



Multicultural Health Equity Collective



WHITE PAPER

EQUITY IN ACTION:

The Impact of Community Engagement
on Diversity in a COVID-19 Clinical Trial

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Abstract

COVID-19 provided a real-time experience and look into the social determinants of health, our public healthcare system, how healthcare disparities can affect our whole society, and the critical need to remedy underrepresentation of diverse communities in clinical trials. The disproportionate impact of COVID-19 on people of color created an urgency for racial and ethnic representation in the COVID-19 clinical trials. As we get more control over the COVID-19 pandemic, increasing diversity in clinical trials remains an urgent issue to help close healthcare gaps, eliminate disparities in the prevalence and treatment of other diseases, and strengthen the clinical data used by healthcare professionals to determine the best treatment programs for their patients.

Yet, many challenges remain to increasing diversity in clinical trials, including medical mistrust. This paper expounds on the importance of community involvement to help overcome this issue and explores community engagement approaches that were taken by Pfizer to help increase diversity among participants in the Pfizer-BioNTech clinical trial for the COVID-19 vaccine. Important elements of Pfizer's approach to community engagement were flexible and collaborative Pfizer leadership, involvement of long-term multicultural partners, regular and ongoing communications with community stakeholders, information transparency, culturally competent and relevant educational materials, mutual respect, and partnership development.

Community involvement in clinical trials to help build trust, educate the public, raise awareness and help design clinical trial protocols to make them more accessible has been recommended by previous studies on clinical trial diversity and is supported by recent guidance issued by the FDA to enhancing the diversity of clinical trial populations. Respect and engagement of community leaders in the clinical trial process can help drive successful outreach and educational efforts on clinical trials in diverse communities. Through early engagement, and sustained, intentional efforts, it's possible to achieve success in diversifying clinical trials.

The successful results of community engagement efforts for the Pfizer-BioNTech COVID-19 clinical trial opened many possibilities for different approaches to achieve clinical trial diversity. Pfizer was receptive to these ideas and has begun efforts that may lead to long term systemic change. It is evident from feedback received from Pfizer partners involved with the COVID-19 clinical trial efforts that Pfizer's partnerships with diverse multicultural organizations remain fertile ground for innovative solutions.

The Urgency of Clinical Trial Diversity

COVID-19 provided a real-time experience and look into the social determinants of health, our public healthcare system, how healthcare disparities can affect our whole society, and the critical need to remedy underrepresentation of diverse communities in clinical trials.

As the virus spread throughout the U.S. and data was compiled on the effects of the novel coronavirus on the population, we learned that communities of color were being affected the most. According to the COVID Racial Data Tracker, in cases where race was known, infection rates among people of color were 2.5 times higher and deaths were 1.7 times higher than in white people in 2020. Early data indicated that while making up 13% of the population, Black people were 24% of US COVID-19 deaths, dying at over two times the rate of White people. As reported in May 2020, Latinx and Indigenous communities were suffering higher incidence rates of COVID-19 infection than what would be expected for their share of the population – Latinos were infected two to four times higher depending on their state residence and in New Mexico, Native American communities accounted for 60% of cases but only 9% of the population.

The disproportionate impact of COVID-19 on people of color created an urgency for racial and ethnic diversity in the COVID-19 vaccine clinical trials. Doing so would help ensure that we understood the safety and efficacy across populations and could also

increase confidence in getting the vaccine among people of color, who also have a history of lower vaccination rates overall. If we were to be successful in stopping the spread of the novel coronavirus and reaching herd immunity we would need to have people from all communities, especially those most affected, to get vaccinated.

As we get more control over the COVID-19 pandemic, increasing diversity in clinical trials remains an urgent issue to help close healthcare gaps and eliminate disparities in the prevalence and treatment of other diseases. The consequences of not having diversity in clinical trials are serious. Drugs and vaccines can affect groups of people differently due to various causes, sometimes due to underlying experiences and environmental exposure as well as genetic variants. A lack of representation of these differences weakens the clinical data used by healthcare professionals to determine the best treatment programs for their patients and prevents trial investigators from learning more about the product being studied.



