

# Industry Efforts to Enhance Clinical Trial Diversity

JULY 2022





linical trials are the foundation of the work our industry does to bring treatments and cures to patients. But right now, there is an opportunity to improve on an important piece of these trials: diversity.

Underserved communities have faced significant barriers to participating in clinical trials. We're helping to change that. PhRMA is proud to support patient advocacy organizations, academia, health systems, clinical trial experts and health equity experts on community-based collaborations that address the systemic challenges and mistrust that stand between where we are now, and a world where clinical trials better reflect the patient populations the treatments will serve.

Many of our member companies are taking individual steps to build trust and encourage broader, more diverse clinical trial participation. A recent survey of many PhRMA members found 97% of respondents reported specific measures they're taking to address access issues for clinical trial participants. In the pages of this report, you'll find dozens of case studies covering this work.

Relationships among the biopharmaceutical industry, community stakeholders, policymakers and partner organizations matter. Together we can advance more inclusive clinical trials and make sure that the medicines of the future represent the people they are meant to treat.

Best,

Stephen J. Ubl  
President and CEO  
PhRMA



# Introduction

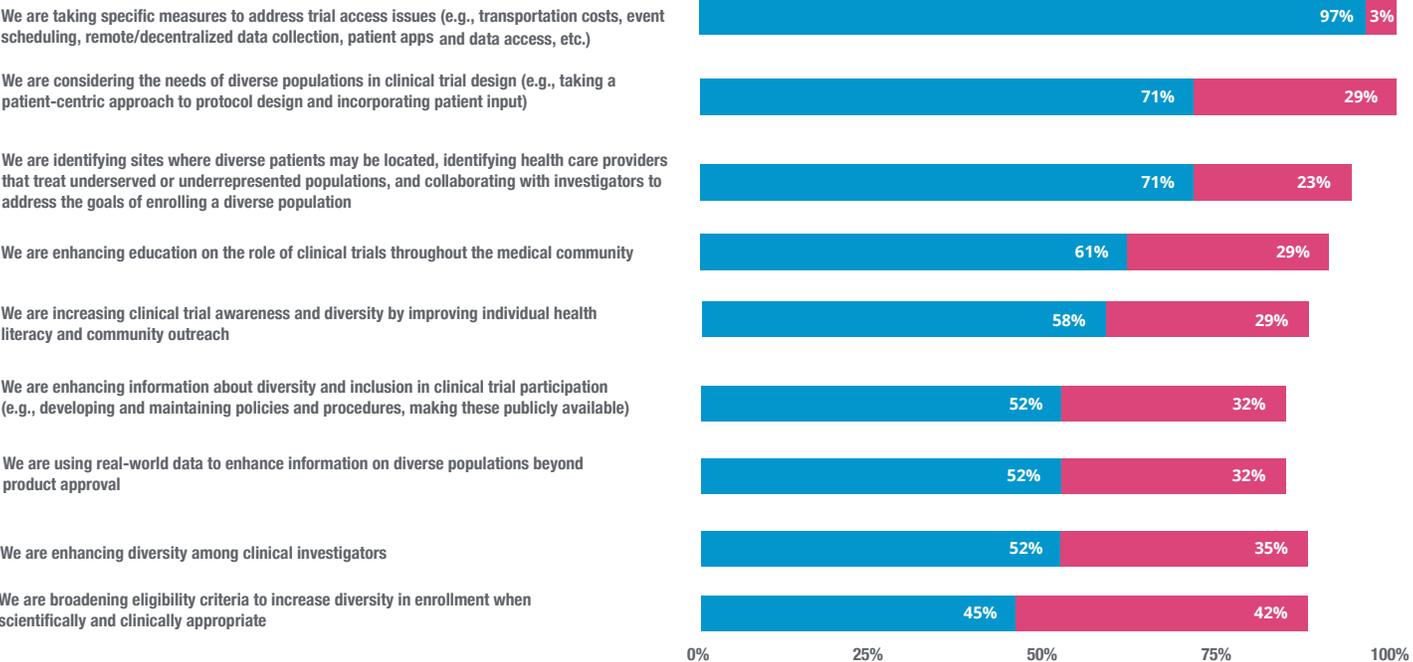
As we look at the development of new drugs and medical solutions, it is essential to take meaningful and thoughtful action to help ensure that underserved communities, who have historically faced significant barriers to participating in the development of health advances, want and can participate every step of the way.

Many individual biopharmaceutical companies have been working for years to enhance clinical trial diversity within their studies. They have partnered with community organizations, specifically considered the needs of diverse patient populations in protocol design, sought to expand the diversity among clinical investigators and broaden eligibility requirements.

In fact, in a January 2021 survey among 31 of our 33 member companies, 97% reported taking specific measures to address access issues for clinical trial participants. Eighty-seven percent (87%) of these member companies were adapting protocol design to increase diversity, including the use of decentralized trials, remote trials, and mobile technology. And 84% reported working to increase patient education and awareness of clinical trials.

**All PhRMA member company survey respondents have or are planning to address trial access issues and are considering the needs of diverse populations in clinical trial design**

