

A Case Study: Balanced Site Performance Leads to Shorter Timelines and Lower Costs

Background

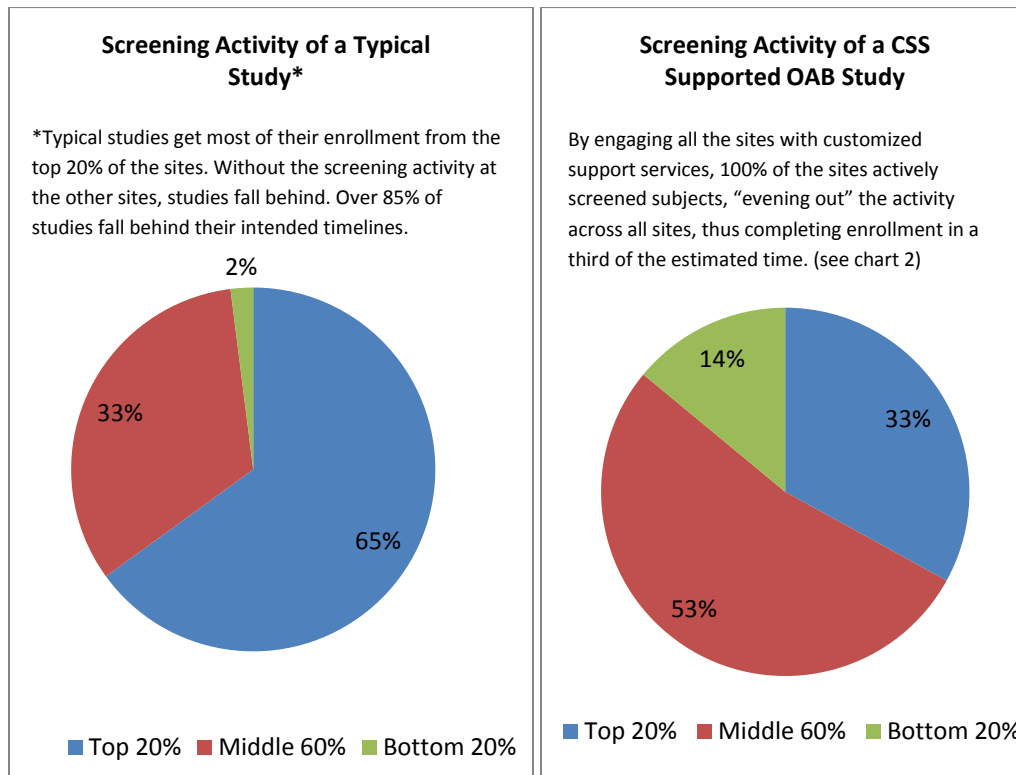
It is common knowledge in the clinical trials industry that within any given multi-site study, 20% of the sites will enroll a maximum of one subject, and often none at all, while the top 20% enroll the majority of the subjects. Over 85% of all studies fall behind their intended enrollment timeline.

Clinical Site Services (CSS) recognizes that site performance is the number one issue, not patient recruitment. Sponsors and CROs do not provide the necessary support to sites to help them meet and exceed their screening and enrollment goals. CSS believes in developing the right enrollment “tools” and provides unique customized services to assist sites in identifying subjects for their trials and increase their overall effectiveness.

Situation

In a recent overactive bladder (OAB) study, CSS worked with the CRO prior to the study start up to develop tools which sites could use to reach out to the OAB population. These tools included in-office awareness materials, community awareness, and advertising outreach. CSS worked with each site to develop an enrollment plan which included tactics that would best meet their needs. Once the study began, CSS worked with each site to execute their enrollment plan, monitoring the success of each tactic.

Chart 1: Comparing the percentage of screening activity by all sites (top 20% of sites, 21%-80% of sites, and bottom 20%) of a typical study, compared to a CSS supported OAB study.



CSS increased the enrollment activity at all sites and helped to complete the trial early. See Chart 2

Solution #1 – Enrollment Tools

By providing the sites with the right tools, developing enrollment plans, and supporting each site with enrollment support services, the screening goals were met within 37% (at week 10) of the planned timeline of 27 weeks. Providing sites with the right tools and support services increased the percentage of sites screening thus shortening the timelines.

Tools Created:

In-office awareness materials:

- Doctor-to-Patient Letter
- In-office 70" awareness banner
- Study criteria cards

Community Awareness tools:

- Brochures & Flyers
- Study Website
- Study easels and cards

Outreach Tools:

- Television
- Radio
- Print
- Internet messages

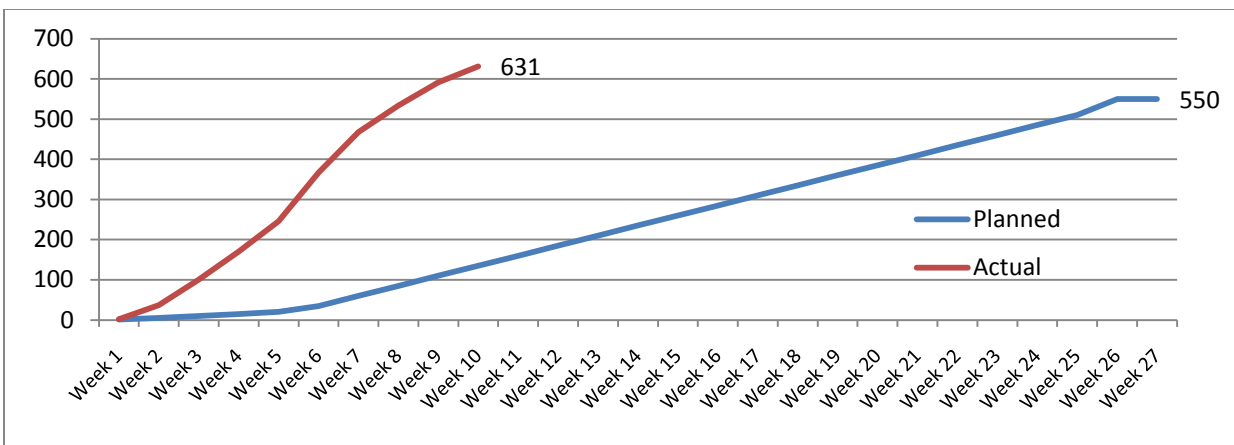
Solution #2 - Support Services

Each site was assigned a Site Enrollment Specialist who worked with the sites to develop a custom enrollment plan utilizing the study tools developed to support their enrollment needs. The Site Enrollment Specialist worked with each site on a weekly basis to make sure their enrollment plan was being implemented and to assess the results of each tactic.

Results

By working with each site to execute their enrollment plan, 100% of the sites had screened at least six (6) subjects. While the top 20% of the active sites still over performed, having the remaining 80% contributing a significantly greater amount put the study ahead of its timeline goals by more than 17 weeks.

Chart 2: Actual Vs. Planned Screening Timeline



Overall Benefits

- Study timelines are met
- Costs are kept to a minimum
- Sites are more compliant and motivated when actively screening
- Sponsor was able to monitor the sites' progress and make informed decisions throughout the study