

Efforts at Rho to Increase Racial Diversity in Clinical Trials

Sharon Duffy

Associate Director, Clinical Monitoring at Rho

Shauna Martin

Senior Learning and Performance Specialist at Rho



Background of Racial Diversity in Clinical Trials

An important component of any strategy to increase diversity in clinical trials is involvement of the Clinical Research Associate (CRAs). CRAs have direct contact with site personnel at all stages of the trial, starting at the feasibility and qualification stage where conversations begin about a site's patient population and recruitment techniques. During the study conduct, CRAs are able to have detailed conversations with site staff to delve into recruitment challenges.

In recent years, more emphasis is being placed on increasing racial diversity in clinical trials. Research indicates that subject enrollment in clinical trials does not match the population that is most likely to suffer from the disease. Often times, sites lack effective plans for increasing diversity in subject enrollment. Research also shows that racial minorities are less aware of clinical trials and often have negative perceptions of clinical trials.

Lack of racial diversity in clinical trials has far-reaching consequences. Racial minorities are likely to be diagnosed with certain diseases and are more likely to die prematurely from them. Having a lack of subject enrollment from those racial minority groups drastically limits the production of life-saving interventions for those diseases. Lack of racial diversity in clinical trials also exacerbates health disparities between races, and racial minorities may experience unanticipated side effects and lack of drug efficacy because of underrepresentation in these trials.



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There are many benefits to increasing racial diversity in clinical trials. First, in support of conducting research studies according to sound scientific principles, it is imperative to have the subject population in a clinical trial reflect the actual population with that disease. Another important benefit to increasing diversity in clinical trials is that it allows underrepresented racial minority populations access to cutting-edge therapies. Clinical trials offer access to the types of health care that racial minorities may not be able to access elsewhere. Supporting this effort is also good business practice in that studies can be enrolled faster with the most representative study subjects. The draft guidance from the FDA that highlights racial diversity in clinical trials, “Enhancing the Diversity of Clinical Trial Populations: Eligibility Practices, and Trial Designs” (June 2019), supports and encourages these efforts.

CRA's Role in Addressing Racial Diversity in Clinical Trials

CRAs at Rho, along with their study teams, are partnering with their sites to increase awareness and implement strategies to meet racial diversity enrollment goals. Rho works to ensure CRAs understand the burden of the disease across minority populations. Study teams and CRAs encourage sites to translate forms for non-English-speaking subjects even if not required by the IRB. CRAs provide training to staff at sites around the benefits of increasing diversity in clinical trials. CRAs also ensure that site staff understand that a potential barrier for subjects who are racial minorities is too little time given to process the benefits and consequences of a study. Potential subjects who are racial minorities likely would be more comfortable having plenty of time to consider benefits and risks before deciding to join a study. Additionally, CRAs encourage sites to inform subjects about study results at regular intervals, which is connected to racially diverse subjects having all the information they need to feel comfortable participating in a study. CRAs advise sites on effective recruitment strategies, and CRAs are also expected to provide feedback around recruitment barriers to project teams.

In order to support CRAs in the effort to address lack of diversity in clinical trials, Rho provides awareness training for all CRAs on increasing racial diversity in clinical studies. In addition, Rho provides CRAs with tools to facilitate conversations with sites around increasing racial diversity in subject enrollment. Another strategy that Rho has employed involves adapting the presentations for site qualification, site initiation, and investigator meetings to inform site staff about recruitment strategies that target racial minorities as it is appropriate for the study. The adaptations to the presentations are intended to foster discussion around the topic during these visits. Topics covered in these presentations include the following:

- The racial/ethnic distribution of the condition under the study
- Information on whether it is the sponsor's expectation that that distribution be approximated in a given study
- Informing site staff about FDA expectations around recruitment from racially diverse populations
- Importance of Phase 3 representing real-world populations
- Benefits of incorporating techniques to enhance recruitment from diverse populations



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- The impact on the outcome of the study if these racial/ethnic groups are not included
- Inquiry as to how the sites intend to recruit subjects from these racial/ethnic populations
- Barriers the site may have in recruiting racial minorities
 - What kind of outreach has worked or not worked for them in the past?
 - What reasons are given from the subjects who refuse to participate?
 - Does the site approach all potentially eligible subjects, regardless of race/ethnicity?
 - If they do not, what are the reasons they would not approach a potentially eligible subject?
- Use of screening logs to track diversity information so that CRAs can follow up if the site is not meeting expectations
- Assistance from recruitment vendors with enrollment challenges related to lack of diversity.

