Health Equity

More Than **800** Medicines in Development for Diseases That Disproportionately Affect Racial and Ethnic Communities

As a nation, we are in a new era of medicine where breakthrough science is transforming patient care, but these innovations are meaningless if they don't reach patients. It is critical that patients have access to medicines, including patients from traditionally underserved communities. Achieving health equity is essential in creating a health care system that truly works.

Unfortunately, systemic racism that exacerbates health inequities has contributed to long-standing disparities in prevalence and severity of disease across racial and ethnic groups. These disparities can be reflected in how often a disease occurs in a certain patient population, how serious the disease manifests itself in patients or how often a disease results in death. Health disparities have many causes and can include limited access to quality health care, including health screenings, living and working conditions, experiences with the health care system/patient confidence, racism, bias in the treatment setting, underrepresentation of minority health care providers, and other social determinants of health, clinical trial participation, language barriers, economics and insurance coverage.

JUST THE FACTS

9.1% - 18.7%

of diverse racial/ethnic groups were uninsured in 2019, compared to 6.3 of white counterparts.[1]

American Indian/Alaska Native persons are

1.6 times

more likely to be diagnosed with COVID-19 than non-Hispanic whites.[2]

Hispanic persons are

2.0 times

more likely to be diagnosed with COVID-19 than non-Hispanic whites.[2]

American Indian/Alaskan Native, Hispanic, and Black populations are

3.5, 3.0, and 2.8 times

more likely, respectively, to suffer hospitalization due to COVID-19, as compared to non-Hispanic whites.[2]

American Indian/Alaskan Native, Hispanic, and Black populations are approximately

twice

as likely to die from COVID-19, as compared to non-Hispanic whites.[2]

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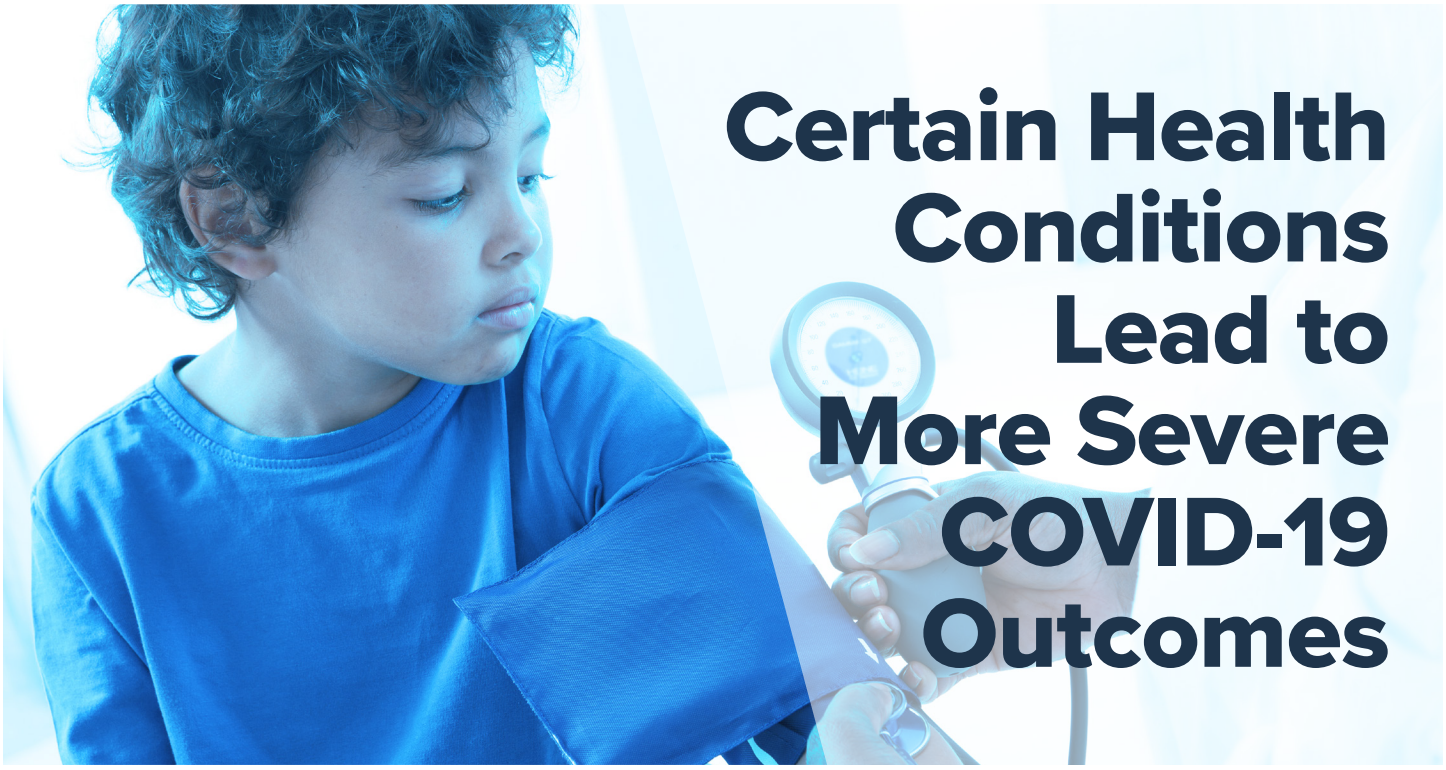
While these disparities are not new to our health care system, the COVID-19 pandemic has shined a light on the long-standing health inequities affecting racial and ethnic groups in America. These inequities manifest themselves in many ways – from discrimination to access and utilization of health care, from education and income gaps to housing conditions.

