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Be a champion for clinical trial diversity

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By: Jonca Bull, M.D.

The FDA is launching a campaign to encourage minorities to participate in clinical trials for all medical conditions.

The first part of the campaign will be launched on June 19, 2016, World Sickle Cell Day, observed annually to help increase public knowledge and raise awareness of Sickle Cell Disease, which primarily affects people of African and Hispanic descent. We want to encourage diverse communities to learn more about how they can become a part of the research process to bring new therapies to the market.

Clinical trials are a critical step in making new medical products available. Medical products—from vaccines to drugs for blood pressure or diabetes management — are tested in clinical trials.

Although FDA generally does not conduct clinical trials, we do the critical work in reviewing the data to assess the safety and efficacy of medical products before they can be used in medical practice. None of this is possible without clinical trials and the patients who go the extra mile by being research participants.

In order to help ensure that medical products are safe for everyone, we need a diverse pool of research participants—racial and ethnic minorities, women, even the elderly.

We know that certain diseases impact some populations differently. For example, diabetes occurs more frequently in blacks and Hispanics, high blood pressure and heart failure occurs more frequently and severely in blacks; and, Asian American communities experience more hepatitis B.

Clinical trials participants need to more closely mirror the patients who will ultimately use the medicine. This is especially important when considering health disparities — diseases that occur more frequently or appear differently in non-white populations. But most clinical trials participants are white and male. That means we may miss vital data that could be used to be make better evidence-based, regulatory decisions. If we do not develop a more diverse pool of research participants, health disparities may persist because we will not know if a medical product is safe and effective in the actual population that will ultimately use it.

And that’s why we’re launching our campaign, which includes a series of educational aids such as videos, a blog, and an infographic. In these videos Shirley Miller, who lives with sickle cell disease, talks about her experience participating in clinical trials and encourages her peers to learn more about research studies.

In another video Dr. Luciana Borio, FDA’s Acting Chief Scientist, discusses why clinical trial diversity matters from FDA’s perspective.

This campaign is taking us one step closer to a world where health equity is a reality for all. It supports FDA’s initiative: “The Year of Clinical Trial Diversity.”

It is a part of our larger effort to improve clinical trials diversity — we also work with stakeholder groups, support research, develop multi-lingual resources, and use social media to promote a community of “Clinical Trials Champions.”

Everyone has a stake in the game —health care providers, researchers, and patients. Share these videos and other materials. Start a conversation today.More information about this campaign and FDA’s OMH can be found here: www.fda.gov/minorityhealth

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Dr. Jonca Bull is FDA's Assistant Commissioner for Minority Health, Office of Minority Health

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