Racial Equity Impact Assessment

Rho has introduced the Racial Equity Impact Assessment (REIA) to CRAs and other members of study teams. The REIA is a tool from Race Forward, which is an organization that is committed to “bringing systemic analysis and an innovative approach to complex race issues to help people take effective action toward racial equity.” Typically, the REIA is used during decision-making processes in which high-impact decisions with far-reaching consequences are being made. The REIA has been used for issues such as policy-making decisions, budgetary decisions, and school system governance.

The REIA is organized as a series of guiding questions that allows groups of stakeholders to determine the impact that their decisions will have on racial minority groups. In addition, the REIA is used to determine what types of representation are needed during each phase of a decision-making process. The questions that comprise the REIA can also be used by leaders to guide their own practice and individual decision-making process.

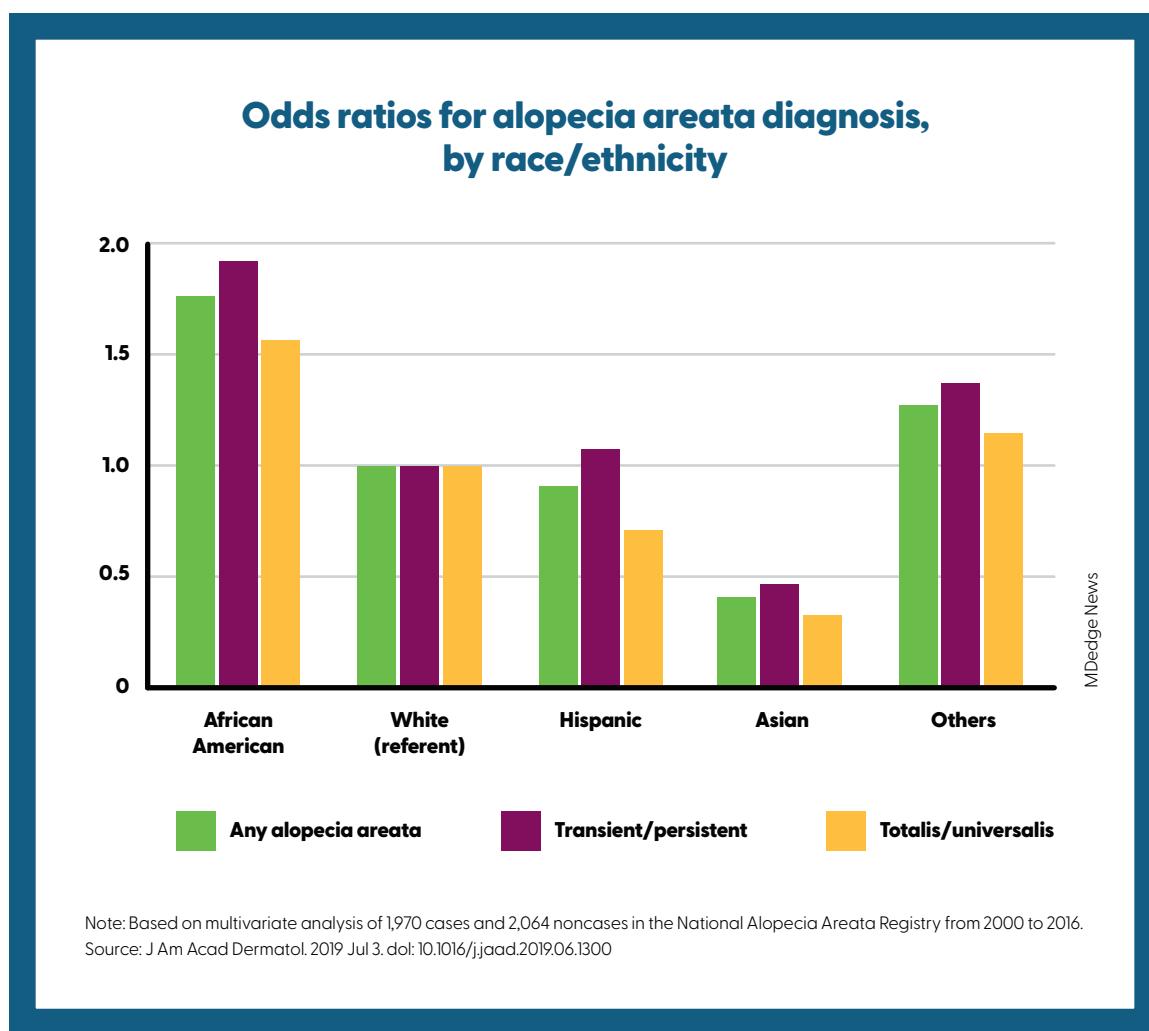
For our purposes at Rho, we have started using the REIA with CRAs as a way of equipping them with equity-focused language that will support the conversations they have with site staff around increasing diversity in clinical trials. The questions from the REIA have been adapted for the needs of Rho’s CRAs. Additionally, we anticipate Rho using the REIA for project leaders and other project team members to have discussions with sponsors around increasing diversity in clinical trials.