The Challenge of Diversifying Clinical Trials

Overview of Participation Rates of Racial and Ethnic Groups and Data Gaps

The lack of adequate representation of diverse communities in clinical trials is well documented in historical reports on the issue and recent data collection by the Food and Drug Administration (FDA). Despite existing legislation that mandates the inclusion of women and members of minority groups in all NIH funded research, participation rates by members of racial and ethnic groups have historically been low. Almost three decades since the passing of the NIH Revitalization Act in 1993, these groups remain underrepresented in clinical trials today.

The most recent data from the FDA in the 2020 Drug Trials Snapshots Summary Report details demographic participation rates in clinical trials for the 53 new drugs approved that year. Study participants remain predominantly White (75%) and though Hispanics/Latinos are 19% of the U.S. population and Blacks/African Americans constitute 13% of the population, they represented 11% and 8% respectively of the total clinical trial participants. Asians who are 6% of the US population, were equitably represented at 6% of total study participants.

Additionally, demographic data collection on clinical trial participation has historically been lacking. In a 2021 report published by JAMA Network Open, a team of examiners found that out of a total of 230 US-based vaccine trials with 219,555 total participants and representing all trial phases, only 58.3% reported race and a mere 34.3% reported ethnicity. Among adult study participants, White individuals were overrepresented (77.9%), Black/African Americans and American Indian or Alaska Native individuals

were underrepresented at 10.6% and 0.4%, respectively, while enrollment of Asian individuals was similar at 5.7%. Although there was limited reporting on ethnicity, the enrollment of Hispanic/Latinos was also low at 11.6%.

Similarly, clinical trials studying the efficacy and safety of cancer treatments are equally challenged and faulty. According to the American Society of Clinical Oncology (ASCO), an estimate of 1% of registered cancer clinical trials that are primarily directed toward racial and ethnic minority populations, and approximately 33% of cancer trials report race and ethnicity in trial results. Relying on the information available overall, 76.8% of cancer clinical trial participants are White, Blacks/African Americans constitute 7.3% and "Others" are 15.9%.

To address this gap in knowledge, Pfizer recently conducted and published a study of the demographic diversity of participants in Pfizer-sponsored clinical trials in the United States, including 213 trials that began enrollment of 103,103 participants between 2011 and 2020. The intent of the study, which looked at race, ethnicity, sex, and age, was to establish a baseline of diversity in Pfizer's clinical trials. The data revealed several differences in racial and ethnic participation, which Pfizer will use as a reference to help improve diversity across its clinical trials in the future.

Previously, no or extremely limited information has been reported by biopharmaceutical companies about clinical trial diversity. Pfizer wanted to better understand our own clinical trials through an equity lens and recently conducted a rigorous, in-depth analysis of demographics in our US clinical trials initiated between 2011 and 2020. It included 213 trials conducted in all five of our therapeutic areas: Internal Medicine, Inflammation & Immunology, Oncology, Rare Disease and Vaccines, along with our legacy Neuroscience portfolio. The analysis was published in July 2021 issue of Contemporary Clinical Trials.

The analysis demonstrated:

- Overall, Black and African American individuals participated in Pfizer trials at a similar rate to the US census level (14.3% vs 13.4%), Hispanic or Latino individuals participated at a rate below US census (15.9% vs 18.5%), women



participated at a rate similar to US census (51.1% vs 50.8%) and men participated at a rate similar to US census (48.9% vs. 49.2%).

- We also examined the percentage of trials that achieved racial and ethnic distribution levels at or above US census levels. Participant levels above census were achieved in 56.1% of Pfizer trials for Black or African American participants, 51.4% of trials for White participants, 16.0% of trials for Asian participants, 14.2% of trials for Native Hawaiian and Pacific Islander participants, 8.5% of trials for American Indian and Alaska Native participants, and 52.3% of trials for Hispanic or Latino participants.
- We noted differences in racial and ethnic participation across different trial types. For instance, vaccine trials had a lower percentage of Black or African American and Hispanic or Latino participants, and a higher percentage of Asian, White, and Non-Hispanic White participants compared with clinical pharmacology or therapeutic trials.
- Clinical pharmacology trials compared with therapeutic trials had higher percentages of Black or African American (37.2% vs 17.0%) and Hispanic or Latino (45.7% vs. 20.1%) participants. Conversely, therapeutic trials had a larger percentage of White participants compared with clinical pharmacology trials.
- We also observed differences in racial and ethnic participation across therapeutic trial types. For example, over 60% of trials in Cardiology, Hematology, Endocrinology and Nephrology had representation above census levels of Black or African American and Hispanic or Latino populations. However, there was underrepresentation of Black or African American and Hispanic or Latino populations in Oncology trials.

