Outcomes4Me

CASE STUDY

Outcomes4Me enables clinical trial recruitment for diverse participants with pre-screen efficiency of 5-10X

THE CHALLENGE:

Clinical trials are becoming exponentially more complex and restrictive as genomics and targeted therapies become more known. It is increasingly difficult to find patients meeting the exact criteria and at the right time in their treatment–while also being representative of the general population. Further, $10M-100M in revenue is lost for every month clinical trial recruitment is delayed. A leading pharmaceutical company chose Outcomes4Me to help recruit patients for 3 clinical trials intended to study the safety and efficacy of a drug for highly specific patient populations.

THE SOLUTION:

Hyper-targeted reach: Outcomes4Me has a growing user base across several different cancer types with a current breast cancer patient population greater than 150,000. It is representative of the breast cancer population at-large across ethnicity, income, geography, and disease stage. Outcomes4Me captures self-reported patient data which enables it to hyper-target the right patients for specific clinical trials. For the Client's 3 trials, it identified >1.7K patients with the following baseline criteria:

- TRIAL 1: HER2+ metastatic breast cancer, excluding an un-mutated mutation
- TRIAL 1: HR-, HER2- metastatic breast cancer excluding an un-mutated mutation
- TRIAL 1: HR+, HER2- metastatic breast cancer excluding an un-mutated mutation

Engaged dialogue: As patients were identified to meet the baseline criteria, they were further screened with self-reported information and/or medical records. They were asked if they had inflammatory breast cancer or were taking insulin for diabetes. Medical records were reviewed for additional exclusion criteria (e.g., prior treatments not compatible with the clinical trial protocol, comorbidities or genomics). Potential participants were asked about their willingness to travel, race, and ethnic group to help ensure clinical-trial equity. Upon request of the client, Outcomes4Me deployed a specific personalized approach for patient outreach to address the highly complex nature of the inclusion / exclusion criteria. A team of clinical trial experts reached out to baseline qualified patients to discuss deeper the goals of the trial, obtain medical records and conduct in-depth self-reported screenings questions.

Patient action: Outcomes4Me created a channel for referring patients and discussing recruitment insights with the client. They met to discuss real-time, pre-screen failures and success drivers and monitor patient demographics; promoting and reporting on trial equity was a critically important measure. Outcomes4Me partnered with each participating clinical trial site to provide a smooth referral process to the patients. Referral to geographically close trial sites for screening only occurred if the patient passed the baseline surveys, a medical record review, and confirmed interest in pursuing the screening process. The defined deliverable was referral of patients with a reasonably high chance to be randomized after the full screening process at the site.

THE RESULTS:

Over a 4-month timeframe, Outcomes4Me screened more patients than traditional methods. In addition, Outcomes4Me provided highly detailed analytics tailored to the customer's clinical protocol.

>1.7k metastatic breast cancer patients with a un-mutated mutation meeting the trials' HR+, HER2- criteria were identified

71% passed self-reported pre-screening questions

>800 Screened for additional exclusion criteria

379 reviewed for medical records (47%)

>99% Screening failures identified at pre-screen stage