Case Study

Doubling the Average Participation Rate of Diverse Populations in Cognivue's FOCUS Study

Neuroscience company Cognivue enrolled more than double the national average participation rate of diverse populations in its Further the Objective and Clinical Understanding of Cognivue Study (FOCUS) study. Velocity supported the study by enrolling the entirety of the study's more than 1,500 subjects across 14 sites and 11 states.

While typical studies of this size average between 2% and 16% participation of diverse populations, 37% of the subjects in the FOCUS study were members of historically underserved and underrepresented populations.

More than 28% of the more than 1,500 subjects enrolled identified as Black or African American, American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, or other non-white. Over 12% of participants identified their ethnicity as Hispanic or Latino. This is twelve times the average Hispanic/Latino participation rate in U.S. clinical trials, which is less than 1% according to the National Institutes of Health.

Velocity led recruitment efforts for the study. The enrollment goal included an objective to enroll a group resembling the racial, ethnic, gender, and educational makeup recorded in the 2020 U.S. census data.

To successfully recruit a diverse study population, Velocity relied heavily on local community outreach and encouraged participant referrals. Velocity also advertised for the study, and stopped recruiting certain demographics when recruitment goals for specific subgroups were reached.

As for future clinical trials, Paul Evans, President and CEO of Velocity, said his company will continue to prioritize diversity in their recruitment programs. "This is our target going forward. Whenever possible, we will enroll diverse populations proportionate to target populations, ensuring the data we gather can support more accurate modeling of real-world outcomes."

1,500+

Subjects enrolled (100% enrollment by Velocity)

14

Velocity research sites across 11 states

37%

Participation rate of underrepresented populations

"I cannot overstate the value this diverse data capture brought to the FOCUS study. Participants in research trials should represent the patients who will use the medical device, and this is often not the case since people from racial and ethnic minorities and other diverse groups are generally underrepresented in clinical research, especially research related to neuroscience." - Tom O'Neill, President and CEO, Cognivue