According to the U.S. Centers for Disease Control and Prevention (CDC), racial and ethnic groups are disproportionately represented among COVID-19 cases and are more likely to be hospitalized or die from COVID-19. In fact, life expectancy for Black and Hispanic lives has decreased by 3 years and 2 years respectively due to the coronavirus pandemic.[3] And, of 131 predominantly Black counties across the nation, the COVID-19 infection rate is 3 times higher than in predominantly white counties, and the death rate is 6 times higher.[4]

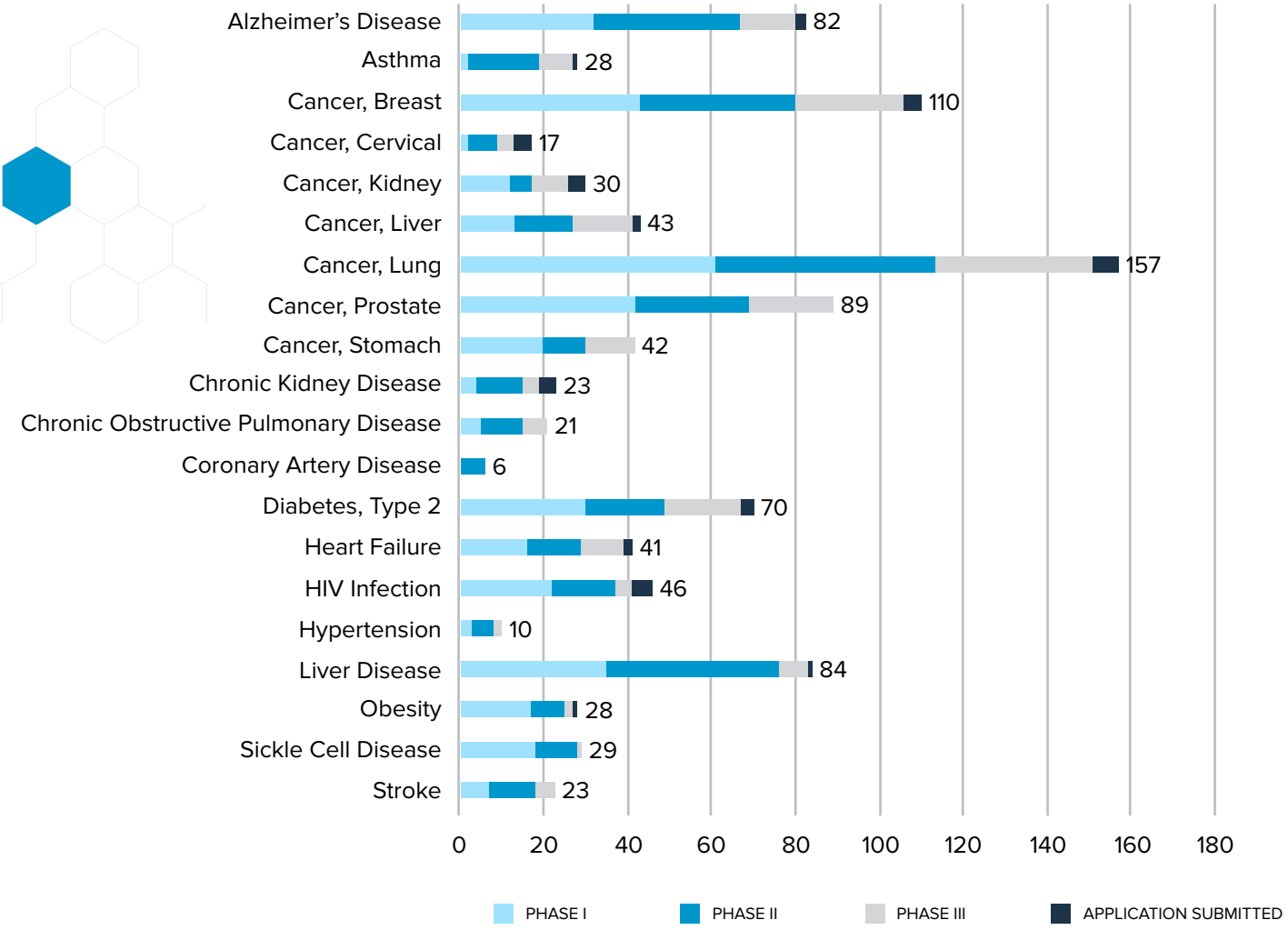


Certain Health Conditions Lead to More Severe COVID-19 Outcomes

Researchers have found that people with certain health conditions are at higher risk of severe illness or death from COVID-19.[5] Many of these conditions are also tied to health disparities and disproportionality affect racial and ethnic groups. According to the U.S. Health and Human Services, Office of Minority Health, diseases that are linked to more severe COVID-19 outcomes and also disproportionally affect racial and ethnic groups include chronic diseases, such as: Alzheimer's disease; certain cancers, including breast, cervical, kidney, liver, lung, prostate, stomach; chronic kidney disease; chronic lung diseases, such as asthma and COPD; type 2 diabetes; heart conditions, such as coronary artery disease, heart failure and hypertension; HIV infection; liver disease, such as cirrhosis and non-alcoholic fatty liver disease; obesity; sickle cell disease; and stroke.

This report explores the medicines in development targeting diseases and conditions which affect racial and ethnic communities at a higher rate than the average population and are also associated with worse COVID-19 outcomes. Today, there are 829 medicines in development by biopharmaceutical research companies to address these diseases, all of which are in clinical trials or awaiting review by the U.S. Food and Drug Administration (FDA).[6]

Medicines in Development for Underlying Medical Conditions Associated with Severe COVID-19 Infection Outcomes



Health Disparities in Minorities

Observed inequities in disease treatment are often due to inequities in social, economic and geographic factors, as well as inequities in access to health care and broader systemic racism issues. Meanwhile, some diseases affect racial and ethnic groups disproportionately for genetic and environmental reasons.

