

April 9, 2021

VIA ELECTRONIC FILING TO: www.rfi.grants.nih.gov

Francis S. Collins, M.D., Ph.D.
Office of the Director, National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Re: Request for Information (RFI): Inviting Comments and Suggestions to Advance and Strengthen Racial Equity, Diversity and Inclusion in the Biomedical Research Workforce and Advance Health Disparities and Health Equity Research (NOT-OD-21-066)

Dear Dr. Collins,

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on the NIH's request for information on approaches to advance racial equity, diversity, and inclusion within all facets of the biomedical research workforce and expand research to eliminate health disparities and foster equity.¹ PhRMA is a voluntary, non-profit association that represents the country's leading biopharmaceutical research and biotechnology companies. PhRMA members are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than \$900 billion in the search for new treatments and cures, including an estimated \$83 billion in 2019 alone. Since the pandemic began PhRMA members have been working around the clock to find new vaccines and treatments to fight against COVID-19.

PhRMA applauds NIH leadership establishing the UNITE initiative to address structural racism and promote racial equity and inclusion at NIH and within the larger biomedical research enterprise.² PhRMA strongly agrees and supports the work of NIH to help ensure scientific discoveries truly benefit all, incorporating diverse skill sets, viewpoints, and backgrounds, including collaboration with multiple stakeholders. These comments include high level examples and background on the work of the biopharmaceutical industry to cultivate talent and increase diversity and inclusion across the entire biopharmaceutical research ecosystem.

¹ Request for Information (RFI): Inviting Comments and Suggestions to Advance and Strengthen Racial Equity, Diversity, and Inclusion in the Biomedical Research Workforce and Advance Health Disparities and Health Equity Research (NOT-OD-21-066). <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-066.html>

² NIH Unite Initiative: (U)nderstanding stakeholder experiences through listening and learning; (N)ew: research on health disparities, minority health, and health equity; (I)mproving the NIH culture and structure for equity, inclusion, and excellence; (T)ransparency, communication, and accountability with our internal and external stakeholders; (E)xtramural research ecosystem: changing policy, culture, and structure to promote workforce diversity. <https://www.nih.gov/ending-structural-racism>

I. BACKGROUND

The events of 2020, including the disproportionate impact that COVID-19 has had on underserved communities, as well as the murders of George Floyd, Breonna Taylor, Ahmaud Arbery, and others, brought into stark reality how these issues have far-reaching effects on the health and well-being of Americans. These prompted many industries to commit to racial justice initiatives. The biopharmaceutical industry made this commitment as well, coming together in June of 2020 to further a very intentional conversation and commitment to action regarding equity.

Many PhRMA member companies have undertaken specific efforts over the years to embed principles of diversity, equity, and inclusion into business practices, foster inclusion and belonging in their workforce and build towards greater equity in opportunity and outcomes. This progress is evident from a wide array of industry initiatives and programs within and across the industry including longstanding collaborations with entities like the CEO Action For Diversity and Inclusion, Inclusion Index Company, Billion Dollar Roundtable, and others.

In February 2020 PhRMA committed³ to be a trusting place to have complex, and sometimes difficult conversations about employee experiences and perspectives. Then, in June 2020, PhRMA member companies united behind Racial Justice Principles⁴ that are specific to the biopharmaceutical industry. The core of the biopharmaceutical industry's Racial Justice Principles acknowledge that systemic racism is as real as any disease, and that the biopharmaceutical industry is not immune.

With this effort, the biopharmaceutical industry committed to:

- Open, honest and real conversations about racial equity and what it means to have a culture of inclusion,
- Expanding opportunities to work and succeed in our industry,
- Advancing policy solutions and research to better address health disparities,
- Diversifying our business practices to better invest in Black and Brown America, and
- Earning trust and addressing systemic issues that deter Black and Brown communities from participating in clinical trials, so that people who want to participate, can.

Uniting behind this core mission has allowed the biopharmaceutical industry to build out the PhRMA Equity Initiative⁵ focused on three specific pillars for which the industry has the unique role and position to advance and implement. These pillars include:

- Health Equity: Drive policies and support research that pushes forward on health equity.

³ "PhRMA Joins CEO Action Plan for Diversity and Inclusion Pledge." February 2020.

<https://www.phrma.org/en/Press-Release/PhRMA-Joins-CEO-Action-Plan-for-Diversity-and-Inclusion-Pledge#:~:text=The%20CEO%20Action%20Plan%20for,will%20expand%20unconscious%20bias%20education.>

⁴ PhRMA's Racial Justice Principles. PhRMA. July 28, 2020. https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/DEI/DEI_PrintAd_FINAL.pdf

⁵ Learn more about this effort at <http://www.PhrMA.org/equity>.

- Clinical Trial Diversity: Work towards enhancing diverse participation in clinical trials to better reflect the intended treatment populations in order to help reduce healthcare disparities.
- Talent: Aim to grow the industry talent pool and create pathways to the biopharmaceutical industry so that its workforce better reflects census representation top to bottom and side to side.