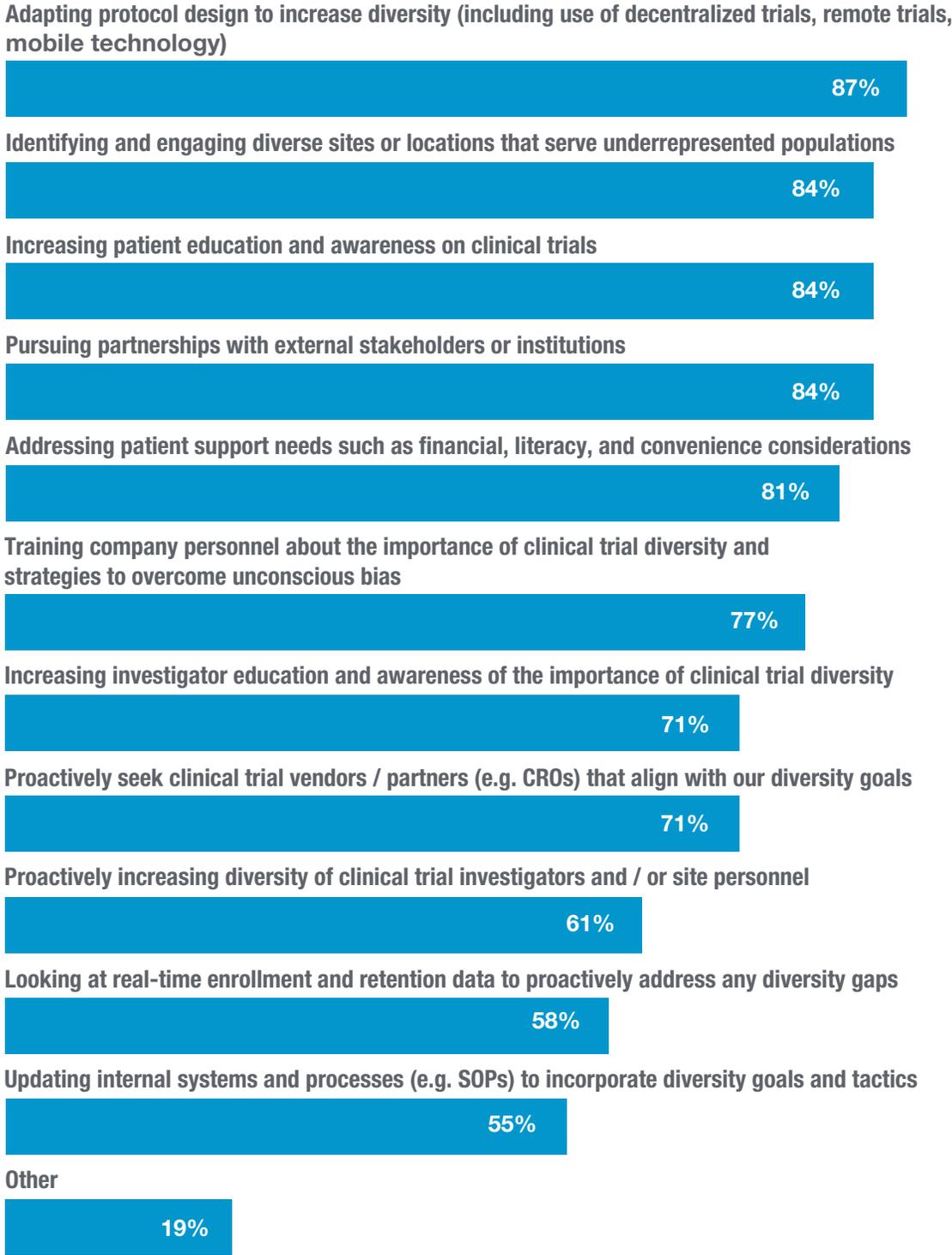
■ Yes ■ In progress



Note: N = 31 PhRMA member companies.  
Source: PhRMA member clinical trial diversity industry survey, January 2021.

# Most PhRMA member company survey respondents are pursuing strategies around protocol design, identifying and engaging diverse sites, increasing patient awareness, and pursuing partnerships

**Question:** What strategies are your company pursuing to improve diversity in clinical trial participation? Select all that apply.



Note: N=31 PhRMA member companies.

Source: PhRMA member company clinical trial diversity industry survey, January 2021.

The following report puts real examples behind these numbers, providing a snapshot of efforts that biopharmaceutical companies have made in recent years to enhance clinical trial diversity. The breadth, depth and dedication to enhancing clinical trial diversity by working directly with underserved communities and by addressing systemic barriers is apparent in this work.

Yet in spite of individual efforts of biopharmaceutical companies, the Food and Drug Administration (FDA), and others, systemic barriers to participation still exist. As a result, clinical trials do not always fully reflect the intended treatment populations.

The impact of COVID-19 on underserved communities and the importance of inclusive clinical trials to combat the pandemic galvanized the pharmaceutical industry, and PhRMA began organizing towards community-based efforts to enhance clinical trial diversity in June 2020.

**This included the voluntary development and adoption of the first-ever, industry wide principles on clinical trial diversity, which focused on:**

- Building trust and acknowledging the historic mistrust of clinical trials within Black and Brown communities,
- Reducing barriers to clinical trial access,
- Using real-world data to enhance information on diverse populations beyond product approval, and
- Enhancing information about diversity and inclusion in clinical trial participation.

Since this time, PhRMA has led discussions with thousands of patients, advocacy groups, health care providers, and leaders from the clinical trial, health equity, and racial justice communities as we have worked to identify challenges and potential solutions to address participation.

We were particularly excited to be joined by over 500 participants from 150+ organizations at our June 2021 workshop on enhancing clinical trial diversity, which sought to identify actionable recommendations that our industry and others could rally behind.

## Five important strategies emerged as optimal drivers to improve clinical diversity in research:

- ***Create a network of clinical trial sites in underserved communities.*** Establishing research sites in locations where potential participants already receive care, including non-traditional locations such as community health centers and pharmacies, can help improve clinical trial diversity.
- ***Develop a diverse pool of investigators and staff.*** Racially and ethnically diverse investigators and staff who reflect the communities they serve are key community ambassadors for clinical trials and can help ensure trials are culturally competent and mindful of unconscious/implicit bias.
- ***Establish long-term relationships and invest in the community.*** Stakeholders of a community-based clinical-trial infrastructure should prioritize long-term and sustainable community building efforts, like investing in health education or supporting the next generation of diverse health practitioners and investigators.
- ***Engage the community in conversations.*** Sponsors should communicate and work toward shared understanding with the community about the importance of volunteer participation in trials. They should also commit to transparent engagement throughout the process, including design of the trial, desired endpoints and the results of the trial. They should also seek input into the elements of design that might impact community members' ability to participate.
- ***Provide sustainable support and standardized platforms.*** Building a data infrastructure that leverages real world data could facilitate investigators identifying and engaging with patients appropriate for clinical trials and should include baseline measurements to improve data on race and ethnicity.