Clearly, we have room for improvement. But we wouldn't have known the areas to focus on without this baseline of understanding. This is an industry first and Pfizer is proud to lead the way. These data

were published to be transparent about the company's baseline, so progress can be tracked as we work to improve diversity in clinical trials.

Why Diversity in Clinical Trials Matters

Researchers and sponsors of research recognize that diversity in clinical trials matters – there are numerous studies and opinion pieces from industry leaders on the topic that point to valid reasons as to why. Ultimately, diverse clinical trials result in data that can be more “generalizable” to a broader population, lead to more informed decisions about safety, efficacy, and labeling by regulatory bodies such as the FDA, and improve the ability of patients, caregivers, and healthcare providers to make more informed decisions about their treatment options.

Federal regulations have encouraged diversification in clinical trials for decades and progress has been made over the years, nonetheless, experts note that greater efforts and improvement are necessary to correct the underrepresentation of many groups. For instance, heart disease is the leading cause of death for American women, yet in the U.S., women are underrepresented in studies for treatments for heart failure, coronary artery disease, and similar problems. Similarly, as noted earlier in this paper, people of color are underrepresented in cancer and vaccine clinical trials. Research from March 2019 also revealed a lack of diversity among cell lines used for laboratory studies for prostate, breast, and cervical cancer. All of these subgroups are generally marginalized in clinical research.

In addition to the rationale behind evidence-based science, ethically, health equity demands that more attention be placed on increasing diversity of clinical trials. In her 2004 Op-Ed for the *Virtual Monitor* entitled “Does Evidence-Based Medicine Offer Fair Benefits for All?,” Wendy Rogers, PhD, FRCAGP, notes that “Part of the appeal of evidence-based medicine (EBM) lies in its perceived fairness. EBM seems to offer the promise of consistent and

impartial evidence about the benefits and harms of treatments due to the transparent use of high quality primary research in systematic reviews and meta-analyses.” However, how is it just if some groups are consistently excluded from primary research? Rogers also notes that, “Patients who have high levels of need and illnesses for which there is little or no evidence about effective treatments may lose out to those with better-researched diseases.”

Researchers have long recognized the need for more heterogeneity in clinical trials and our experience with COVID-19 has placed more emphasis on this demand. There is a need for research evidence that applies to subgroups of ethnic and racial populations, women, the elderly, those with multiple co-morbidities, and other underserved groups. The recent guidance from the FDA acknowledges current inequities in research participation and encourages research sponsors to redesign research protocols and processes to remove barriers to participation by underserved populations. Researchers can also help to increase opportunities for participation.

Pfizer has made a commitment to achieving racially and ethnically diverse participation at or above US census or disease prevalence levels (as appropriate) in all of our US trials, and is taking decisive steps towards meeting this goal.

To be successful in these areas, it is necessary to understand and address the underlying causes of clinical trial disparities.

The Issue of Medical Mistrust

In study after study and in the opinion of experts that have reviewed the factors that contribute to lack of participation of racial and ethnic populations in clinical trials, the issue of medical mistrust is cited as a consequential barrier to increasing diversity in research. Historical events, current discrimination and biases, perceived stigma, and even mistrust of healthcare providers directly cannot only prevent patients from participating in clinical trials, but also prevent them from seeking the care they need or from receiving proper treatment when they do seek care. , Overcoming this barrier is essential to increase diversity in clinical trials, properly care for patients, eliminate health disparities, and build an effective healthcare system.

