

Vaccine Trials and the Black Community

According to the [November 26, 2020](#) New England Journal of Medicine, recent data show that although Black people make up 13% of the U.S. population, they account for 21% of deaths from Covid-19 but only 3% of enrollees in vaccine trials. This problem threatens both the validity and the generalizability of the trial results and is of particular concern in vaccine trials, in which differences in lifetime environmental exposures can result in differences in immunologic responses that could affect both safety and efficacy.

Although they are multiple, a critical factor is the deep and justified lack of trust that many Black Americans have for the health care system in general and clinical research in particular. **The distrust is deeply rooted in centuries of well-documented examples of racist exploitation by American physicians and researchers.**²

We fear that once again the responsibility for addressing the sequelae of centuries of racism is falling on Black people themselves. Our country has yet to comprehend adequately that overcoming racism is not primarily the responsibility of Black people; the racist ideas and practices that constitute today's "structural racism" were created, and have been sustained, primarily by White people. It would be wrong, as well as ineffective, to ask Black communities to simply be more trusting. Clinicians, investigators, and pharmaceutical companies must provide convincing evidence — sufficient to overcome the extensive historical evidence to the contrary — that they are, in fact, trustworthy.

What can we do to earn and deserve increased trust?

First, trial sponsors and regulatory agencies can ensure that the **informed-consent process** is exemplary, including ensuring that all relevant aspects of the design and conduct of the clinical trials are maximally transparent.

Second, politicization of the vaccine trials has engendered widespread mistrust among the general public. The joint pledge by nine pharmaceutical companies that they will “stand with science” and not submit a vaccine for approval until it has been thoroughly vetted for safety and efficacy is welcome, but earning trust will require credible evidence that this pledge is being honored.

Third, to earn and deserve trust from prospective trial participants, we must ensure that they will receive appropriate medical care if they are injured as a result of receiving an experimental vaccine. One way to demonstrate trustworthiness would be for the pharmaceutical companies sponsoring these trials to establish a fund to guarantee health care coverage and death benefits to patients and families as compensation for serious vaccine injuries or possible deaths.

With Covid-19 vaccines, their success in Black and other communities will depend on whether members of these communities not only trust that they are safe and effective, but also believe that the organizations offering them are trustworthy. **Trust could be earned more quickly by a collaboratively designed Operation Build Trustworthiness that matches the seriousness and scope of Operation Warp Speed.** To be effective, this effort would need to be firmly grounded in grassroots involvement of individuals and organizations with solid, **well-earned reputations** for trustworthiness in Black and other minority community

advocates, communication will be essential. Time is running short, and **TRUSTWORTHINESS, NOT TRUST**, must be our first and most urgent priority.