PhRMA and our member companies remain committed to enhancing clinical trial diversity by reducing systemic barriers to participation, supporting community-based trial sites, and working directly with underserved communities. In the pages ahead you will see that commitment in action from our member companies.



## PhRMA Member Company Accomplishments and Goals to Enhance Clinical Trial Diversity

## ABBVIE

AbbVie believes our clinical trials should reflect the populations we serve as we aim to help patients live healthier, longer lives. Ensuring diversity means we can better meet the needs of our patients both today and tomorrow. We are committed to researching and bringing treatment options for diseases that affect patients around the world, including groups of patients who historically have been underserved.

As part of our dedication, AbbVie is committed to being an industry leader in improving clinical research diversity. We rely on real-world data and evidence to guide our diversity and inclusion strategies to ensure participation in AbbVie-sponsored clinical trials appropriately represents patients living with the diseases we are studying. We have been and will continue to analyze our clinical trials to ensure they reflect a diversity in race, ethnicity, age, and gender. To this end, our continuing commitment is as follows:

- Evaluating our clinical trial protocol eligibility criteria against real-world datasets to ensure we are designing inclusive study protocols, enabling under-represented populations to volunteer for our clinical trials.
- Analyzing and ensuring the age, gender, race, and ethnicity of those enrolled in our clinical trials appropriately reflects the age, gender, race, and ethnicity of the patient population we are studying. If diversity gaps are identified within indications in our portfolio, we will create a tailored plan to address specific gaps. This plan may include enhanced community partnerships, clinical research staff education, investigator trainings, new site selection strategies, and targeted patient outreach.
- Routinely re-assessing clinical study demographics to determine if our efforts to ensure participation of under-represented populations have made an impact, pivoting to different strategies if necessary.
- Continuing to refine our clinical trial diversity and inclusion strategies based on analytics and ensuring every team has access to regional indication demographics, including AbbVie resources to help resolve previously identified diversity gaps.

## ALKERMES

On behalf of: Elspeth Carnan, Ph.D.,  
Senior Vice President, Clinical Operations, Alkermes:

As a company focused on developing innovative medicines that aim to address unmet needs of people living with serious mental illness, addiction and cancer, Alkermes recognizes the importance of enrolling patients in our clinical studies who accurately reflect the epidemiology of these disease states. We have a demonstrated history of including racially and ethnically diverse patient populations in our clinical research programs and are committed to continuing our efforts in this area.

Specific to serious mental illness, we have been actively engaged with the STARR (Stakeholders in Treatment, Advocacy, Research and Recovery) Coalition, a non-profit organization committed to supporting mental health clinical research. Most recently, we provided feedback on ways to enhance the “Diversity in Research” site certification module, which we use as part of our site selection process.

Within oncology, we have launched a cross-functional, internal task force committed to enhancing diversity in oncology clinical trials. The task force’s strategic imperatives span clinical trial design, site selection and execution, as well as making connections across the research/care continuum to ensure feedback from community-based and patient advocacy organizations dedicated to health equity, health care providers, researchers, and other caregivers serving marginalized or underserved patients.

## AMGEN

Amgen’s RepRepresentation in Clinical Research (RISE) Team is working to improve clinical trial diversity by working cross-functionally within the company and with key external groups, including partnering with clinical investigators who represent historically excluded communities and collaborating with those who serve diverse patient populations at clinical trial sites. RISE and our partners will work with community organizations that can help to identify and address barriers to participation and to build trust, which is key to increase participation in clinical trials. Amgen is also developing research partnerships to better understand disease risks in specific populations.

Ponda Motsepe-Ditshego, Vice President, Global Medical and General Medicine Therapeutic Area Head at Amgen, and the Global Chair of the Amgen Black Employee Network, is leading RISE and says that it is making progress on its three-year plan but that it will “take a village” to reach the initiative’s goals, relying on multiple Amgen functions and external partners to generate real impact and to address challenges potential trial participants may face. “Some of the barriers,” she said, “are socioeconomic ones, where residents in poorer or rural communities often can’t get to distant sites or afford to miss work to participate in trials. We aim to alleviate these kinds of pressures, especially for those patients who have been underrepresented in research for so long.”

#### Data guiding our road ahead:

- Approximately 40% of Americans belong to a racial or ethnic minority group, but individuals who participate in clinical trials for new drugs skew heavily white – in some cases, 80 to 90%.
- Black/African Americans represent 13% of the U.S. population but only 7% of clinical trial participants.
- Hispanic/Latino people represent over 18% of the U.S. population, but only 11% of clinical trial participants.
- Asian Americans make up 6% of the U.S. population, but make up only 1.7% of participants of clinical trial participants for which at least 70% of trials were conducted in the U.S.
- To enhance diversity in clinical trials, Amgen is exploring ways to ease the overall burden on clinical trial participants, which include improving communication with and awareness of these issues for patients, their communities, and health care providers.

## ASTELLAS

Our underlying goal is designing clinical trials to reflect the unique patient populations who may benefit from the treatments we develop.

Astellas strives to provide innovative, lifesaving treatments to all communities, including underserved and under-represented populations. As part of our broad commitment to advancing health equity, we are working to improve clinical trial access to best represent the patient populations intended to use our medicines.

With PhRMA principles offering a guide to help us further improve diversity in our clinical trial enrollment, Astellas is working to make the clinical trial process more understandable and accessible.

We aim to employ several strategies to increase diversity in our clinical trials:

- Specifically selecting clinical trial sites that are most able to recruit diverse populations
- Making the clinical trial process more accessible through transportation, accommodations and alternative clinical research models, such as decentralized clinical trials, which can help reduce the obstacles of distance, costs and availability.
- Streamlining our outreach processes for clinical trial recruitment and using health literacy best practices to make our forms and tools more reader-friendly.
- Using real-world data to supplement trial data and enhance our understanding of drug effects in diverse populations post product approval.

