

Increasing Clinical Trial Accrual of Minority Patients by Expanding Clinical Operations at Satellite Sites

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1. Background

Multiple myeloma (MM) is the most common blood cancer among African Americans (AA). Despite the fact that AA comprise ~20 percent of the population of MM patients, they only represent 6 percent of patients in clinical trials. Moreover, the MM mortality rate among AA is two times greater than in whites with a five-year age-adjusted mortality rate of 6.2 per 100,000, vs. 3.1 per 100,000 among whites. However, when enrolled in clinical trials, AA patients fare as well as, or better than, white patients underscoring the critical need for inclusion of underserved minority patients in our clinical trials. There is also a clinical and regulatory need to generate efficacy and safety data in minority patient populations that are representative of the background incidence of the disease for inclusion in labeling.

2. Goals

There are many factors contributing to suboptimal clinical trial enrollment among minority MM patients, including being presented with the option to enroll in a trial, lack of awareness of clinical research, socioeconomic factors, and general mistrust of research due to historical maltreatment of minorities in medicine and research. One of the main contributing factors is that our trials are often not conducted at community sites where MM minority patients are treated due to lack of clinical trial resources, including infrastructure, study coordinators, and clinical staff.

Our center sees more than 500 new patients each year, making us a center of excellence for MM care in New York City (NYC). We are also home to one of the largest and most diverse patient populations, which affords us the opportunity to have an inclusive clinical trial program.

3. Solutions and Methods

We hired advanced practice providers (APPs) who worked with clinical trial managers (CTMs) to lead the MM-focused clinics and to advance the clinical trials programs at the sites. CTMs focused on clinical operations and logistics by assessing the feasibility of each clinical trial to the site population. APPs train infusion nurses, pharmacy, and support staff on clinical trials and Good Clinical Practice.

4. Outcomes

Underserved areas in NYC were identified by using NYC.gov and overlaying a heat map of the MM patient population using underserved area parameters. We identified areas of the most need and matched the locations with our closest satellite site: Brooklyn and lower Manhattan. As of December 31, 2022, we have successfully opened clinical trials at our satellite and enrolled 12 patients. In addition, we have several clinical trials currently in the study start-up process.

5. Lessons Learned and Future Directions

Minority patients continue to be underrepresented in clinical trials. There are many barriers to clinical trial enrollment. Travel, cost, and lost wages from work can significantly impact enrollment. By attempting to offer clinical trials in the community, we hope to reduce the stressors of clinical trials and improvement overall patient representation.