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Novartis Looks To Take Its Diversity Show On The Road

Company In Early Stages Of International Expansion

by [Alaric DeArment](#)

Head of clinical trial diversity and inclusion Kim Fookes spoke with *Scrip* about Novartis's US trial diversity initiatives and early plans to expand them abroad.

Kim Fookes is only about a month into her role as global head of diversity and inclusion in clinical trials at [Novartis AG](#), but her work to help improve clinical trial diversity – especially in the US – predates that by several months, and the company has been making efforts in that regard for multiple years. Now, Novartis is looking to take some of the lessons it has learned in the US abroad as well.

Fookes has worked for Novartis for two and a half years, joining in April 2019 from [AbbVie Inc.](#), and has been leading trial monitoring for the US region; the company appointed her to the diversity and inclusion role in August.

“One of the first introductions I had when I was joining Novartis was with someone who told me they had a grassroots effort already in place in the US to help enhance diversity in our clinical trials, so that piqued my interest,” Fookes told *Scrip*, adding that her previous employers had not initiated such efforts when she was there.

But as with many diversity executives at many drug companies, it was the COVID-19 pandemic that highlighted the issue for her. (Also see "[How BMS Is Tackling Clinical Trial Diversity](#)" - *Scrip*, 20 Aug, 2021.)

“My deeper involvement came last year, with many issues coming to a head around disease

burden, access to care, civil rights in the US – all highlighting these health inequities within the US,” she said.

As head of the trial monitoring group, she joined a taskforce to establish a comprehensive strategy to enhance diversity in trials, which delivered the strategy in October 2020 and since then has been further developing and implementing it, starting in the US.

For all her experience in trial management, Fookes said trial diversity has been an educational experience for her as well. For example, it highlighted the disparities in breast cancer deaths between Black and Caucasian women. (Also see "[Breast Cancer Trial Enrollment Illustrates Diversity Challenge](#)" - Scrip, 19 Aug, 2021.)

“If you’ve been involved in clinical trials for a long time in your career, I think there’s some biases to overcome – including my own,” she said. “I needed to realize what I knew of the clinical research world when I started hearing some of the statistics shared last year and since – I realized I didn’t know as much about the clinical research world [as] I thought.”

Devising Strategies

The strategizing on trial diversity was timely not only because of the pandemic, but also because of the 2020 US Census.

“What I realized as a member of the taskforce, and it became one of our strategies, is that we really needed to leverage the data and digital that we had already,” Fookes said.

That meant using data from the census or from third parties to provide information on the diversity of the patient population of a particular indication, as some diseases are two to three times more likely to occur in those populations.

“Because of that, we need to target those populations and make sure we’re enrolling them in our trials,” she said.

The effort, as it turns out, has been more multifaceted and complex than a simple commitment to enroll more diverse populations. Rather, it has involved a comprehensive effort at multiple levels of each trial.

Novartis works both with its portfolio teams – which it calls global teams – but also works first with country teams, particularly for the US, as their job is to find the right sites, work with community groups and engage communities.

In order to make trial diversity more transparent, the company’s enrollment dashboards show not just overall enrollment, but also enrollment in subpopulations, “so that it’s very evident

what we're aiming to enroll in terms of either Hispanics, Latinos, females, African-Americans – any of the subpopulations that we're trying to enroll, so that it's visible to the entire organization what our targets are, including the subtargets," Fookes said.

There is also a system that allows the company to monitor enrollment in real time as it is occurring so that it can monitor progress against targets and make changes as needed before it is too late.

In addition, every study team must create a diversity plan targeted to the population it is trying to recruit. There is also a toolkit that involves patient-facing videos and brochures.

Community Outreach

Toolkits are also available for external use by sites that already exist in communities but may not know how to engage the community around them.

"We've been able to partner with some external people who are doing a great job engaging their diverse community and being able to share those practices across the US," she said.

In that kind of engagement, Novartis goes in for the long haul to avoid the perception that it will take what it needs and then leave, Fookes said, adding that her team has heard of such cases happening with other companies before.

"We really want to support a long-term effort within those communities," she said.

To that end, the company's philanthropic arm, the Novartis US Foundation, announced in July a 10-year partnership with 27 historically Black colleges, universities and medical schools (HBCUs), along with Coursera, the National Medical Association and the Thurgood Marshall College Fund. The initiative includes an investment of \$13.7m to establish three digitally enabled research centers at the Morehouse School of Medicine. These include a clinical trial center of excellence that could serve as a model for expanding to other HBCU medical schools, with the aim of increasing diversity among trial investigators and participants. Another \$20m, in partnership with the Thurgood Marshall College Fund, will go toward the education of up to 1,200 Black and African American students.

Plans To Expand Abroad

Efforts to improve clinical trial diversity are about both addressing a key aspect of inequity in health care and also about good science, given that differences in genetics as well as social determinants of health can be critical to understanding differences in drugs' efficacy and safety across populations or when programming the artificial intelligence algorithms increasingly used in drug discovery and development. (Also see "[Clinical Trial Diversity Efforts Look Beyond COVID-19](#)" - Scrip, 24 Jun, 2021.)

While the US has been ground zero for many companies' trial diversity initiatives, the issue naturally affects other nations as well. Many of the inequities that affect Black people, Native Americans and Latinos in the US have analogues, for example, among Roma in Europe, Indigenous Australians or immigrants in Canada.

"We conduct research in about 70 countries, and we were intentional with our first year ... with the strategy focusing on the US for many reasons, but we have already done an analysis to decide other countries that we want to look at," she said.

The plans are still in the earliest stages – Fookes said the company has just started to discuss expanding in the last month – and the exact plans are still unclear, but Novartis is considering actions in Canada, the UK, France and Brazil. "Similarly, we have found that they have diverse populations and have been growing more diverse over the last few years," she said.

The next step is to engage with people in those countries, share with them what the company has been doing in the US, discuss their own barriers and challenges and see if some of the strategies it has used can apply there as well.