PhRMA has put substantial processes and organizational structure in place to leverage experts across multiple disciplines to understand best practices, develop effective strategies, and obtain guidance regarding direction and priority initiatives.

Organizing industry efforts around those focus areas, PhRMA and its member companies see this as a multi-year commitment, requiring a sustainable foundation. Selected examples of actions so far include but are not limited to:

- Surveyed PhRMA members on how they advance diversity and inclusion in the workplace, in their communities and the patient communities they serve.⁶
- Reached out with intention to stakeholders and underserved communities, creating new vehicles to gather feedback and build new partnerships.
- Pushed back against the former administration’s executive order restricting diversity training for our employees.⁷
- Embarked on active listening tours with the communities we seek to better serve to understand the deep and understandable mistrust of the medical research community and connect the historical experiences of patients to health equity.⁸
- Launched a multi-year effort that seeks to bolster practices and infrastructure to foster greater clinical trial diversity by adopting the first ever industry wide principles on clinical trial diversity that will take effect in April 2021.⁹

These recent actions are part of a greater, years-long effort and are part of the industry’s recognition that the status quo needs to change. The biopharmaceutical industry looks forward to being a part of that change. To help advance these goals, it is imperative that industry, government, community partners, patient advocacy organizations, academia, and others find ways to collaborate appropriately on clinical trial diversity in order to reduce barriers and improve access for diverse populations.

II. GENERAL COMMENTS

PhRMA notes that it would be helpful for NIH to specify which department and/or person is on point for consolidating feedback, developing strategy and taking action on this RFI. PhRMA

⁶ The Biopharmaceutical Industry: Improving Diversity & Inclusion in the Workforce. PhRMA. December 2020. <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/S-U/TEconomyPhRMA-DIReportFinal.pdf>

⁷ PhRMA Statement on Presidential Executive Order Restricting Diversity. PhRMA. October 1, 2020. <https://phrma.org/Press-Release/PhRMA-Statement-on-Presidential-Executive-Order-Restricting-Diversity-Training>

⁸ [PhRMA’s Equity Initiative. phrma.org/equity](https://phrma.org/equity)

⁹ PhRMA Principles on Conduct of Clinical Trials. PhRMA. October 14, 2020. <https://www.phrma.org/en/Codes-and-guidelines/PhRMA-Principles-on-Conduct-of-Clinical-Trials>

further suggests that a direct report to the Director of the NIH be appointed and empowered to lead this effort. PhRMA offers that this could be the head of National Institute of Minority Health and Health Disparities (NIMHD) or perhaps there is an opportunity for creating a new role (e.g., a Chief Diversity Officer). This will help ensure accountability for the two main focal points: diversifying the biomedical workforce and addressing health disparities and health equity in research.

Additional clarity on how this grant fits into the overall NIMHD strategy at NIH would also be informative.

In addition to the general comments above, PhRMA provides specific comments below for consideration by NIH.

III. ALL ASPECTS OF THE BIOMEDICAL WORKFORCE

The biopharmaceutical industry is proud to be part of a research ecosystem that develops more innovative medicines than any other country in the world. There is rich evidence demonstrating the inter-connected contributions of NIH-supported research and the biopharmaceutical industry to the research ecosystem. Strengthening diversity and inclusion across the entire research ecosystem and biomedical enterprise means each player must do their part. The reasons for lack of participation in clinical trials are complex and multi-factorial. It is therefore imperative that the practices for diversity and inclusion within NIH's intramural and extramural research systems and those of the biopharmaceutical industry are closely aligned. Sharing of practices, initiatives to enhance clinical trials infrastructure, cultural competency and the use of public-private partnerships are all important ways for stakeholders to advance these goals.

a. Perception and reputation of NIH as an organization.

To promote the perception and reputation of NIH as an organization that supports work force diversity and advocates for racial and gender equity in NIH-funded research, PhRMA provides the following considerations from its own initiatives.¹⁰ The biopharmaceutical industry is taking part in the considerable growth in corporate initiatives and strategies to promote diversity and inclusion and recognizes the benefits to their business and employees, the communities in which they operate, the patients they serve, and the society as a whole, and is committed to enhancing diversity and inclusion within and across their organizations and external stakeholders. Three areas of focus for these broader efforts across industries include, a) increasing diversity of boards of directors or corporate boards; b) directing executive-level positions to oversee Diversity and Inclusion (D&I) strategies; and c) identifying and creating roles for additional D&I professionals.

