment period

SITUATION

| CHALLENGES | SOLUTIONS | |
|--|--|--|
| Monotherapy required by the protocol (except for one combination treatment) but no longer consistent with current standard of care | Target underserved / underinsured patients who may not have access to adequate medical treatment and, therefore, have not been exposed to secondary treatment Target primary care physicians to draw on newly diagnosed patients who will be more likely to meet eligibility criteria | |
| Sites without bilingual staff to support recruitment of Spanish-speaking individuals | Target English-speaking minority populations with high disease prevalence Develop strong network with community physicians who can serve as sub-investigators with Spanish-speaking patients Identify bilingual temporary support staff | |
| Sites with insufficient database of patients who have Type 2 diabetes | Develop a comprehensive, local outreach program to supplement pool of patients from existing practice | |
| > Significant competition in diabetes clinical research | Develop outreach programs that are unique and differentiated from traditional advertising programs Work closely with sites to ensure adequate infrastructure to implement proposed strategies | |

IMPLEMENTED SOLUTIONS

BEST PRACTICE WEBINARS

DAC Patient Recruitment Services launched this recruitment initiative with a series of Best Practice Webinars to obtain maximum program buy-in and understanding among investigators and staff. Attended by investigators and clinical research coordinators at all participating sites, webinars promoted personal accountability for screening activity and allowed sites to discuss challenges and strategize solutions. To maximize webinar participation, the sponsor was advised to offer multiple sessions with at least two date and time options.



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Though continuing education credit was not a service component for this study, DAC is certified by the California Board of Registered Nursing (Provider Number 13917) to offer CEUs for successful completion of its recruitment and retention training programs.

63% of diabetes sites surveyed ranked webinars as an effective recruitment strategy

PHYSICIAN OUTREACH AND REFERRAL

DAC collaborated with site staff on the coordination of physician dinners and meetings to introduce the study to potential referring physicians and their staff. Supporting collateral included slide presentations and study reference materials. Additionally, weekly fax reminders and/or postcards were sent on behalf of investigators to referring physicians to help keep the study top-of-mind.

95% of sites considered physician outreach an effective recruitment strategy

MEDIA KITS

Designed to aid sites in educating patients about the study opportunity and identifying potentially eligible participants, media kits comprised a physician-to-physician letter template and a physician-to-patient letter template on CD, two study posters for strategic placement in waiting and/or examination rooms, five study eligibility cards with key inclusion and exclusion criteria, and 100 fliers for distribution to diabetes patients and caregivers.

100% of sites said support materials were useful for informing patients about the study

COMMUNITY OUTREACH

To raise study awareness among patients and clinicians, DAC forged relationships with various organizations focused on Type 2 diabetes, including local chapters of the American Diabetes Association, American Association of Diabetes Educators, National Institutes of Health, and National Medical Association, among others. More specifically, DAC promoted the study through advertisements in organizational newsletters and postings on organizational websites. With diabetes disproportionately affecting African Americans and Latinos, DAC also aligned with the National Medical Association's Project I.M.P.A.C.T. which endeavors to increase minority participation in clinical trials.

95% of sites said community outreach was effective for identifying study participants

DIRECT-TO-PATIENT ADVERTISING

DAC developed targeted advertisements for local newspaper, print, radio, and television outlets. The media mix varied by site based on interest and past success. Call center services supported sites in pre-screening ad respondents.

Only 42% of sites reported previous use of patient advertising With 94.7% of sites missing enrollment targets, advertising was highly recommended



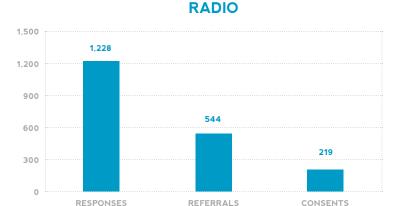
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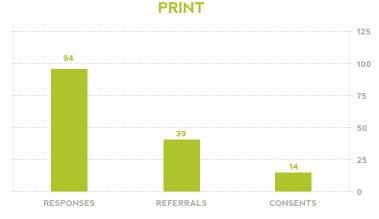
ACHIEVEMENTS

- > Average rate of enrollment increase per month = 150%
- > Rollout Month 1 increase = 230%
- Month 1 Month 2 increase = 139%
- Month 2 Month 3 increase = 82%
- > Project completed 2 weeks early

ADVERTISING OUTCOMES

| ADVERTISING MEDIUM | RESPONSES | REFERRALS | CONSENTS |
|--------------------|-----------|------------------------|-----------|
| Radio | 1,228 | 544 <mark>(44%)</mark> | 219 (40%) |
| Print | 94 | 39 (41%) | 14 (36%) |

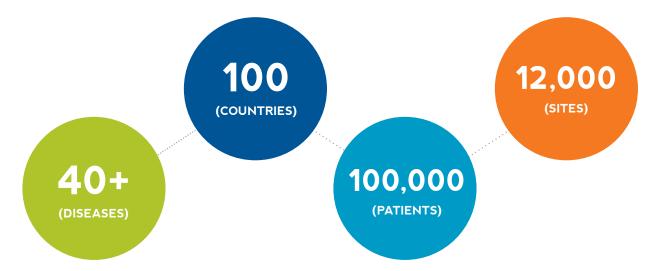




A multidimensional patient recruitment strategy was required for this study sponsor to compete amid other studies vying for the same patient demographic. The program's viability was determined by its ability to captivate and inform the target audience; meet regulatory standards governing patient communication; and allow for accurate tracking, monitoring and metric reporting. Achieving enrollment success was contingent upon the clinical trial sponsor's understanding that patient recruitment and retention strategies are only as effective as the clinical sites commissioned to implement the plans. By aggressively educating and engaging sites, the sponsor was able to mitigate competitive challenges, maintain statistical advantage and realize enrollment success.



20 years of experience managing recruitment and retention programs representing:



A pioneer in patient recruitment and retention for global clinical trials, DAC Patient Recruitment Services (formerly D. Anderson & Company) develops customized programs that yield rapid enrollment, risk reduction and return on investment. Our unique strategies have boosted enrollment by 100 percent and reduced attrition by 48 percent on average. We've successfully managed recruitment and retention programs representing 100,000 patients at 16,000 sites around the world.

SERVICES INCLUDE

- Country-Customized Recruitment and Retention Programs
- > Clinical Project Management
- Award-Winning Creative Services

- > Strategic Site Selection
- Certified Clinical Staff Training

PART OF THE FAMILY

DAC Patient Recruitment Services is proud to be part of the Imperial Family of Companies—a clinical research support organization also comprising ClinicaLingua Translation Services and Imperial Graphics. Together, these three vertically integrated brands focus on patient recruitment, translation services and site material production and fulfillment. DAC offers industry tenure, clinical expertise and creative acclaim not found with other patient recruitment providers. Working in synergy with our sister companies, we offer start-to-finish clinical trial solutions with the power of three companies through the convenience of one contact and one contract.