The COVID-19 pandemic underscored the health inequities that exist in our country. Moving forward, we recognize that enhanced diversity in our trials can be an important part of the solution. Learn more on our clinical trials website [here](#).

## BIOGEN

*“To effectively support the goal of access for everyone, we must consider everyone.”*

Biogen’s Clinical Trial Health Equity Forum, led by Global Clinical Operations in collaboration with other functions across R&D, Patient Advocacy, and others, is working to ensure our clinical trial study participants reflect the target population of all our indications and disease areas such as lupus, multiple sclerosis, ALS and Alzheimer’s disease. We build race and ethnicity goals into the recruitment plans for U.S. clinical trials with the goal of ensuring participants enrolled accurately represent the patient population and epidemiology of the disease.

For example, to connect patients to clinical trials that may be relevant to them, we launched Biogen Trial Link, which was designed with input and direction of the Community Advisory Board. Biogen’s Community Advisory Board includes Black, African American, Latino, Hispanic, Asian American, Pacific Islander and Native American members. Their perspectives and insights guide our drug development, giving them a voice to help co-develop clinical trial educational materials and tactics approaches.

We are also adding diversity and cultural sensitivity training to clinical trial sites, and we have partnered with the National Minority Quality Forum (NMQF) to launch a Clinical Trial Index and Clinical Trial Learning Community. The Index maps clinical trial site locations against U.S. heat maps of Medicare/Medicaid beneficiary data by patient demographics, helping identify gaps in access to clinical trial participation and to identify appropriate sites in key locations. Further the Clinical Trial Learning Community brings together local stakeholders and subject matter experts within the community to integrate routines in local care networks to increase participation in clinical trials. We also have built sustained community outreach and education programs and general clinical trial education with the Center for Information and Study on Clinical Research Participation (CISCRP) AWARE, Proximity Health Solutions and HEAL Collaborative.

We are honored to have won the Reuters Global Pharma Patient Champion Award for our partnership with the CISCRP in forming the Community Advisory Board, and transparently share our progress on this important issue in our Year in Review.

## BIOMARIN

At BioMarin, we create pioneering treatments for people with genetic diseases around the world, and we are deeply committed to enrolling representative populations in our clinical trials. Our vision is to become a leader in promoting and practicing clinical trial diversity (CTD) in rare genetic diseases, with a mission to develop a blueprint for clinical trial diversity in the represented population that is far-reaching impactful, sustainable, and measurable.

Our progress to date includes:

- Established a CTD working group, comprised of cross-functional leaders in clinical trial design and conduct
- Completed a comprehensive Baseline Assessment by the CTD working group, identifying strengths and areas for improving diversity in BioMarin clinical trials to date, along with recommended strategies to enhance clinical trial diversity in future trials

Going forward, we are particularly focused on advancing three major recommendations from the CTD working group, which fall under BioMarin's greater DEI Initiative:

- Partner with patient advocacy groups on the goal of increasing representation of underserved communities in our clinical trials
- Partner with investigative sites on the goal of increasing representation of diverse populations in our clinical trials
- Expand educational efforts to reach and address needs of diverse and underserved communities

The CTD working group has created strategies and activities to support the three recommendations above. Examples of recent activities include:

- Developed and published patient pamphlets in 17 languages to educate prospective study patients about gene therapy, and to highlight how these studies differ from other hemophilia studies

- Reduced barriers to participation in our clinical trials by offering virtual visits, home health nursing, mobile tools (eDiaries), and patient stipends
- Conducted a deep dive analysis on historical and current real-world data to understand disease demographics and geography, which will further support site selection and enrollment targets for minority populations
- Secured a supplier to provide unconscious bias training to our clinical/investigative sites, with a goal of launching this training in Q4 2022
- Amending our criteria for clinical trial sites to accommodate sites that will help us to recruit trial participants from underrepresented communities

Moving forward, the study teams will collaborate with relevant functions to implement strategies and activities that are most appropriate for the stage of the programs. Progress against objectives will be evaluated by the CTD Working Group at least twice each year, with the goal of identifying lessons learned and best practices, and adjusting actions as needed.

## **BRISTOL MYERS SQUIBB**

Our teams are working tirelessly to increase diversity in clinical trials. In 2020, Bristol Myers Squibb committed to locating 25% of U.S. clinical trial research sites in racial or ethnically diverse communities (defined as > 30% non-white) by 2022, which we have been exceeding since inception. We believe this will lead to better science and patient outcomes.

### **BRISTOL MYERS SQUIBB FOUNDATION**

To further increase diversity in clinical trials by developing a more diverse investigator workforce, the Bristol Myers Squibb Foundation created a \$100 million, five-year initiative that was launched in 2021. The program's goal is to develop more than 250 community-oriented clinical trial physicians and mentor more than 250 medical students from populations underrepresented in medicine (URM). Named for the director of Virginia Commonwealth University's Massey Cancer Center and the first African-American director of a National Cancer Institute-designated cancer center, the Robert A. Winn Diversity in Clinical Trials Award Program is delivered in partnership with the American Association for Cancer Research. In 2022, it received a \$14 million donation from Gilead Sciences, Inc. to support 10 early-stage investigator physicians and 10 URM medical students for each of the next four cohorts.

## EISAI

When Eisai began designing the Clarity AD clinical trial, the Company made a commitment to improve racial and ethnic diversity in the study. Initiated in March of 2019, Clarity AD is a global placebo-controlled, double-blind, parallel-group, randomized study in 1,795 patients with mild cognitive impairment (MCI) due to AD or mild AD dementia (collectively known as early AD) with confirmed amyloid pathology in the brain. Eisai selected sites and investigators with access to diverse communities, implemented outreach activities with local community centers and churches, and leveraged relationships with patient advocacy groups and community leaders. Additionally, the company introduced decentralized clinical trial activities to reduce participant burden.

As a result, approximately 25% of Clarity AD's total U.S. enrollment includes Hispanic (22.5%) and African American (4.5%) persons living with early AD and mirrors the U.S. Medicare population. This is particularly important as the Centers for Medicaid and Medicare Services recent national coverage determination with coverage evidence development for AD anti-amyloid monoclonal antibodies requires that the clinical trials in this drug class are representative of the diversity of the national population diagnosed with AD.

