LIFE LINE SCREENING®
The Power of Prevention

AORTIC STENOSIS

A medical device study for the detection of aortic stenosis

THE CHALLENGE

Life Line Screening was tasked with recruiting our customers to participate in a medical device clinical trial. Over the course of 7 months, study coordinators made tens of thousands of outbound calls to 6 different regions in the United States, collecting demographic information, and ultimately scheduling 955 study participants for in-person appointments. 726 study participants completed a 60-minute appointment in private hotel conference rooms where a collaborative team of staff from Life Line Screening, an imaging company, and the sponsor were able to collect the required data for the trial. Study participants were fitted to an Edwards Lifesciences AIQ cuff, where the ClearSight system was able to provide real time, noninvasive, hemodynamic monitoring. The imaging company echocardiogram technologists performed an echocardiogram alongside the ClearSight system assessment. Data from these two tests were compared to illustrate the effectiveness of the sponsor's ClearSight system in detecting cardiovascular anomalies such as aortic stenosis.

OUR SOLUTION

OUTBOUND CALL CENTER

After completing detailed study-specific training, dedicated study coordinators from Life Line Screening's call center were tasked with providing high quality study participants to clinical trial screening locations across the country.

PROJECT GOALS

- Provide Life Line Screening customers with education about cardiovascular health
- Collect pre-screening information to ensure candidate eligibility
- Provide study participants with a comfortable and private screening experience while adhering to clinical trial protocol
- Collect high-quality study data from the time of consent to the completion of the study using Good Clinical Practice guidelines
- Utilize different regions of the United States for data collection to obtain a diverse sample of study participants

To accomplish this, customers between the ages of 18 and 85 who live within 25 miles of a trial location were contacted, educated about the clinical trial, and if interested, digitally consented with Adobe Sign. After scheduling the study participants for an appointment, Life Line Screenings study coordinators would collect important demographic information such as medical and medication history, ethnicity information, and history of smoking. Prior to their appointments, study participants would receive a call and email reminder from their dedicated study coordinator.

IN-PERSON APPOINTMENT TEAM

Life Line Screening staff would check in each study participant in a private hotel conference room and verify consent. A staff member from both the imagining company and the sponsor would collect additional clinical trial data and prep the study participant for their assessments. Once the echocardiogram and ClearSight system assessment were concluded after about 45 minutes, a Life Line Screening team member would provide them with a stipend for their time and travel. At the end of the day, members from each team would review study participant attendance before uploading all study data including handwritten case report forms and images from the echocardiogram.

DATA ENTRY AND SIGN-OFF

Life Line Screening study coordinators would complete a quality control check on all case report forms to ensure that accurate, high-quality data was collected throughout the duration of the trial. After medical review of each image, a Life Line Screening cardiovascular physician would provide an overview of any disease found from the echocardiogram data. All case report forms were sent for final sign-off by a Life Line Screening principal investigator before being entered into a digital platform and shared with the sponsor for review.

RESULTS

- 1128 customers interested in participating, consented, and pre-screened for eligibility
- 955 eligible study participants scheduled for an in-person appointment
- 61 total screening days organized with 10-20 appointments held each day in private brick-and-mortar screening locations
- Study participants recruited for 6 different regions:
  - Cleveland, OH
  - Boston, MA
  - Miami, FL
  - Santa Ana, CA
  - Los Angeles, CA
  - Houston, TX
- Collaboration between Life Line Screening staff, the imaging company echocardiogram technologists, and sponsor engineers
- 726 study participants completed their appointments where all data was collected, uploaded, quality control checked, sent for signature, and digitally entered.