A recent report by The Commonwealth Fund on

“Understanding and Ameliorating Medical Mistrust Among Black Americans,” notes research by Laura Bogart, Ph.D., and others that has found that “medical mistrust is not just related to past legacies of mistreatment, but also stems from people’s contemporary experiences of discrimination in healthcare – from inequities in access to health insurance, healthcare facilities, and treatments to institutional practices that make it more difficult for Black Americans to obtain care.” From a historical perspective, the Tuskegee syphilis study is widely cited as a reason for mistrust and is significant for its level of deception, the duration of the study, and the fact that it concluded in fairly modern times in the 1970’s. , However, the mistrust in clinical investigators generated by these historical abuses, is sustained today by racial and ethnic disparities in healthcare, a lack of cultural diversity and competence among physicians, and unequal treatment when it comes to medical care. ,

Approaches that have been recommended to address the general issue of mistrust in healthcare providers and the healthcare system can be applied to encourage increased diversity in clinical trials. These include 1) improving communications, 2) increasing transparency, 3) creating welcoming environments, and 4) eliminating access barriers.



Guidance on Clinical Trial Diversity and Community Engagement

The Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law on July 9, 2012, requires the FDA to investigate how well demographic subgroups (sex, age, race and ethnicity) are represented in clinical trials and if subgroup-specific safety and effectiveness data is available for all new drug applications. As also mandated by law, the FDA submitted the FDA Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data in August 2014, and set three priorities:

- **Quality** - Improve the Completeness and Quality of Demographic Subgroup Data
- **Participation** - Identify barriers to subgroup enrollment in clinical trials and employ strategies to encourage greater participation
- **Transparency** - Making demographic subgroup data more available and transparent

Since then, the FDA has been working with industry, sponsors, stakeholders, advocacy groups, and the public to advance work in these areas of responsibility.

After decades of work directed at helping to understand the barriers and improve diversity in clinical trials, in November 2020, the FDA issued Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry, providing more momentum to finally solve the issues and help achieve increased diversity. While the document does not establish legally enforceable responsibilities, it offers recommendations on critical issues that have been identified as barriers to participation in clinical trials.

As supported by previous studies and of note for the focus of this paper, under the section Adopt Enrollment and Retention Practices That Enhance Inclusiveness, the FDA recommends to “Consider fostering community engagement through medical societies, focus groups, community advisory boards, disease registries, and community-based participatory research, the latter of which promotes the design of clinical research with the assistance of community members and leaders to more effectively meet the needs of potential participants.” In addition, it recommends to “remain engaged with communities after the conclusion of the clinical research and

share trial updates to continue to strengthen bi-directional relationships with communities” as well as several other recommendations for community engagement as a means to help engender more trusting relationships with clinical trial participants.

The Goal of Community Engagement

Community engagement in clinical trials, especially as it relates to multicultural communities, can be described as the following:

- The involvement of patient advocates, community organizations, and trusted leaders across and throughout the continuum of the clinical trial process that supports mutual respect, strategies, and actions for authentic partnerships to address barriers to clinical trial participation.

The goal of community engagement in clinical trials or medical research is the development of “collaborative partnerships that can ultimately advance both science and patient care.” Research suggests that successful approaches to community-engaged research can:

- build trust between researchers and communities, encourage participation among under-represented groups, and
- enhance the relevance and uptake of research findings.

In 2018, as a result of a study on African American Community Engagement, Pfizer entered a partnership with the National Medical Association (NMA) and the National Black Nurses Association (NBNA) to help increase diversity in clinical trials. The study pointed to medical organizations that treat African Americans having esteemed positions to help drive change in health-seeking behaviors among African American patients. Such partnerships with trusted organizations in the community are key to help increase diversity in clinical trials.

A key value demonstrated by involving community in the clinical trial development and implementation process is respect. Engaging with and listening to trusted community voices recognizes the concerns, interests, and values of the communities that have been underrepresented in clinical trials. Allowing for this, shows an appreciation for clinical trial participants as people, not “guinea pigs,” and can help build trust among community members.

