

Increasing Diversity in Clinical Trials:

CRIO Sites Have 2X Patient Diversity Than Average



INTRODUCTION

The new FDA guidance to enhance diversity in clinical research subjects has brought ethnic and racial diversity to the center stage for sponsors. In this document, the FDA encourages sponsors to develop a Race and Ethnic Diversity Plan to incorporate into each protocol. More specifically, the FDA suggests that to achieve these diversity targets, sponsors must expand their reach. Given sites' historical role in sourcing patients, one obvious way this can best be accomplished is by contracting directly with sites that have access to diverse patient populations.

CRIO has already demonstrated that CRIO-enabled sites are high-enrolling and quality-driven, and now we have proof that CRIO sites also have more diversity. We found that on average, 17.5% of the subjects at CRIO sites are Black or African American. This is more than two times the national average of 8% according to data released by the FDA's Center for Drug Evaluation and Research.

Measuring Diversity

An analysis of CRIO's U.S. database was conducted for all enrolled or completed subjects, running queries for responses to the Race question that trials typically include in the Demographics procedure.

Next, we filtered for research sites that have been utilizing CRIO's eSource for a critical threshold of time and excluded sites that were not actively enrolling subjects. Because sites chose different verbal formulations in their answer sets, we coded the responses. For answers where multiple races were selected, we defaulted to the first answer selected (which tended to be "White", therefore undercounting diversity).

We then calculated the percentage of Black or African American subjects across all studies.

The Results

Data was extracted across 644 CRIO sites, obtaining racial composition of over 60,000 subjects from thousands of protocols. Mainly, we uncovered that CRIO sites have an average of 17.5% Black or African American subjects.

Our analysis of this high average revealed that the top third of CRIO sites have more than the 17.5% CRIO average for Black or African American subjects. Many of these sites specifically focus on enrolling patients from underrepresented populations. As high as 96%, these top enrolling sites for African American subjects raised the average across CRIO.

KEY FINDING:

On average, 17.5% of subjects at CRIO sites are Black or African American.

The following table and graph show the varying percentages of Black or African-American patients represented on CRIO sites. For 26% of CRIO sites, over 17.5% of the subject population is Black, while 15% of sites using CRIO have a Black subject population between the national average of 8% and the CRIO average of 17.5%. Lastly, we found that 60% of CRIO sites had less than 8% of Black or African-American enrollment in their studies. Overall, we found that over 40% of sites using CRIO have a greater proportion of Black or African American subjects than the FDA-reported national average. These findings illustrate that CRIO sites seem to implement a strong diversity mix into their studies when compared to sites that do not utilize CRIO technology.

% of Black or African American Subjects	% of CRIO Sites
Greater than 17.5%	26%
8% - 17.5%	15%
Less than 8%	60%

Fig. 1 - Varying percentages of Black or African American patients represented on CRIO sites

Percentage of CRIO Sites with Varying Proportions of Black/African American Subjects