While Eisai is pleased with the improvement in the Clarity AD study, the Company recognizes there is still much important work to be done in this area, especially with the African American community. At future medical congresses, Eisai will present data about the ethnic and racial demographics of the Company's multiple Alzheimer's disease trials conducted in the U.S. As part of Eisai's human health care mission(hhc), the Company will continue to work with communities and build new relationships with people and organizations that can help develop and implement strategies to address health disparities.

## ELI LILLY

To engage the community in conversations and create a network of clinical trial sites in underserved communities, Eli Lilly is selecting trial locations and partnering with local patients, patient advocacy groups, regulatory agencies, health care professionals, and community organizations.

Driving our work are the following three goals:

- **Create a Robust Clinical Trial Strategy and Reach Diverse Populations:**

To achieve diversity in participants across trials, our U.S. clinical trial teams aim for each trial participant to match the composition of the U.S. patient population that might use that trial's medicine once approved. Across clinical trials globally, we identify and address barriers that keep underrepresented populations from participating.

- **Intentionally Select a Diverse Range of Trial Sites and Investigators:**

We are recruiting more clinical trial investigators and external advisors who represent women and racial/ethnic minorities so that investigators and advisors reflect the U.S. population in gender and race/ethnicity.

- **Increase Diverse Representation through Partnerships and Collaboration:**

We collaborate with patients, patient advocacy groups, regulatory agencies, health care professionals and community organizations to identify and implement solutions that will result in diverse representation, improve health equity and generate evidence to support better patient outcomes.

With more progress to make, we have already seen results.

In 2020, Eli Lilly and Co reported that among the recent 12,000 U.S. patients Eli Lilly and Co. had enrolled in clinical trials, 39 percent were minorities—roughly the same as among the U.S. population. Hispanics were 18 percent and African Americans were 11.5 percent of our clinical trial patients, compared with 18-percent and 13-percent in the U.S. population, respectively.

Most recently, Eli Lilly and Company and The Network for Excellence in Health Innovation (NEHI) announced a collaboration to form a Community Focused Research Organization which will offer diverse perspectives and foster collaborative strategies to close the gaps in health and health care disparities and address barriers to participation in clinical research trials among underrepresented groups.

Lilly is committed to decentralizing clinical trials to mitigate barriers to participation for all populations. As part of this effort, Lilly is deploying Mobile Research Units directly to underserved communities and communities of color in order to increase access to clinical trials and help assure more trial participation by diverse populations.

## GENENTECH

To further establish long-term relationships and invest in the community, Genentech's Advancing Inclusive Research® Site Alliance is a coalition of clinical research sites committed to advancing the representation of diverse patient populations in the company's clinical trials, testing recruitment and retention approaches, and working across the industry to help achieve health equity for all patients.

Each of the Alliance centers focuses on increasing the participation of historically underrepresented patient groups in Genentech's trials. The Alliance also works collaboratively to share key learnings and explore innovative ways to increase clinical trial access for every patient who might benefit.

Quita Highsmith, Chief Diversity Officer at Genentech, explains, "we're partnering with highly experienced and trusted research centers located in areas with higher Black and Hispanic/Latinx populations to meet patients where they are and take practical and meaningful strides towards eliminating the systemic inequities of our healthcare system."

Through the Alliance, Genentech plans to add more research centers and additional disease areas with the ultimate goal of building a robust and sustainable clinical research ecosystem that actively includes diverse patient groups.

Founding Alliance partners are:

- City of Hope Comprehensive Cancer Center, Duarte, California
- Mays Cancer Center, home to UT Health San Antonio MD Anderson San Antonio, Texas
- O'Neal Comprehensive Cancer Center, University of Alabama at Birmingham, Birmingham, Alabama
- West Cancer Center, Memphis, Tennessee

The Alliance is an example of Genentech's 2025 Diversity and Inclusion Commitments to Advance Inclusive Research and Health Equity, which include incorporating population-specific assessments and inclusive research action plans for all of Genentech's clinical development programs.

## GILEAD SCIENCES

To expand our clinical trial site network in underserved communities, Gilead launched the Expanded Access Program, that allows therapies still in clinical trials to be used at home in severe cases and to increase accessibility to life-saving therapies.

We select Expanded Access Program sites (and COVID-19 trials) in locations that reflect the epidemiology of the outbreak and regional need across a broad U.S. geographic area, including many urban centers with a significant burden of COVID-19 cases in New York, New Jersey, Michigan, New Orleans, and Chicago.

Gilead is bringing representative populations into our clinical trials across Virology, Oncology, and Inflammation using a Human Centered approach to clinical trial designs; engaging patients where they are through decentralized trials and partnering with communities via patients, patient advocacy groups, and online communities. Gilead has hired a Head of Diversity in Clinical Trials and is using real world data to identify representative populations in every new program/study design. Gilead has partnered with patients through COVID-19 Patient Council, TNBC Patient and Community Council, and Global Community Advisory Group for HIV pre-exposure prophylaxis (PrEP), as well as participated in developing “How to Guides” with Patients and other Industry partners with Patients Focused Medicine Development (PFMD). We are enriching site selection for clinical trials for diversity through multiple factors including but not limited to real world data, cultural competency training, and translations of clinical trial material to ensure that every person can have access to clinical trials. We are evaluating how to further reimburse for travel or support un/under-insured communities.

A manuscript, Proactive strategies to optimize engagement of Black, Hispanic/Latinx, Transgender, and nonbinary individuals in a trial of a novel agent for HIV pre-exposure prophylaxis (PrEP), was written in collaboration with our investigators, members of our Global Community Advisory Group, and colleagues here at Gilead which was published in PLOS One (June 2022). This manuscript focuses on the efforts to increase the representation of groups historically underrepresented in clinical trials, who are also disproportionately affected by HIV infection, Black, Hispanic/Latinx, Transgender, and Gender Nonbinary individuals.