Pfizer's Approach to Community Engagement for the COVID-19 Vaccine Clinical Trial in the US

Invitation to Partners of the Multicultural Health Equity Collective: How Sustained Relationship Building Helped

Pfizer has a long history of working with multicultural partners to address healthcare disparities through various policy, education, access and Foundation initiatives. For over 30 years, Pfizer has been committed to providing patients with prescription assistance and connecting them to resources and programs to help them access their Pfizer medicines where, and when, they need them. Today, that assistance is provided through Pfizer RxPathways, which in various forms over the last 15 years has prioritized reaching and educating patients in communities with the highest rates of need through collaborations with trusted community partners. Historically, these outreach efforts have been with multicultural community partners, including Dia de la Mujer Latina, given the high rates of uninsured and underinsured people in these populations.

The Pfizer National Government Relations team has worked collectively with various internal partners to also support joint efforts with key multicultural healthcare influencers. For instance, Pfizer was a founding supporter of the National Hispanic Medical Association, established in 1994, and the National Medical Association's first Colloquium on African American Health in 1999. Additionally, Pfizer was a founding partner of the corporate roundtables for the National Black Caucus of State Legislators, the National Black Nurses Association, and National Association of Hispanic Nurses. These, as well as many other patient advocacy groups that Pfizer supports, share a commitment to working on important health access issues and to achieving health equity.

Having worked together to maximize multicultural partnership impact over many years, these two driving forces within Pfizer created a synergistic bond by formally launching the Multicultural Center of Excellence (MCoE) in 2014 and in 2021, announced a new name for the group – the Multicultural Health

Equity Collective – to align more specifically with Pfizer's overall value of equity. The Multicultural Health Equity Collective (The Collective) focuses on helping to improve health equity across ethnic groups and other underrepresented communities facing significant health disparities. It engages with Pfizer colleagues throughout the business and external partners to advance four objectives – diversity in clinical trials, disease awareness and education, access and advocacy, and solving for the social determinants of health.

The disparate impact of the COVID-19 pandemic on communities of color revealed a double pandemic of historical health inequities affecting US racial and ethnic communities. In its emergency response efforts to develop a COVID-19 vaccine, Pfizer was thrust to the center of this crisis and the Collective was there to help with a clarity of purpose and a force of sustained multicultural community partnerships that could be activated for the mission. Leaders of Pfizer's Corporate Affairs and Global Product Development teams worked closely together to convene members of The Collective via regular conference calls with 12 key organizational representatives to seek information regarding the impact of COVID-19 on diverse communities, listen to their concerns, answer questions regarding vaccine clinical trials, and request their assistance to educate their communities about Pfizer-BioNTech's COVID-19 clinical trial.

Pfizer Corporate Affairs also arranged one-on-one meetings with organizations that requested additional information or had interest in furthering their engagement with the diversity in clinical trials initiative. The cadence and method for engaging was possible due to the internal partnership with the vaccines COVID-19 clinical trial development team, which was also spearheading diversity initiatives with clinical trial sites, stressing the importance of diversity in the COVID-19 clinical trial, selecting sites that were in areas with diverse populations and high incidence of infection, and encouraging sites to engage with their communities. The collaborative approach and interactions of the Pfizer teams with representative community organizations helped to establish transparency and build on the foundation of trust with the partners that led to successful outcomes in diversifying the vaccine trial in the US.

The impact of these sustained partnerships over the course of time is best summarized by Mark Alexander, PhD, secretary of the National Executive Committee and Chair of the Health and Wellness Committee of the 100 Black Men of America, Inc.:

As engaged members of the Pfizer Multicultural Advisory Council (PMAC) prior to the pandemic, we learned of Pfizer's commitment to addressing the roots of race/ethnic health disparities in America – the social determinants of health. When the COVID pandemic struck, there was no reluctance by the 100 to support Pfizer's clinical trial

diversity efforts. Our established relationship with Pfizer allowed us to help assuage any suspicion of vaccine research/acceptance amongst our membership and in the communities that we serve.