Alzheimer's Disease

Black Americans are 2 times more likely and **Hispanics are 1.5 times more likely** to develop Alzheimer's disease than non-Hispanic white Americans.[1]

Liver and Stomach Cancer

Asian Americans and Pacific Islanders are twice as likely to have and die from liver and stomach cancer as non-Hispanic whites.[2]

Kidney Cancer

American Indians and Alaska Natives have the highest incidence and deaths rates for kidney cancer than any other racial or ethnic population.[2]

Chronic Kidney Disease

Black Americans, Hispanics, Pacific Islanders and American Indians have an increased risk for chronic kidney disease.[3]

Obesity

Black Americans are 1.3 times more likely to be impacted by obesity compared to non-Hispanic whites.[4]

Asthma

Black Americans die from asthma at a higher rate than any other racial or ethnic group.[5]

Diabetes

Hispanics, American Indians and Alaska Natives have the highest rates of diagnosed diabetes.[6]

Sickle Cell Disease

Sickle cell disease is most common in Black Americans, affecting 1 in 365 people.[7]

Heart Disease and Stroke

Black Americans are 2 to 3 times more likely as non-Hispanic whites to die from preventable heart disease and stroke.[8]

Sources:

1. Alzheimer's Association
2. American Cancer Society
3. National Kidney Foundation
4. U.S. Health and Human Services
5. Asthma and Allergy Foundation of America
6. American Diabetes Association
7. U.S. Food and Drug Administration
8. The Journal of Clinical Hypertension

Innovative Medicines in the Pipeline

Biopharmaceutical research companies have 829 medicines and vaccines in development to treat the diseases and conditions that lead to more severe negative outcomes from COVID-19 infections. Among the candidates in development that may mitigate those outcomes by improving disease management are:

- A long-acting injectable capsid inhibitor is being developed as an anti-retroviral (ARV) treatment for **HIV infections**. The medicine inhibits HIV-1 replication in human peripheral blood cells by inhibiting capsid protein formation (the capsid protein is the shell around the virus containing genetic material). It is being studied in both heavily treatment-experienced patients with multi-drug resistance and treatment-naïve patients living with HIV.

- A gene-edited cell therapy that could potentially be a one-time treatment for **sickle cell disease**, uses zinc finger nucleases (ZFNs), which consists of a protein with a DNA-cutting enzyme, to modify a patient's own hematopoietic stem cells to produce normal-shaped red blood cells using fetal hemoglobin. Normally, levels of fetal hemoglobin begin to decline after birth, while levels of adult hemoglobin increase. Since only adult hemoglobin contains the part of hemoglobin defective in patients with SCD, increasing fetal hemoglobin may be therapeutic for patients.

- A potential first-in-class medicine in development for **asthma**, blocks TSLP, an immune system messenger protein that is critical in the development and persistence of inflammation of the airways. It is believed that by blocking TSLP, the release of pro-inflammatory proteins by immune cells will be stopped, resulting in the prevention of asthma exacerbations and improved asthma control.

- A potential treatment for **renal cell carcinoma**, a type of kidney cancer, is designed to stimulate cancer killing cells in the body by targeting CD122 on the surface of the immune cells. This experimental immunotherapy is being studied in combination with an approved immune checkpoint inhibitor which works by unleashing the body's own powerful immune system to target and kill cancer cells. The treatment works by increasing the number of tumor-infiltrating lymphocytes (TILs) which generate an immune response leading to increased therapeutic activity of the checkpoint inhibitor to attack cancer cells while leaving normal cells alone.

- A medicine is being developed for the treatment of large hemispheric infarction, a severe form of **ischemic stroke**, where brain swelling (edema) leads to a disproportionately large number of stroke-related deaths and disabilities. The medicine targets and blocks the sulfonylurea receptor 1-transient receptor potential melastatin 4 (SUR1-TRPM4) channels that mediate stroke-related brain swelling. In clinical trials the medicine has demonstrated potential to reduce brain swelling, disability and the risk of death.

