Cognitive Testing in Diverse Populations to Further the Objective and Clinical Understanding Study (FOCUS)

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KEY TAKEAWAY: Historically underserved and underrepresented populations have a 37% research participation rate in the FOCUS cognitive testing study in the United States (US).

BACKGROUND

One of the great challenges facing clinical trial recruitment in the US is obtaining a research sample that reflects of the diversity of the country's population. While racial and ethnic minorities comprise 39% of the US population, they account for roughly 2% to 16% of clinical trial participants by some estimates.[1]

In an assessment of 4,105 US clinical trials registered in ClinicalTrials.gov from March 2000 to March 2020 that reported race/ethnicity data, researchers found the majority of enrollees were White (median 79.7%), which outpaces the US White population in the 2020 US Census of 71%.[2,3] The assessment found median 10%, 6%, and 0% participation among Black, Asian, and American Indian enrollees, respectively.[2] In the 2020 US Census, these groups represent 12.4%, 6.0%, and 1.1% of the population, respectively.[3] In a separate analysis, participation in clinical trials by Hispanic/Latino enrollees is just 1%, though they represent 18.7% of the US population.[1,3]

The aim of the FOCUS study was to collect cognitive testing data from a diverse population and develop expanded normative ranges for the Cognivue *Clarity*® and Cognivue *Thrive*® devices to reinforce application of the testing platform to broad populations of age, sex, race, ethnicity, and education. The Cognivue *Clarity*® and Cognivue *Thrive*® devices are the first FDA-cleared tests of cognitive performance based on modern cognitive neuroscience. The Cognivue *Clarity*® device provides a 10-minute comprehensive assessment while the Cognivue *Thrive*® device provides a 5-minute cognitive screen (Figure 1).

The Cognivue *Clarity*® device evaluates visuospatial performance as well that of executive function/attention, memory, discrimination, reaction time, and speed processing. The Cognivue *Thrive*® device evaluates visuospatial performance along with performance in memory, executive function, reaction time, and speed processing.

Testing with the Cognivue *Clarity*® and Cognivue *Thrive*® devices reliably, objectively, and quantitatively assesses cognitive performance beyond traditional cognitive tests using paper and pencil or computer tablets. After testing, the Cognivue *Clarity*® device's 10-minute assessment and the *Thrive*® device's 5-minute screening provide immediately accessible results for clinicians in a clinical report and/or in a CSV file. Both formats are easy to access, reference, and interact with on demand.

The Cognivue *Clarity*® and Cognivue *Thrive*® devices are adjunctive tools for evaluating cognitive function and are not stand-alone diagnostics. Clinical contextualization is required.

Figure 1. The Cognivue *Clarity*® device

METHODS

Cognivue partnered with Velocity Clinical Research, the world's leading integrated site organization, to lead the recruitment efforts for the FOCUS study. The enrollment goal included an objective to enroll a group resembling the racial, ethnic, gender, and educational makeup recorded in the 2020 US census data.

Study subjects were recruited through local community outreach, participant referrals, and advertising. Recruitment was stopped once goals for specific sub-groups were reached, to model real-world outcomes.

The Cognivue *Clarity*® device's 10-minute test and the Cognivue *Thrive*® device's 5-minute test were administered to assess scoring and normative ranges in addition to validation comparison against performance on accepted gold-standard neuropsychological test batteries within the diverse study cohort.

RESULTS

The FOCUS study recruited more than 1,500 subjects from 14 sites in 11 states. Over 28% of subjects identified their race as Black or African American, American Indian or Alaska Native, Asian, Native Hawaiian or Pacific Islander, or other non-white, and over 12% of participants identified as Hispanic or Latino (Figure 2).

Ultimately 37% of participants recruited for the FOCUS study were underrepresented minorities, while 61% of participants were non-Hispanic White (Figure 3).

Participants in the FOCUS study had a mean age of 50.2±16.3 years (range 18-89); 59.2% were female; and 51.8% had ≥12 years of education (Figure 4).

Figure 3. Participation of Non-White Hispanic Population and Underrepresented Minorities/Groups in FOCUS vs US Population[4]

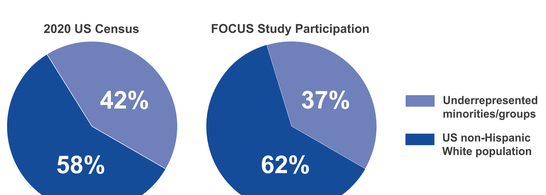


Figure 2. FOCUS Race and Ethnicity Diversity Capture Compared to US General Population and Average Trial Participation[1-3]

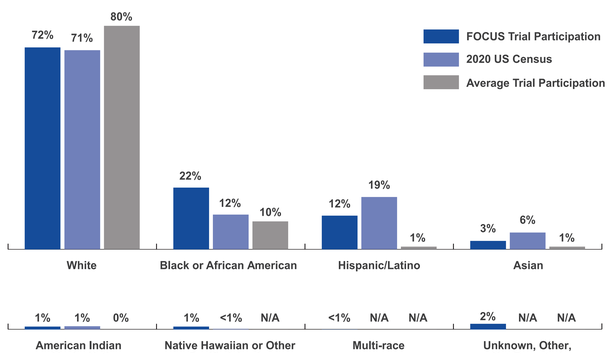
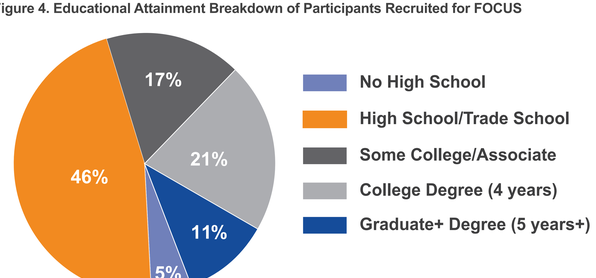


Figure 4. Educational Attainment Breakdown of Participants Recruited for FOCUS



CONCLUSIONS

Working in collaboration with Velocity Clinical Research, with study sites throughout the US, Cognivue was able to reach a 37% research participation rate of historically underserved and underrepresented populations in the national FOCUS study. Because these groups represent 39% of the US population, participant demographics in the FOCUS study more closely match those seen by clinicians daily.[1] Additionally, the level of education among FOCUS participants also closely matches that of the US, in which 63% of the population has less than a Bachelor's degree.[5]

The FOCUS study concluded in Winter (December) 2022 and results are currently being analyzed.

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