Gilead sponsored a diversity and inclusion hack-a-thon with the University of Colorado - Leeds School of Business to develop opportunities to increase representation from college-aged and/or Latinx populations.

Gilead proudly supports The Robert A. Winn Diversity in Clinical Trials Award Program that rewards early-stage investigator physicians from diverse backgrounds committed to increasing diversity in clinical trials, and for underrepresented in medicine (URM) medical students.

The first cohort of Winn Career Development Award Scholars entered the program in November 2021. These physicians from 22 states across the U.S. include 34 women and 18 men who represent a diverse cross section of races and ethnicities, as well as a range of experiences in the therapeutic focus areas of cancer (hematologic and solid tumors), immunologic disorders and cardiovascular diseases.

Scholars are paired in mentoring relationships with established clinical investigators and serve as mentors to URM medical students in the Winn Pipeline Award program.

Gilead's Research Scholars Program supports early-career researchers doing highly innovative basic and clinical research in areas of unmet medical need and how the program is working to reduce barriers to entry for underrepresented applicants and ensure that research proposals are representative of diverse voices.

It all adds up to our continuing commitment to expand clinical trial diversity and the patients we serve.

## GSK

To develop a diverse pool of investigators and staff and to engage the community in conversations, GSK is increasing staff diversity and culture competency, focusing on trial diversity through five key approaches:

- Characterize the populations most likely to be affected with the disease and barriers to access
- Engage with communities and advocacy groups to build trust, enhance awareness and provide education and outreach
- Understand and advocate for current clinical trial diversity guidelines from agencies and professional organizations as well as from community and patient advocacy groups

- Embed scientific questions for population-related responses within study protocols
- Train and support GSK staff and research collaborators for success in enrolling diverse populations in clinical studies

Three core pillars anchor our strategy to create a more diverse patient population:

- **Data quality:** Improving capabilities and coordinated standards to gather and report information necessary to understand the disease, as well as generate more useful patient insights and identify product-specific information.
- **Patient engagement and insights:** Adapting our recruitment and engagement processes to the needs of the different patient populations we serve. Building trust with patient advocacy groups, investigator networks, regulatory agencies, and industry partners to increase participation and retention of diverse patients in our clinical studies.
- **Culture and transparency:** Educating our staff to achieve diversity culture competency and cultivating partnerships to provide a greater understanding of the benefits of clinical trial diversity.

2022 Aspirations & Recent Examples of CTD:

- GSK's Environmental Social and Governance set a Global Demographics & Diversity aspiration that <75% of all trials initiated in 2022 will have proactive plans in place designed to enroll appropriately diverse trial participants consistent with the disease epidemiology to be able to access the clinical needs of those most burdened by disease.
- We already have some great examples of where we're doing this well – these examples show us that it is possible to enrol diverse and “harder to reach” populations if the commitment is strong.
- For example, we've worked hard to diversify trials to reflect real patient populations for Blenrep (treating Multiple Myeloma), bepirovirsen (a treatment for chronic Hepatitis B), our clinical studies on RSV, as well as ViiV's clinical studies on HIV treatments and prevention.

## INCYTE

Incyte is a global organization and seeks to create medicines for people of all races and ethnicities. It is essential that diverse communities are appropriately represented in clinical trials in order for researchers to understand and treat disease in the broadest possible context. Unfortunately, several studies have shown that under-represented, minority populations in the United States are less likely to be included in clinical research.

Incyte is committed to taking the necessary steps to encourage diversity in our own clinical trials. To that end, we intend to explore opportunities to increase racial and ethnic diversity in clinical trials through our Clinical Trial Diversity Working Group. We are making it a priority to remove participation barriers, improve diversity, and pave the way to a healthier future for everyone.

## LUNDBECK

To further establish long-term relationships and invest in the community, the Lundbeck Diversity Steering Team is assessing and monitoring our progress against the Lundbeck Clinical Trial Diversity Principles:

### **Develop & Execute a Clear Strategy to Achieve Diversity in Our Trials Globally**

We aim to ensure that trial participants mirror the full diversity of the patient population in the country or region AND the disease we are studying. This requires our concentrated effort to involve underrepresented populations in our marketed regions through focused patient-inclusion criteria; attention to the diversity of clinical trial sites and investigators; removal of barriers that could impede the participation of certain groups in clinical trials; and use of real-world data to inform development efforts and improve understanding of diseases and products.

### **Collaborate with Patient Advocacy Groups Choosing to Make Diversity a Priority**

Lundbeck has a longstanding focus on community outreach, and we are committed to expanding partnerships with organizations that possess a like-minded focus on diversity. In collaboration with external partners, we strive to establish trust with diverse patient and caregiver populations, gain deeper insight into unmet patient needs and build awareness about open clinical trials to further enhance our clinical trial diversity.

## Implement Integrated Oversight Approach to Inform, Analyze and Act

Lundbeck aims to continuously inform and reform our internal thinking and processes by actively monitoring clinical trial diversity targets and utilizing real-world data to ensure we are driving inclusion of underrepresented populations in our clinical trials.

We also proudly support the Disparities in Headache Advisory Council (DiHAC), launched in the summer of 2020, as the COVID-19 pandemic wracked a disproportionate toll on communities of color.

Comprised of advocacy-organization leaders, BIPOC (Black, Indigenous, People of Color) headache patients and healthcare providers, the Council is focused on identifying solutions that can address racial disparities in headache medicine.

The Council is also working to diversify the engaged headache patient community. Members meet regularly for cross-cultural competency training and for presentations from leaders of disparity-reduction campaigns in other disease states.

## MERCK & CO., INC.

As a global health care leader, Merck recognizes that we have a responsibility to address the needs of the increasingly diverse patients and communities we serve. Since clinical trials are necessary before new medicines can be brought to patients, it is important to have diverse representation to help ensure the medicines and vaccines we develop are safe and work well for all people.