Listening and Responding: Ongoing Communications

Once the community outreach was begun to help diversify Pfizer-BioNTech vaccine clinical trials, Pfizer committed to regular ongoing communications with engaged partners. Multicultural organizations that were involved included HCP professional organizations, national community leadership and mentoring groups, faith-based institutions, a community health worker training association, patient advocacy groups, and policymaker caucuses. All of the participating organizations had national influence, trust from their representative communities, and reach into various cities and local areas throughout the U.S.

The cross-functional Pfizer team that spearheaded the community engagement efforts included the co-leaders of The Collective, and the leads for clinical trials diversity, vaccine clinical development, and participant experience. With the participation of various team members, Pfizer held educational sessions with its community partners from the start of clinical trial enrollment continuing to date to provide truthful, real time information to the organizations, their members, and communities. These sessions were effective in engaging partners and building trust in the clinical trial process. As remarked by Millicent Gorham, executive director of the National Black Nurses Association:

Pfizer was consistent in keeping partners apprised of the need for clinical trial diversity. It made strategic alignments across all communities, emphasizing that diversity was key in its move towards health equity. Access to innovations and transparency are critical factors in terms of health equity and sustainable partnerships. It was also key to hear directly from and have discussions with the research team.

Another partner commented that “the presence of Black leadership within Pfizer who are committed to improving the lives of oppressed people” was a factor that contributed to the success of the initiative.

Pfizer colleagues who participated in this process

with community leaders identified the impact of support and flexibility from Pfizer leadership as a driving force leading to the success of the collaboration. Pfizer executives encouraged the cross-functional teamwork and allowed team members to pivot from regular responsibilities to prioritize the effort. This allowed for heightened receptivity to advice from participating partners and quick responses from colleagues to partners’ questions and concerns.

Development of Educational Materials

The adaptation of educational materials for community outreach to diverse audiences about the vaccine clinical trials was made possible from the insights shared by partners of The Collective. For instance, community representatives emphasized the importance of developing culturally appropriate messaging versus simple translation for Spanish-dominant Latinos, as well as using appropriate imagery on communication assets. Recommendations were also made on dissemination and distribution efforts of messaging and materials.

Pfizer’s nimbleness in responding, acting on, and investing in partner suggestions made a difference in community educational efforts. Venus Ginés, Founder and CEO of Dia de la Mujer Latina remarks:

Dia de la Mujer Latina (DML) has raised concern over the disparities in clinical trials and how “information and communication” were the two biggest barriers. Pfizer not only heard us but they invested in the education and training of Promotores/Community Health Workers, who are our trusted source of information and who are trained on how to communicate the message during Hotline Encounter Calls.

Pfizer also partnered with the National Newspaper Publishers Association to place advertorials in local periodicals that cater to the African American/Black community. Partners made recommendations regarding the best placements for this campaign. Additionally, spokespersons volunteered from among partner leadership to reach population subgroups via radio interviews to educate the public about the trials and encourage audiences to volunteer.

Information Transparency

Pfizer began sharing news about its COVID-19 vaccine clinical trials with partners of The Collective on July 1, 2020, upon the release of early positive data from the Phase 1/2 study of the mRNA-based vaccine by Pfizer and BioNTech. Two weeks later it extended an invitation to a select number



of partners to a briefing on the COVID-19 vaccine clinical trial and an information sharing session to gain insights and expert advice on Pfizer's next steps to mitigate barriers and improve opportunities for underrepresented communities to participate in the trial. The first meeting was held on July 17, 2020, and Pfizer immediately instigated a policy of information transparency, sharing critical information about the trial with its partners.

At each subsequent group meeting and at individual organizational meetings, Pfizer shared information about its clinical trial development efforts and its progress toward recruiting diverse clinical trial participants with organizational leaders and members. A significant next step happened ten days later when The Collective co-leads, Niesha Foster, Vice President of Product Access, Global Health and Social Impact, and Melissa Bishop-Murphy, Senior Director, National Government Relations and Multicultural Affairs, announced the beginning of enrollment for Phase 2/3 of the Pfizer-BioNTech clinical trial and shared a list of trial sites with organizational partners of The Collective. Of note, the Pfizer team had taken great strides to identify sites in close proximity to areas with a high prevalence of COVID-19 infection and with high-density multicultural populations.

