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Amgen VP Encouraged By Initial Clinical Trial Diversity Efforts

Progress Also Made In Diversifying Management

by Mandy Jackson

Ponda Motsepe-Ditshego, who leads Amgen's clinical trial diversity efforts, admits they are in early stages but noted progress internally and externally at better representing diverse patient groups.

Amgen, Inc. vice president Ponda Motsepe-Ditshego was a general practitioner in South Africa before moving on to work for biopharmaceutical companies in Africa, Europe and North America, so she has firsthand experience with bias in health care systems and mistrust of the medical establishment that keeps some people from participating in clinical trials. And while bias and mistrust are big hurdles, Motsepe-Ditshego said she is encouraged by progress occurring at Amgen and other companies trying to recruit more diversify populations in their trials.

In addition to her role as global medical affairs therapeutic area head for the company's general medicine portfolio, Motsepe-Ditshego is global chair of the Amgen Black Employee Network (ABEN) and leads Representation in Clinical Research (RISE), the company's effort launched in 2020 to increase the diversity of patients enrolling in its clinical trials.

"This is not going to change overnight," she said. "This is a journey ... and it will take a village and it will take time. What encourages me is what I see when I look at the industry right now. We're all pulling in the same direction, which is wonderful to see. It's very exciting. Everybody recognizes this is top of mind and very, very important. And we're all committed – whether it's through BIO, whether it's through PhRMA or TransCelerate."

Industry has taken steps toward improving trial diversity, together and as individual companies. (Also see "[Q&A: BIO CEO Michelle McMurry-Heath Outlines Diversity Goals](#)" - Scrip, 10 Aug, 2020.) BIO and PhRMA, in addition to offering guidance on improving clinical trial diversity, have

provided input to the US Food and Drug Administration as it outlines policy proposals and they have surveyed their members to assess the efforts that companies have made independently.

(Also see "[Has There Been A Sea Change In Trial Diversity Efforts?](#)" - Scrip, 12 Jan, 2022.)

- [How CRA's Diverse Seed-Planting Bore Inclusive Fruit](#)
- [How Janssen/HealthiVibe's Program Found The Right Messages To Improve Trial Diversity](#)
- [How Little Moderna Made Big Waves In Trial Diversity](#)
- [For Novavax, Building Trust Was Key To Improving Diversity](#)

FDA Draft Guidance Calls For Trial Diversity Plans

By [Alaric DeArment](#)

14 Apr 2022 Many companies have been signaling their commitment to diversity and inclusion in trials, but the new draft guidance spells out how they should address it and what the FDA wants to see. [Read the full article here](#)

Amgen's focus on diversifying its clinical trial enrollment began in 2016 with ABEN, whose members came together to produce a white paper on the issue. "It's a story about the power of an ERG, an employee resource group," Motsepe-Ditshego said. "It's also the beauty of a group of like-minded people who are passionate about something that needs to be done."

After she joined ABEN and eventually brought the idea for RISE to Amgen's upper management, Motsepe-Ditshego said she had immediate buy-in from upper management, including CEO Robert Bradway, chief medical officer Darryl Steep, senior vice president of global development Rob Lenz and executive vice president of research and development David Reese.

"I remember going to Dave to say 'Hey, this is something I'd like to lead and focus on under ABEN. This is something that I think is important. I'd like to have a dedicated team so we can really start moving the needle,'" Motsepe-Ditshego said. "And he said, 'You're giving me a five-year strategy. Can you do it in three?'"

She noted that it was important to have strong support for RISE all the way to the top of Amgen's management team, including Reese, who considers it "mission critical work."

RISE Team Focuses On Trial Design, Prevalent Diseases

"Today, we have a dedicated team and our idea is to make sure that we ensure full representation across all our clinical trials," Motsepe-Ditshego said. "We want to ensure that the studies that we

conduct across [therapeutic areas (TAs)] here at Amgen include people who've been historically excluded and that we're treating those conditions where they are mainly affected and making sure that they are part of the research work that happens.”

As RISE thought about its three-year strategy, Amgen’s clinical trial diversity group focused on specific pillars, including clinical trial designs that might impact this underrepresented communities, particularly in diseases more prevalent in Black and Hispanic populations, such as cardiovascular disease and diabetes, asthma and systemic lupus erythematosus (SLE), and multiple myeloma.

“We're very much looking at our portfolio, what's currently there, but more importantly in our pipeline, and trying to ensure that the programs that we impact are those programs that have conditions where there's higher unmet need and higher prevalence,” Motsepe-Ditshego explained.