Our company has a long history of efforts centered on achieving appropriate representation in our clinical trials, and since 2018 we have had a dedicated team of experts focused on achieving greater diversity in our studies. Our multi-faceted approach is integrated into our clinical research at every stage, and includes:

- Selecting trial sites in regions where individuals from groups underrepresented within the broader population live. We closely evaluate epidemiology, racial diversity data and U.S. Census information to select trial sites located in regions that reflect the demographics of the patient populations that we're trying to recruit.

- Supporting infrastructure improvements to develop clinical trial sites that serve all populations. This includes collaborating with eight Clinical Trial Diversity Centers of Excellence across the U.S. on recruitment and retention strategies; supporting training for physicians of color to become Principal Investigators through the National Medical Fellowships Clinical Research University and participating in the Beacon of Hope collaboration to expand recruitment efforts to medical schools at Historically Black Colleges and Universities.
- Collaborating with trusted voices to educate communities about clinical research and the benefits of participating in clinical trials. We collaborate with community-based organizations to develop and share educational materials and programs designed to build trust in the research process and broaden community participation in our trials.

*“When planning our research programs, we prioritize diversity in our clinical trials, bringing together cross-functional teams to understand what we need to accomplish to ensure we meet our goals,” said Adrelia Allen, director of clinical trial patient diversity. “One of the most critical components of these plans is identifying where the patients are that we need to reach, and then selecting trial sites with this in mind.”*

During the planning stages for our trials, we establish patient enrollment goals to ensure diversity based upon the prevalence, incidence and burden of disease in specific patient populations. We continually review our enrollment figures, comparing them to U.S. Census data to evaluate whether trial participants reflect local demographics. We also examine data for patients who were screened but didn’t enroll in the trial, which provides insights into changes we can make to increase enrollment in specific populations.

*“We track trial participant demographics in real time, which enables us to quickly identify any deficits,” said Allen. “This provides an opportunity to work with our sites to make adjustments so we can achieve our enrollment goals. I’m encouraged by improvements we’ve made in enrolling a more diverse patient population in our trials.”*

- Enrolling sites in 2021 showed that 53% of our sites were in areas with a diverse population (defined as >30% non-white, by U.S. Census data). More than 50% of US patients randomized in clinical trials to date in 2022 were from underrepresented groups (including Asian, American Indian/Alaska Native, Hispanic/Latino and Black/African American).

We are proud of the progress we've made so far, but we recognize there is more work to be done to enable greater diversity in our clinical trials and help address health inequities. We will continue to advance this important work in collaboration with our partners to try to make a positive, measurable and lasting impact on societal barriers to health and address multiple dimensions of health equity.

## ENDPOINTS NEWS

### Merck, Sanofi join Novartis' 10-year quest to improve clinical trial diversity as historically Black colleges pitch in

*Merck and Sanofi are joining Novartis' 10-year commitment to increasing diversity in clinical research through a collaboration with historically Black colleges and universities.*

*With new grants worth \$17.7 million, the so-called Beacon of Hope program now totals more than \$50 million in commitments over the decade-long project, which aims to address health disparities and enhance diversity, equity and inclusion across drug research and development, particularly in clinical trials.*

*The three Big Pharmas will work with four HBCUs, which have seen increasing enrollment in recent years, to set up what they call Clinical Trial Centers of Excellence, or COEs. The partners aim to improve clinical study capabilities and ramp up inclusion of communities of color.*

[Learn More](#)

## NOVO NORDISK, INC.

Novo Nordisk Inc. (NNI)'s commitment to ensure diverse representation in our clinical trials is key to our patient-centered business approach.

*“We are focused on making Diversity, Equity, Inclusion & Belonging (DEI&B) a shared belief and lived commitment across our stakeholders to embrace differences, listen, learn and act and be bold and push boundaries,” said Doug Langa, Executive Vice President, Head of North America Operations and President of Novo Nordisk Inc. “Over the past year, we have been increasingly intentional around our DEI&B efforts, including working diligently and proactively to include sites and investigators in our trials that engage with diverse patient populations, while raising awareness of the opportunities for clinical trial partnership and participation.”*

This also includes enhancing access through telemedicine and decentralized clinical trials. With a deliberate focus on developing and improving upon our patient-facing materials and resources, and leveraging patient insights, we continuously improve upon our trial design and operational strategies.

We accomplish this by expanding our conversations with community and patient groups, health care practitioners, professional organizations and our own employee resource groups, to identify innovative ways to address barriers to clinical trial participation, such as access, mistrust and health disparities – staying focused on and dedicated to patients, providers and communities.

## SANOFI

Sanofi believes that all individuals should have the opportunity to be included in clinical trials, particularly people from diverse, often under-represented populations. We recognize the responsibility to understand any differential in efficacy or safety within diverse populations, guided by evolving scientific understanding. Sanofi is committed to listening and learning from diverse communities so we can design and conduct our clinical trials to be as inclusive as possible.

Sanofi Clinical Trials Inclusion & Diversity Team has the overarching goal to help teams ensure trial populations reflect the demographics of the disease for which treatments are being developed. To achieve this, we are engaging with all our stakeholders and evolving our entire ecosystem – including using early patient insights to help drive more inclusive study design and diversity-focused site

identification and recruitment & retention strategies. We have established internal clinical trial D&I governance and accountability with clear goals, study-level support, and continuous benchmarking, tracking and reporting on progress. We are also providing cultural competency training to our employees and to the study teams at our trial sites.

Sanofi is committed to partnering with other industry leaders to make a meaningful impact in clinical trial diversity and inclusion. We recently announced that we are joining Novartis' 10-year commitment to increasing diversity in research through the Beacon of Hope program, an initiative to support collaboration with historically Black colleges and universities. Sanofi also worked with TransCelerate to launch their Diversity of Participants in Clinical Trials Initiative to equip sponsors and ecosystem stakeholders with actionable tools and resources to improve outcomes through diversification of participants in clinical trials. Additionally, Sanofi is co-funding trials with NIH specifically to understand how well approved medications work for disadvantaged children of color living in urban areas.