Industry Commitment to Clinical Trial Diversity

The research-based biopharmaceutical industry recognizes the importance of including diverse patients in clinical trials for new medicines so that the clinical trial population reflects the intended treatment population. Critical to enhancing clinical trial diversity is addressing the systemic issues that deter Black and Hispanic communities from participating in clinical trials, so that those who want to participate, can. Unfortunately, underrepresentation of racial and ethnic groups in clinical trials for new medicines has a long history.

To help address this long-standing mistrust and other issues, PhRMA and its member companies recently issued the first-ever industry-wide principles on clinical trials diversity, adding a new chapter to the already existing *Principles on Conduct Clinical Trials & Communication of Clinical Trial Results*. The new clinical trial diversity principles address:

Building Trust and Acknowledging Past Wrongs. Some patients may not trust medical research due to historic mistreatment, including examples such as the U.S. Public Health Service Tuskegee Syphilis Study and Henrietta Lacks, whose cancer cells were harvested without her knowledge and have been used over the decades since. Today, patients and research participants' rights are protected by law and ethics committees, including institutional review boards that oversee clinical trials. Our member companies are also committed to enhancing diversity among clinical investigators, working with communities to educate about the role of clinical trials and improving our community outreach so that those who want to participate can do so.

Reducing Barriers to Clinical Trial Access. To enhance clinical trial diversity, it is imperative for researchers to plan studies and development programs that promote inclusion of diverse populations, implement protocols that define the intended treatment and enrollment populations and seek input from those communities throughout the process. For example, sponsors should consider recruitment challenges and enrollment barriers that may occur as a result of factors such as planned visit schedules, location and financial implications, as well as how these factors might be addressed. Innovative trial designs or tools, like digital health technologies, can also be utilized to make trials more accessible. It's also important that researchers adopt practices for determining science-based eligibility criteria that do not inhibit the diversity of the clinical trial population.

Using Real-World Data to Enhance Information on Diverse Populations Beyond Product Approval. During the post-approval phase, collecting clinical real-world data or evidence can be an important method of supplementing trial data, in compliance with all applicable local laws and regulations. These data can also serve as an effective and efficient means to enhancing understanding of drug effects in diverse patient populations.

Enhancing Information About Diversity and Inclusion in Clinical Trial Participation. Lastly, biopharmaceutical companies that adopt these new principles commit to sharing information about their policies or practices to increase clinical trial diversity online.

At the core of these principles is the need for the industry to better serve historically underserved populations. By committing to enhancing diversity in clinical trial populations, we can better reflect the patients that will use the new therapy or medicine being studied and solve for improved health outcomes. Clinical trials for the development of new medicines should aim to reflect the patient population they are targeting to help. Ultimately, diverse clinical trials may provide additional information about the medicine.

It is with these core principles in mind that the biopharmaceutical industry commits to continuing to work with patients, patient advocacy groups, regulatory authorities, health care practitioners, academics and policymakers to help define the systematic and impactful approaches that can enhance the diversity of clinical trial participants and help reduce health care disparities. The biopharmaceutical industry is committed to addressing systemic racism and enhancing clinical trial diversity through engagement with diverse patients, communities and stakeholders across the United States.

Sources:

1. U.S. Department of Health and Human Services (HHS), Office of Minority Health, Minority Population Profiles
2. U.S. Center for Disease Control and Prevention (CDC), Risk for COVID-19 Infection, Hospitalization, and Death by Race/Ethnicity, updated April 23, 2021
3. Arias E, Tejada-Vera B, Ahmad F. Provisional life expectancy estimates for January through June, 2020. Vital Statistics Rapid Release; no 10. Hyattsville, MD: National Center for Health Statistics. February 2021
4. Yancy CW. COVID-19 and African Americans. JAMA. 2020;323(19):1891–1892. doi:10.1001/jama.2020.6548
5. CDC, People with Certain Medical Conditions, March 29, 2021
6. Number of medicines obtained through public government and industry sources, and the Springer "AdisInsight" database; current as of **June 8, 2021**