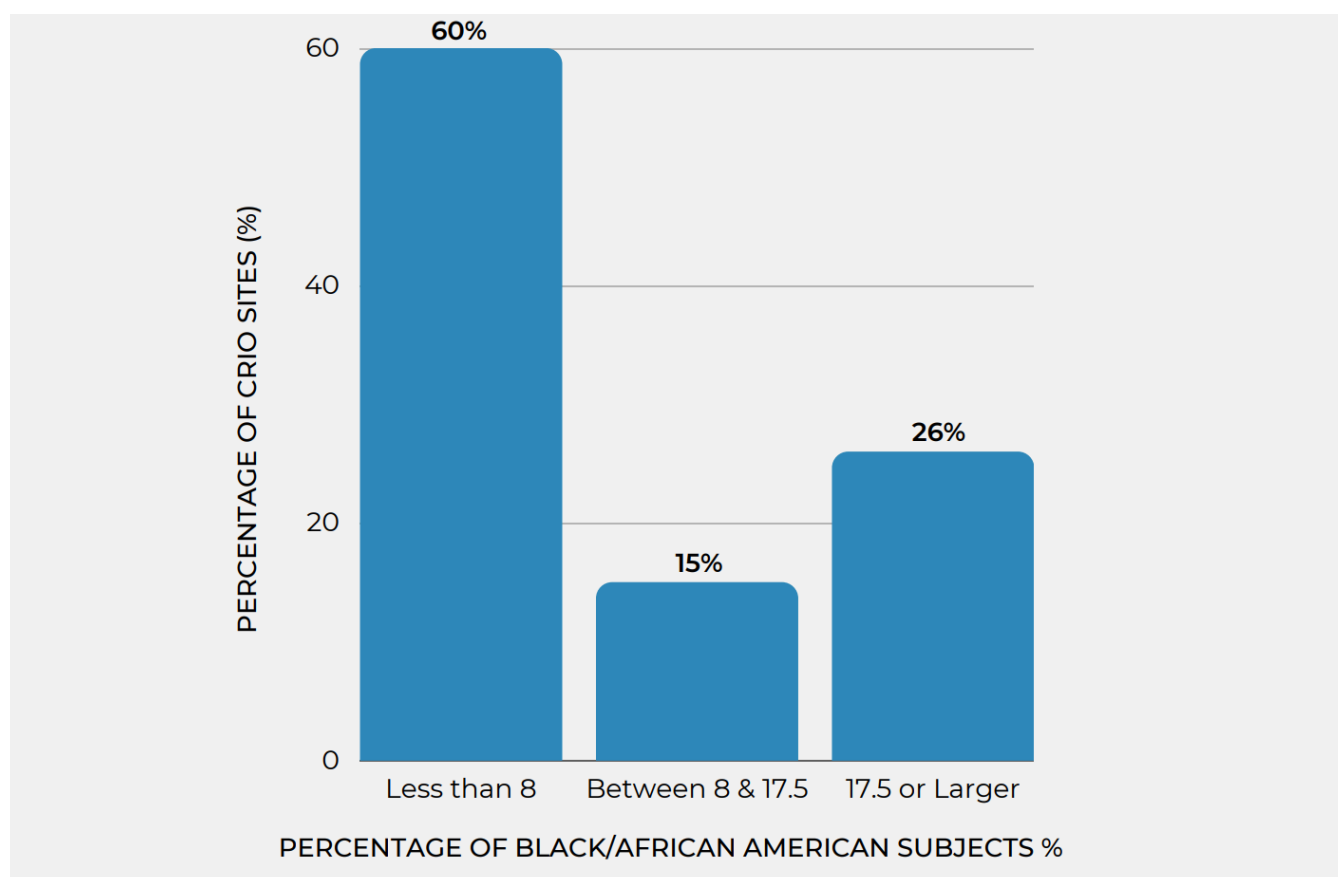


Fig. 2- Graph illustrating varying proportions of Black/African American subjects across CRIO sites

Why Are CRIO Sites Producing Such Diversity?

Many of the diversity-focused CRIO sites are deeply embedded in neighborhoods with high populations of low-income and racially underrepresented individuals. Generally, private research sites often enhance recruitment by strategically establishing sites away from large healthcare systems. These larger healthcare systems tend to invest in affluent, predominantly white communities where the average patient has private insurance with high reimbursement rates. This is not necessarily the patient population that actively seeks out clinical research trials since they tend to have access to high quality care and may want to exhaust all standards of care before seeking novel treatments. Thus, many CRIO clients, especially some of the newer sites, explicitly target diverse neighborhoods as a way of reaching new patient populations for clinical trials.

CRIO Sites Prioritize Diversity in Recruitment Strategies and Staffing

Randomize Now, located in Peachtree City, GA, is an example of a new site accessing minority populations to increase diversity in clinical research. Dr. Lovie Negrin, Founder and Director of Research at Randomize Now, asserts that an integral part of their strategy is seeking out PIs, research staff, and community collaborators who align with their mission of increasing diversity.

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Dr. Lovie Negrin, Founder and Director of Research, Randomize Now

For example, Dr. Negrin says that one of their GI studies is embedded in a clinic located in rural Georgia. While most sites are typically found in urban areas, Dr. Negrin’s team increases diversity by intentionally including an otherwise overlooked community.

LGBTQ+ community health center Whitman-Walker Institute, founded in 1973, is located in Washington, D.C. This community-centered organization has been trailblazing in the healthcare industry by ensuring medical care and research are accessible and equitable for the most vulnerable populations. From participating in antiretroviral trials at the front lines of the HIV epidemic to their current work in gender-affirming care, the Whitman-Walker Institute contends that they are dedicated to highlighting the importance of social justice when conducting research or providing medical care.

Eleanor Sarkodie, a Research Data Analyst at Whitman-Walker, attributes the retention of this diverse patient base to diverse staffing practices and the investment in patient education. These practices have created trust within the larger DC community, further widening Whitman-Walker’s reach. The Whitman-Walker Institute not only includes members of the LGBTQ+ community as part of their studies, but they also continually recruit a majority Black population.

Conclusion

CRIO’s technology has empowered site operators to partner effectively with research-naive physicians, allowing them to bring in new patient populations historically underserved by the clinical research industry. As a result, the CRIO technology and site network can serve as powerful levers to help sponsors realize their diversity plans.

ABOUT CRIO

CRIO is a leading provider of eSource solutions for clinical research. Our platform streamlines data collection and management, ensuring protocol compliance and reducing errors. By eliminating paper binders and automating workflows, we help clinical sites and sponsors save time and money, improve data quality, and enhance patient safety.