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Case Study: Autoimmune Study-Phase III

Rho currently is managing an upcoming autoimmune Phase III study conducted in alopecia patients, a condition common found in the African American population. Rho managed and monitored this sponsor's Phase II study, and it was noted that the African American demographic was underrepresented in that study. Approximately 12% of overall enrolled subjects identified as African American.



Note: Based on multivariate analysis of 1,970 cases and 2,064 noncases in the National Alopecia Areata Registry from 2000 to 2016.
Source: J Am Acad Dermatol. 2019 Jul 3. doi: 10.1016/j.jaad.2019.06.1300

We identified this as an opportunity to address in the upcoming Phase III study. Currently, the study is conducting Site Qualification Visits with sites being initiated in Fall 2020. At that time, we anticipate Rho employing additional strategies to support our client with enrolling subjects that reflect the racial demographic of those who most prominently suffer from this disease.



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Rho used the Site Qualification Visit presentation as a way of raising awareness among site staff about the scientific benefits of enrolling African Americans in the Phase III study. During the conversations at the Site Qualification Visit, some site staff reported to the CRA that they are using social media as a way of raising awareness among racial minorities. Sites that are located in areas with primarily Caucasian residents indicated to Rho CRAs that they are agreeable to using strategies in their recruitment practices in an effort to increase racial diversity in subject enrollment. Still, staff from sites that are located in areas with a mostly Caucasian resident population have expressed concern at having a limited pool of racial minorities from which to recruit. Other sites are wondering if the push to increase racial diversity in clinical trials means that sponsors will begin placing a cap on the number of Caucasian subjects that are enrolled in the study. Since this work is still in its infancy, Rho has a unique opportunity to concentrate our efforts and implement multilayered strategies to support sponsors and sites with increasing racial diversity in clinical trials.



Sharon Duffy

Associate Director, Clinical Monitoring at Rho

Sharon Duffy has over 25 years of clinical research experience at both large and small CROs and sponsor companies. Starting as a CRA, she later moved into monitor training, process and compliance support. She received her B.A. in Biology from the University of Virginia.



Shauna Martin

Senior Learning and Performance Specialist at Rho

Shauna Martin has over 17 years as a public school educator ranging from classroom teacher to instructional coach to district-level administrator. Shauna works with the Organizational Development team to design, develop, and deliver quality learning experiences for employees as well as consult with various sectors of the company to improve existing systems and processes. Shauna received her B.A. from the University of Virginia and her M.A. from East Carolina University. She holds a M.A. in Curriculum and Instruction and school administration certification and is currently a doctoral student at UNC-Wilmington where her concentration is educational administration.