This initiative focuses on the following efforts:

- **Clinical Research Diversity Collaboration Hub:** This one-stop-shop collects and shares information and insights across the ecosystem and includes diversity roundtable events, experience-based guidance for sponsors, a diversity regulation landscape assessment, and development of pragmatic toolkits inclusive of templates and tools to be leveraged by the broader ecosystem.
- **Race & Ethnicity Enrollment Data Benchmarking:** Identify priority disease states with disparity between disease prevalence and study representation among racial or ethnic groups to establish a benchmark for tracking future progress.
- **Leverage Our Existing Solutions:** Investigate ways to improve diversity of participants in clinical trials by leveraging TransCelerate's existing set of assets, such as the recent success story surrounding our Patient Experience Initiative's Study Participant Feedback Questionnaire and its translation into multiple languages for use with multiple patient populations.

Our Sanofi team represents more than 145 different nationalities with one thing in common: genuinely believing in our mission to help people around the world live healthier lives.

## TAKEDA

Takeda is working to achieve greater health equity for all patients by addressing health disparities and inequities that disproportionately impact underserved communities, including access to clinical trials.

Takeda engages in multidisciplinary, cross-company and cross-industry practices and collaborations to help reach all patients. Takeda's current initiatives include efforts to engage and build trust with individuals whose support and participation is essential to clinical programs.

The core tenets of the approach are as follows:

- Alignment and commitment to PhRMA's Principles on Conduct of Clinical Trials embedded within the clinical operations and trial execution processes
- Frequent touch points with patient advisory councils and disease-specific patient advisory boards, who represent diverse and critical perspectives that inform the way clinical trials are designed and conducted and the way information is shared with patients
- An enhanced focus on medically underserved communities through Takeda's clinical operations group
- A dedicated R&D Director of Diversity, Equity and Inclusion in clinical trials, responsible for implementing the diversity and inclusion strategic vision for Takeda's clinical research programs

Takeda has completed multiple discrete engagements with patient advisory councils, resulting in enhancements to several areas of our clinical trials website, including:

- Incorporation of design elements to ensure accessibility to people of different ages and cultures and to viewers with varying levels of comfort with technology and health literacy

- Inclusion of a translation tool, making clinical trial information accessible in 34 languages and offering translation of non-study specific website details, as well as specific information on individual clinical trials.

Takeda is actively engaged in activities to elevate partnerships and programs that prioritize inclusivity and diversity in clinical trials around the world, help ensure they become our standard of operations and support efforts to improve clinical trials industry-wide.

Some of these broad-based initiatives focus on:

- Identification, engagement and empowerment of research centers that serve underrepresented patient populations and are ready to participate in clinical trials
- Continued investment to increase clinical trial capacity, including investigator training in community centers that serve underrepresented patient populations
- Mentoring and support programs for students and early career investigators from underrepresented communities to establish successful paths in clinical research and industry more generally

## UCB

Enhancing Diversity Equity and Inclusion in UCB clinical trials:

A key objective for us at UCB is to ensure that the participants in our clinical trials are truly reflective of the patients who need and may benefit from the medicines we develop. Three key actions have been put in place to support UCB's long-term success:

- We developed and implemented new guidance on “Enhancing Diversity Equity and Inclusion in our Clinical Trials.” Our study teams use this guidance to define diversity for their disease areas and patient populations. This information is then used to create actionable items to enhance diversity by focusing on some key areas of considerations when designing and operationalizing a clinical trial, such as protocol design, country, and site considerations, leveraging different data sources and

patient and community engagement ultimately to bring our clinical trials closer to reality. This was a key step to ensuring each clinical trial at UCB reflects the diversity of the population of those who need and will benefit from new, innovative therapy in the future.

- We are leveraging ways to find and connect with diverse patient populations by using digital and data driven approaches to address health inequities. Approaches like decentralized clinical trials, use of real-world data, and personalized tools to enhance the patient experience are helping us innovate our ways of working. Also, by understanding the needs of diverse populations through deep patient listening and insight generation and we can look into ways we can broaden eligibility criteria for enrollment when scientifically and clinically appropriate, we continue to improve representation in clinical studies.
- We are exploring and deploying tactics to diversify clinical trials based on learnings from our collaborations as well. We do this by participating in various external engagement opportunities and learning from other leaders working in this space. UCB leaders engage with cross functional teams, serve as panelists at key industry meetings, and as subject matter experts at industry partnering events (PhRMA, TransCelerate, Deloitte, NCCSQA, SOCs, ACR). Additionally, a UCB subject matter expert recently co-authored a publication with Tufts Center for the Study of Drug Development after partnering on a research project focused on the diversity of clinical researchers. Each of these efforts are key as our teams who continue to learn, create, and implement DE&I best practices in clinical development and measure our progress.

As the landscape and guidance on diversity in clinical trials continues to evolve we believe these approaches position us well to adapt and implement approaches to increase representation in clinical studies and build trust in the communities of underserved patient populations.

# CONCLUSION

Health Equity is good medicine. It improves treatment outcomes and builds trust in the medicines and in health care for underrepresented communities. From community partnerships and training for staff to supporting diverse investigators and community-based research sites, we are shifting the culture and the reality of clinical trials to better represent the communities we serve.

While much more progress is needed, these PhRMA member initiatives are a welcome and an important beginning toward building and delivering health equity in the medicine development process.

The progress documented among member companies is significant and growing. From increasing diversity among investigators and building sustainable community relationships, to opening trial sites in underserved communities and increasing the use of real-world data. From award money for researchers in underrepresented neighborhoods to digital innovations able to gather trial data from home, the direction is clear: more access for more people, leading to more equitable health care systems.

These accomplishments mark an historic start, destined to flourish in the years ahead. PhRMA is proud to support this evolution in clinical trial design, access and staffing. To complete our goal, where access to clinical trials are greatly expanded so that those who want to participate can, we support comprehensive multi-stakeholder collaborations that better meet diverse patient populations where they are with sustainable, community-based trial sites.

We hope this report will also serve as an invitation to expand these collaborations.

