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How BMS Is Tackling Clinical Trial Diversity

Site Selection Is A Critical Component

by Alaric DeArment

The company's director of clinical trial diversity strategy, Lorena Kuri, talked to *Scrip* about how she became interested in trial diversity and what BMS is doing to increase it.

Like all the drug makers that have lately made a priority of improving clinical trial diversity, [Bristol Myers Squibb Company](#) knows it faces numerous obstacles, some of which could take significant investment to overcome. Meeting that challenge is all in a day's work for BMS' director of clinical trial diversity strategy, Lorena Kuri.

"I'm privileged enough to be in a company that has been looking at this way before the pandemic hit," Kuri told *Scrip*. "Of course, it brought clinical trial diversity to the top of mind of many stakeholders in the health care ecosystem," she continued. "It also elevated and brought clinical trials to the attention of ... the general public."

Indeed, the pandemic brought subjects like Phase III randomized, controlled trial design from the realm of specialists to the popular imagination. But it also laid bare the extent to which COVID-19 studies did not enroll enough people from diverse populations, even when those very populations were the worst affected.

In August 2020, a group of pharmacy and medical researchers published an article in *The New England Journal of Medicine* on racial disproportionality in COVID-19 trials pointing out that despite Black, Latino and Native American communities suffering the worst consequences of the pandemic, those groups were significantly underrepresented in trials of [Gilead Sciences, Inc.](#)'s Veklury (remdesivir). (Also see "[#ClinicalTrialsSoWhite: How Drug Makers Are Using COVID-19 To Improve Trial Diversity](#)" - *Scrip*, 16 Apr, 2021.)

Since that embarrassing revelation, many companies – Gilead included – have gone to great

lengths to improve trial diversity and publicize those efforts. For its part, BMS has found success with a variety of tactics.

Recognizing The Issue

At present, there are many barriers to ensuring there is a representative racial and ethnic mix in trials. According to BMS, these include study protocol designs with inclusion and exclusion criteria that may inadvertently eliminate underserved populations; insufficient diversity among staff and sponsors; unconscious bias and need for cultural sensitivity; mistrust in the health care system due to historical and ongoing challenges with access and equitability; need for increased education and awareness of trials; and trial sites not being readily accessible.

Kuri's interest in trial diversity began when she was working on the commercial side of the industry in Latin America for other large pharma companies. There, regulators would often respond to drug approval applications by demanding data more representative of their own populations.

"Because of being exposed to the impact that not having enough clinical diversity has in the lives of patients around the world, I decided to pivot my career three years ago," she said. "I wanted to do something [and] when I saw that BMS was serious about it, I merged my purpose and my passion."

Breast Cancer Trial Enrollment Illustrates Diversity Challenge

By [Alaric DeArment](#)

19 Aug 2021 INFOGRAPHIC: Data on industry-sponsored breast cancer studies posted on ClinicalTrials.gov shows how much work remains for drug makers to ensure their studies enroll diverse populations. [Read the full article here](#)

In her position with BMS, Kuri reports to the clinical trials engagement and enrollment team and works with research sites and then studies themselves at the study-specific level.

"I've been working for the past two years to assure that I engage with internal and external stakeholders within the clinical operations and R&D areas, as well as some other enabling areas like the patients, the focus groups, specific study teams, business insights and analytics, the [People & Business Resource Groups] themselves, corporate communications and many others to assure that we build the processes to make this effort sustainable."

BMS created the People & Business Resource Groups (PBRGs) as internal advisors on diversity and inclusion efforts related to business initiatives. They report directly to members of the company's leadership team.

BMS noted to *Scrip* that PBRGs are analogous to employee resource groups in other companies

and provide input into all clinical trial patient materials; their feedback is meant to ensure materials are culturally competent and relevant to patients. The company said that since BMS created the PBRG Advisory Committee in early 2020, it has provided input and feedback in more than 25 interventions, including recruitment materials, conference content and communication brochures.

Site Selection A Critical Component

An example of where BMS has focused its clinical trial diversity efforts is prostate cancer, where numerous studies are underway testing its approved checkpoint inhibitors, the PD-1 inhibitor Opdivo (nivolumab) and the CTLA-4 inhibitor Yervoy (ipilimumab). (Also see "[BMS Sighs In Relief As Opdivo Returns To Sales Growth](#)" - Scrip, 28 Jul, 2021.)

Kuri pointed out that prostate cancer affects Black patients at a higher rate than white patients, with about a 60% higher incidence. Yet, she said, participation in prostate cancer clinical trials among Black patients is about 4%. In response, BMS has done outreach in African-American communities, reaching out to organizations like fraternities, barber shops and churches, while also factoring in Black enrollment through its site selection and investigator relationships and ensuring cultural sensitivity in materials it sends out. In doing so, it has managed to increase Black participation in prostate cancer studies to 17%. *[Editor's note: This article has been updated to note that Black participation in BMS's prostate cancer studies is 17%, not 7%-10%.]*

"That's something that we're willing to continue and to increase because we know that there's more, for us, to be done," Kuri said.

Traditionally, cancer studies have often focused primarily on large academic cancer centers, which tend to be located in big cities: think Memorial Sloan Kettering Cancer Center in New York, The University of Texas MD Anderson Cancer Center in Houston or the Fred Hutchinson Cancer Research Center in Seattle.

To be sure, that will likely be the case for most sponsors and most oncology studies for the foreseeable future. But BMS also seeks to ensure that 25% of US clinical trial sites are in highly diverse communities, Kuri said.

"We are building an entire ecosystem beyond that, to ensure that the patients that walk through those doors are diverse and reflective of the real world and aligned with that community," she said.

That also means using population data. The company has established a threshold whereby at least 30% of the population where sites are located is non-white, based on Census data.

Other companies have used similar methods to use site selection to improve diversity, even

employing technology like artificial intelligence and machine learning, as Johnson & Johnson did when it was developing its COVID-19 vaccine, using AI/ML to predict where outbreaks would happen and where it could ensure greater diversity in studies. (Also see "[*Real-World Data, AI Play Key Roles In COVID-19 Vaccine Programs*](#)" - Scrip, 11 Nov, 2020.)

Much of the process of ensuring trial diversity consists of working with internal teams, as well as unlearning and relearning things and amending and changing internal processes, Kuri said. That means being comfortable with a lot of ambiguity and challenges. Overall, it's a continuous process, but one where she hopes to see a finish line.

"I hope that roles like mine are no longer needed," Kuri said. "Of course, I always want to work, but hopefully we can think about clinical trial diversity as an industry, from design, and not as an afterthought or not only during a pandemic."