An informational toolkit on clinical trials and the COVID-19 study was offered to anyone interested in sharing the information with their members and constituents. Members were invited to a special session to review the contents of the toolkit and provide insights for the development of creative and educational materials. These resources were then provided in English and Spanish along with the first progress report on the recruitment of racial and ethnic participants in the clinical trials. What followed were regular updates on this data and the development of bilingual PSA's that highlighted the impact of COVID-19 on Black and Latino communities and the need for people of color to participate in clinical

trials. The PSA campaign was supported by landing pages in English and Spanish and the materials were released to The Collective partners to help increase awareness and dissemination of the messages.

Throughout the process, Pfizer continually stated and reconfirmed its commitment to ensuring diversity in the Pfizer-BioNTech COVID-19 vaccine clinical trial and in September also affirmed its commitment to safety and the well-being of vaccinated individuals by announcing a historic pledge to this effect with eight other biopharmaceutical companies. A direct communication about the initiative was shared with multicultural partners and as data read-outs from the Phase 2/3 trial neared, a subsequent communication highlighted Pfizer's CEO Albert Bourla's reaffirmation of this commitment to safety and efficacy, as well as to manufacturing quality and consistency.

By November 2020, more frequent updates ensued as Pfizer prepared clinical trial data submissions for review and finally its request to the FDA for emergency authorization. Ongoing communications continued after the Pfizer-BioNTech-COVID-19 vaccine received authorization for emergency use and conversations shifted to addressing new studies on boosters, variants, and pregnant women, as well as on vaccine confidence. These regular communications and engagement efforts with partners made an impact. As Mr. Alexander shares:

For several years, we have advocated for the increased participation of Blacks in sound and trustworthy medical research. Engagement with Pfizer during the pandemic has strengthened our resolve to encourage members of our community to participate in clinical trials.

Partnership Development

In addition to group meetings, Pfizer met and responded to interests of separate organizations working with distinct communities to further develop partnerships and culturally effective educational and outreach strategies. A training

program for community health workers – promotores – was developed in partnership with Dia de la Mujer Latina to help mitigate misinformation in the Latino community; a series of webinars were held with community leaders in the African American community through the 100 Black Men of America and for Latinx physicians with the National Hispanic Medical Association; and information campaigns created and designed by several groups were supported. These projects developed deeper connections with certain organizations, generated stronger commitment to the cause, and signaled Pfizer's general concern for the well-being of the people that were most affected by COVID-19 beyond simply considering them as research subjects.

The partnerships with the core group of The Collective organizations were multi-pronged and provided various touchpoints to engage. One of The Collective's original objectives was to leverage partnerships with multicultural organizations throughout Pfizer's business units as they seemed relevant. The urgency surrounding the development of the COVID-19 vaccine and the prioritization of Pfizer's equity value were in alignment and created multiple opportunities for partners of The Collective across the company. These were internally shepherded by The Collective leadership and consequently helped to expand and further deepen partnerships with certain groups.

Results

From one internal partner's perspective, "just bringing the groups together to be heard made them willing partners in spreading the word about the clinical trial." We cannot understate the importance of that singular action. This engagement also "helped Pfizer colleagues understand that the source of answers for the community lies with the advocates that are steeped in community."

Overall, Pfizer's community engagement efforts helped spread the word about the Pfizer-BioNTech COVID-19 clinical trial to diverse communities and likely had an impact on the success of the trial with regards to diversity. Approximately 30% of US participants in the clinical trial were from diverse communities – 6% were Asian, 10% were Black/African American, 13% were Hispanic/Latinx, and 1.3% were Native American. The continuation of the partnerships that are now supporting vaccine confidence efforts may also be having an impact on vaccine uptake in the various racial and ethnic

communities. The continued partnerships, now deepened from the joint experience with the COVID-19 pandemic, comprise one of the biggest benefits to Pfizer from its community engagement efforts.

From the partner's perspective, the experience seemed to enhance their commitment to get more involved in supporting clinical trial diversity initiatives. In the case of Dia de la Mujer Latina, the two trainings that were developed for community health workers on Dispelling Myths about Clinical Trials and Vaccines and Clinical Trial Community Navigation Program, provide a framework for future workforce development within the community health worker/promotores landscape to support the goal of increased clinical trial diversity.

