› CASE STUDY

VERISTAT

Improving Clinical Trial Efficiency by Achieving Patient Recruitment On-Time

How Site Engagement Drives Patient Recruitment Success for a Lagging Trial

Background

Patient recruitment delays are common challenges in clinical trials that can lead to costly delays. In fact, nearly 80 percent of patient recruitment timelines in clinical trials are not met and over 50 percent of the patients are not enrolled within the planned timeframes.[1] Some studies suggest that each day a clinical trial is delayed can cost a sponsor $1M in expected sales.

To improve your trials' chances of keeping patient recruitment and enrollment on track, Veristat utilizes a proven strategy of site engagement techniques. Three of these strategies include the implementation of an in-house call center to address patient concerns, educational materials to keep sites engaged, and study branding to encourage compliance and patient responses.

Learn how we rescued an ongoing Phase IV safety study that was not recruiting on time.

GOAL: Supplement patient enrollment support to current CRO struggling to achieve enrollment timelines

Phase IV safety study

Chronic obstructive pulmonary disease

Need 1,000 more patients across 60 sites

THE SITUATION

A pharmaceutical company came to Veristat for help bolstering patient recruitment and enrollment for a Phase IV FDA mandated safety study for a difficult patient population with a placebo arm. Another CRO had been recruiting on the study for 20 months thus far and was falling behind on the recruitment timeline. The patient population consisted of patients with chronic obstructive pulmonary disease (COPD). Veristat was asked to recruit and enroll 1,000 patients across 60 sites over the next year. Our clinical teams worked side-by-side with the current CRO. We were asked to recruit half of the patients and the other CRO continued working on the other half. All enrollment variables remained the same for both CROs, e.g. number of patients, number of sites, investigator grant budgets, etc. – neither CRO had any resourcing advantages.

THE SOLUTION

Veristat's team focused our efforts on site engagement. We deployed our unique site engagement methodology consisting of a dedicated and specialized trial specialist team to manage the site interactions. They made weekly calls to the sites to discuss study start-up activities, patient recruitment, and enrollment updates, and to talk through any site challenges. Additionally, our team developed a suite of study-branded digital marketing assets – including a website, milestone cards, and branded collateral – to keep both sites and patients engaged throughout the recruitment, enrollment, and study monitoring visits.

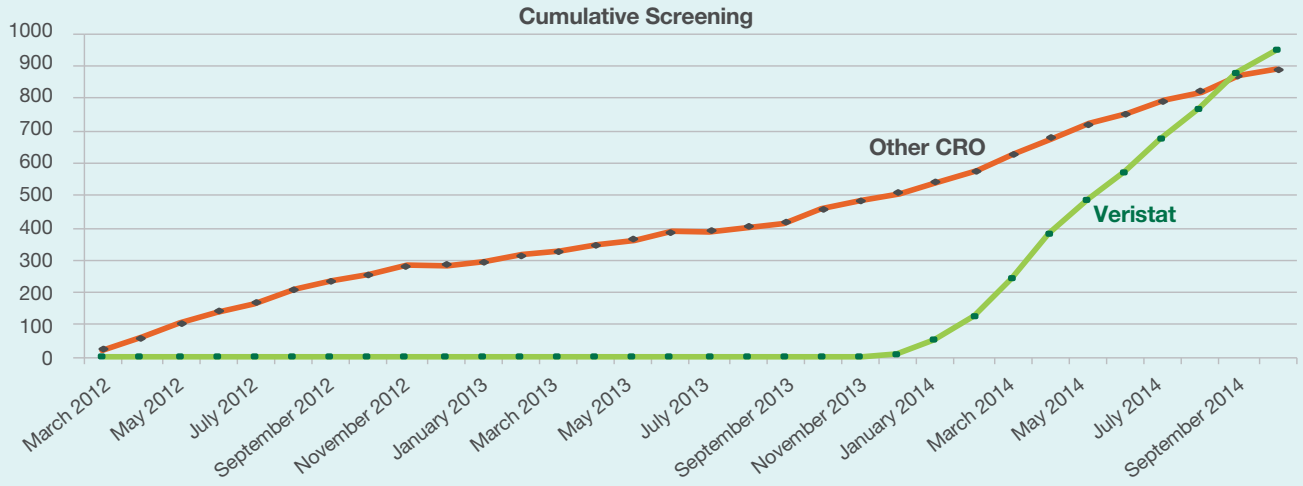
As a result of our site engagement efforts, our screening and randomization rates were 50% higher as noted in the table below.

	Recruitment Before Veristat		Recruitment After Veristat	
	Total	AVG per month (22 months)	Total	AVG per month (27 months)
Screening	511	23	1197	44
Randomized	283	13	591	22

IMPACT

Site Engagement Delivers More Patients in 66% Less Time

We achieved the client's goal of meeting their patient recruitment timeline, therefore keeping their Phase IV study on track. Ultimately, our client did an analysis at the end of the study and concluded that our site engagement techniques led to the success of our expedited patient enrollment times. Veristat recruited 950 patients in 10 months when it took the other CRO 31 months to recruit 890 patients. More patients were recruited in one-third of the time it took the other CRO, with all other variables being the same, apart from the engagement strategies we deployed.



Other CRO began recruitment in March 2012
31 months of recruitment yielded 890 patients

Veristat began recruitment in December 2013
10 months of recruitment yielded 950 patients

ABOUT VERISTAT

Veristat is a smart, effective and impactful CRO focused on advancing medical therapies through the clinical development and regulatory submission process. Our work delivers meaningful clinical impact and our regulatory submission expertise is unrivaled in our industry. Veristat teams have worked on over 75 regulatory submission projects that have resulted in nearly 50 submission approvals to date from various regulatory agencies around the world. We partner with and guide biopharmaceutical companies from non-clinical planning through to market approval so that new therapies become available to improve and save people's lives.

Learn more about our patient recruitment, strategic consulting, data analysis, or regulatory submission expertise.

Contact Veristat Today

Learn more about Veristat and how we can assist you with study start-up, site engagement, and patient recruitment challenges.

www.veristat.com

[1] https://www.clinicalleader.com/doc/considerations-for-improving-patient-0001