



Increasing Site Performance Case Study

In today’s reality of meeting enrollment goals, the Pareto principle of 20% of the sites enrolling 80% of the study subjects seems to hold true for most studies. This reality puts a lot of strain on the “performing” sites and ends up costing the sponsor delays in their timeline and instituting expensive patient recruitment campaigns.

Clinical Site Services (CSS) is a Site Performance Company. Our services focus on supporting the sites and managing trial enrollment to maximize site performance and meet or exceed timeline and financial goals. We believe in investing in enrollment strategies in order to minimize costs and maximize results. By increasing the number of performing sites, study budgets are used more efficiently and enrollment is completed earlier.

Situation:

CSS was approached by a large CRO to assist them with increasing enrollment on a large 79 site national trial. At the time CSS’s services began, 30 weeks had passed, less than 20% of the sites had screened three or more subjects, and only 64 patients were enrolled.

Challenge:

The client needed to increase the number of sites screening and enrolling, generate more screenings from private practice and recruitment, increase the enrollment rate, and complete the study in nine months.

Solution:

CSS developed an integrated **Site Performance Strategy** to meet the client’s goals. The components included:

1. Site Assessments
2. Patient Awareness Tool Kit
3. Monthly Study Coordinator Teleconferences
4. Site Assistance Services
5. Customized Site Recruitment Planning
6. Recruitment Ad Development
7. Patient Recruitment Campaign Execution

Results

The site performance campaign ran for 28 weeks and enrolled 326 subjects to complete enrollment one month ahead of the client’s goals. By increasing the number of performing sites, study budgets were used more effectively and enrollment was completed earlier than scheduled.

	<u>Prior to CSS</u>	<u>Site Performance Strategy Program</u>	
Weeks	30	28	
Total sites	79	79	
Total Screening	117	535	<u>457% increase</u>
Sites screening 3+	15 (19%)	55 (70%)	
Total Enrolled	64 (16%)	326 (84%)	
Ave. # Enrolled/site	.81	4.13	<u>509% increase</u>