As a result of these successful community engagement efforts, and its public commitment to have participants of its clinical trial reflect the racial demographics of the countries and communities where it conducts its studies, Pfizer has added staffing and funding resources to its clinical trial diversity team to focus on enhancing community engagement throughout the clinical trial ecosystem. Staff will work directly with The Collective and its partners, its clinical trial sites, and other research partners in outreach efforts and to enhance the participant experience. New goals, higher prioritization of diversity, and heightened commitment to equity are also results from the intense engagement with diverse community partners as the result of the health emergency caused by the COVID-19 pandemic. Earlier in the clinical trial development process. Enhanced educational and communications materials that will resonate with diverse communities will be developed and these efforts could lead to more diverse clinical trials. Ultimately, this will mean having the evidence and knowledge that innovative medicines will be effective for a broad population and healthier outcomes for patients.

Conclusions and Opportunities

The effects of COVID-19 on the U.S. population revealed a dual pandemic of health inequities – the disproportionate impact of the novel coronavirus on people of color and longstanding health disparities, including underrepresentation in clinical trials, caused by factors including the social determinants of health and issues of systemic racism in healthcare. There is significant regulatory, ethical, and scientific support for increasing diversity in clinical trials. However, historical abuses, deeply rooted systemic racism, and current bias and discrimination in the healthcare system have created significant obstacles to achieving diversity in clinical trials, including wide mistrust in the system.

In addition, other social determinants of health contribute to preventing diverse populations from participating in clinical trials. Issues such as insurance status, transportation, costs, geographic location, and more, often present obstacles to participation in clinical trials for people from underrepresented communities. Of critical importance is to overcome the issue of medical mistrust that is common among diverse communities.

While participation rates of multicultural communities in clinical trials have historically been low, there are positive signs indicating that this can be improved, however much more needs to be done. Respect and engagement of community leaders in the clinical trial process can help drive successful outreach and educational efforts on clinical trials in diverse communities. Through intentional efforts, it's possible to achieve success in diversifying clinical trials.

Community engagement, information transparency, culturally-relevant educational materials, are all impactful to overcoming mistrust. Pfizer's sustained partnerships with multicultural partners over the last two decades were critical to the success of the community engagement efforts that were initiated to help diversify the clinical trial for the COVID-19 vaccine. Other relevant community engagement initiatives by other researchers also point to effective community engagement practices to help diversify clinical trials.

The opinions of community partners about Pfizer's commitment to health equity are influenced by Pfizer's ongoing engagement in grassroots community efforts and by the involvement of

diverse representation of Pfizer leadership in these efforts. Diverse leadership represents a sensitivity and compassionate understanding of the needs of traditionally underserved and underrepresented communities.

The successful results of community engagement efforts for the Pfizer-BioNTech COVID-19 clinical trial opened up many possibilities for different approaches to clinical trial diversity. Pfizer was receptive to these ideas and has begun efforts that may lead to long term systemic change. It is evident from feedback received from Pfizer partners involved with the COVID-19 clinical trial efforts that Pfizer's partnerships with diverse multicultural organizations remain fertile ground for innovative solutions.

As Pfizer continues to lift health equity as a principal value and objective for the company and remains focused on increasing clinical trial diversity, consideration of broadening eligibility criteria and modeling new study designs for clinical trials, as recommended by the FDA, could be considered. Smartphones, which have helped Blacks and Hispanics bridge some digital gaps, can be exploited as a key element of mobile health to facilitate participation of these groups in clinical trials. Further inclusion of community insights to develop culturally relevant educational materials for future clinical trials can be prioritized. National and local partner networks can be utilized to help advance recruitment efforts of Pfizer clinical trial sites.

Finally, the Multicultural Health Equity Collective will continue to have diversity in clinical trials as one of four primary objectives for the work of this group and will apply the learnings from the experience with the COVID-19 clinical trial to help move this agenda forward with Pfizer's Clinical Trial Diversity team.

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