Within the company’s mid-stage pipeline, the RISE team is looking closely at the clinical trial program for olpasiran, a short interfering RNA (siRNA) therapeutic targeting lipoprotein(a), also known as Lp(a), for the treatment of atherosclerotic cardiovascular disease (ASCVD) in people with elevated levels of Lp(a). Olpasiran reduced the genetic marker of greater risk for ASCVD complications by up to 90% in a Phase II trial and Amgen is preparing to launch a Phase III program for the drug. (Also see "[Amgen To Rapidly Move Olpasiran Into Phase III For Lp\(a\) Reduction](#)" - Scrip, 31 May, 2022.)

Motsepe-Ditshego noted that the presence of Lp(a) is more common in women and Asian patients, and appears to be particularly prevalent in black women. “We want to critically study and understand what that scientific rationale is and, in order to do that, we're looking at ways that we can partner to ensure that we know what's happening with Lp(a) because we know that this is a driver to increase ASCVD,” she said.

Partnering With Trial Sites, Working In Communities Of Color

Another pillar important to the RISE team’s work, in addition to clinical trial design, is partnering with the right trial sites and investigators that can recruit diverse populations and create new benches of investigators. A third pillar is listening to the needs and concerns of doctors and patients working and living in diverse communities. To date, Amgen has had community advisory board meetings with doctors and patients in Black, Hispanic and Native American communities.

“It was really inspiring and I think a lot of this stuff is what we know – the mistrust based on historic [treatment], but there's also a lack of education,” Motsepe-Ditshego said. “There's also issues that came up around health literacy in the way we talk about the trials, the way the informed consents are written, and so all of those insights we're going to put together and start

framing what we call our ‘community engagement plans.’ We will now start going into the community so we can ensure that we’re bringing the trials to them and not always expecting them to come to us for the trials.”

In asthma, Amgen Inc. recently committed \$1m to the Asthma and Allergy Foundation of America (AAFA) for the organization’s Health Equity Advancement and Leadership (HEAL) program, which is focused on building and supporting community-based interventions as a means to address treatment inequities in asthma.

Amgen, whose asthma biologic Tezspire (tezepelumab) was approved late last year for patients regardless of their eosinophil levels, is supporting the HEAL program to understand the social determinants of health that become barriers to accessing appropriate care for severe asthma in Black communities, Motsepe-Ditshego said. (Also see "[Amgen Expects Quick, Broad Adoption Of Tezspire In Severe Asthma](#)" - Scrip, 20 Dec, 2021.)

Addressing Diversity Inside Amgen

Amgen also is working on improving diversity and inclusion within the company itself, starting with outreach to school-age children through participation in science education programs and grants to organizations that encourage children and young adults to become interested in science and related careers. Inside Amgen, the company has made sure to consider diverse candidates when making new hires and provided mentorship and other opportunities to help women and minority employees advance into leadership roles.

Motsepe-Ditshego noted that children, especially girls, should be exposed to science and potential careers in the field early in their education so that they know from a young age what it is possible for them in the future. She benefitted from teachers who encouraged her interest in science and mentors who encouraged her career in medicine, and at Amgen has benefitted from mentorship via the company’s Women Empowered to Be Exceptional (WE2) program.

Motsepe-Ditshego has shared her enthusiasm for science and medicine with students as well through speaking engagements at schools, including through the Amgen Biotech Experience, an Amgen Foundation-backed science education program for classrooms.

Amgen’s latest Environmental, Social and Governance (ESG) report shows that it still is working toward parity. While 52% of the company’s employees are women, only 49% at the management level and 44% at the executive level are women. And while 51% of employees in the US and Puerto Rico are ethnic minorities, just 44% of managers and 32% of executives are minorities. Also, only 4% of Amgen’s employees in the US and Puerto Rico are Black versus 20% who are Asian and 25% who are Hispanic.

“If you look at the increase of women in management positions, it’s been substantial, I think

even in the last two or three years,” Motsepe-Ditshego said. “We were looking from an ABEN perspective at how many promotions happened [and] we had a 200% increase in Blacks to become VP.”

Both at Amgen and outside of the company, she noted that there has been progress in increasing the numbers of women and minorities in science, but there is room for improvement in biopharma’s executive ranks. “The challenge is where the progress is seen,” she said. “I think the challenge is when it comes to leadership positions or senior leadership roles. That probably is not as big as just the increase of women in general.”