¹⁰ The Biopharmaceutical Industry: Improving Diversity & Inclusion in the Workforce. PhRMA. December 2020. <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/S-U/TEconomyPhRMA-DIReportFinal.pdf>

As NIH considers its own approach, PhRMA suggests the following foundational approaches that have been deployed by the industry to support D&I efforts:

- Empowering and utilizing employee resource groups,
- Enabling the infrastructure to advance D&I through leadership positions, councils, and teams,
- Education and training to support an inclusive workplace,
- Setting D&I goals and tracking efforts and initiatives to assess impact and success, and
- Leveraging external partnerships to build a diverse talent pipeline and support broader goals.

b. New or existing influence, partnerships, or collaborations NIH could leverage to enhance its outreach and presence with regards to workforce diversity.

Collaboration plays an important role in fostering research and innovation across the entire innovation ecosystem, and the biopharmaceutical industry has established multiple different partnerships in ways that are valuable for all stakeholders. Partnerships across the ecosystem have the capacity to drive information and foster information sharing, help coordinate services across different parties, improve communication and establish feedback mechanisms – all of which contribute to a stronger and more sustainable innovation research ecosystem. The NIH could consider including D&I programs modeled off of work from the industry to reach and support underrepresented populations in biopharmaceutical research, such as targeted scholarships, mentorship or experiential learning experiences to overcome geographical, financial and relational barriers to accessing the research ecosystem. A specific example from one PhRMA member company to bring underrepresented researchers into the ecosystem is a scholars program that aims to open the door to cutting-edge research opportunities for undergraduate students. Made possible through a global commitment from the company’s foundation, the program allows undergraduates from across the world to participate in cohort-based, full-time, independent research projects under the guidance of scientists at world-class institutions. To date, over 4,200 students from more than 760 colleges and universities have participated, benefitting from this research and mentorship, seminars and networking events and interaction with their peers and leading scientists. Of the alumni who have maintained contact, more than 95% of scholars who have graduated from colleges are now pursuing an advanced degree or career in a scientific field.¹¹

The industry also believes that building a diverse STEM pipeline of researchers will translate to more diversity in the biomedical research ecosystem. To help build up a strong and diverse pipeline of researchers, NIH could consider ways to directly partner with communities or educational institutions to provide targeted opportunities. For example, a member company is working to build bridges to currently underrepresented students in STEM with a program that

¹¹ The Biopharmaceutical Industry’s Sustained Commitment to Inspiring and Advancing Tomorrows STEM Workforce. PhRMA. October 2020. Pg. 45. https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/S-U/STEM-Report_Final.pdf

gives company employees the opportunity to mentor high school students on STEM career pathways and work together to solve “real world” STEM issues such as health literacy.¹² Another member company has a virtual lab experience program. As a result of economic or geographic limitations, millions of students do not have access to one of the most central aspects of being a scientist, which is working in a laboratory. This free online platform is dedicated to driving more inclusion in the research process by providing users with access to personalized instruction, virtual lab experiences and networking opportunities across the global scientific community.¹³ Another PhRMA member company and their foundation are actively seeking partnerships with Historically Black Colleges and Universities (HBCUs) to increase the reach.¹⁴ Similarly, another PhRMA member company participates in the HBCU Partnership Challenge, a commitment to working with HBCUs to forge stronger, strategic partnerships and incorporate these colleges and universities within their D&I efforts.¹⁵ Adopting these or similar practices are just a few of the ways that NIH could build bridges to communities and educational institutions to strengthen the pipeline of talent necessary to build a diverse STEM workforce.

c. Factors that present obstacles to training, mentoring or career paths leading to under representation of racial and ethnic groups in the biomedical research enterprise.

Research from economists at the Harvard-based Opportunity Insights finds that if women, people of color, and children from low-income families became inventors at the same rate as men from high-income families, innovation in the U.S. could increase as much as four-fold.¹⁶ While skills and ability play a role in determining future STEM workers, socioeconomic factors such as family income and neighborhood can have a significant impact on whether students grow up into STEM or research fields.

NIH could consider creating specific networking and mentorship opportunities for underrepresented populations as they are considering their career options. These programs have the potential to expose students to career options they might not have considered previously. Researchers from Opportunity Insights also find evidence that increasing exposure to research through activities such as mentorship programs could help expand the STEM pipeline.¹⁷ The biopharmaceutical industry has seen first-hand how effective mentorship and networking can be used to encourage all students, including underrepresented populations, to join and remain in the STEM field. For example, one PhRMA member company uses mentorship and networking to build the pipeline of STEM professionals. It hosts a one-year summer program and afterschool internship program aimed at LGBTQIA high school students who have an interest in STEM.

¹² The Biopharmaceutical Industry’s Sustained Commitment to Inspiring and Advancing Tomorrows STEM Workforce. PhRMA. October 2020. Pg. 50. https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/S-U/STEM-Report_Final.pdf

¹³ The Biopharmaceutical Industry’s Sustained Commitment to Inspiring and Advancing Tomorrows STEM Workforce. PhRMA. October 2020. Pg. 51. https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/S-U/STEM-Report_Final.pdf

¹⁴ The Biopharmaceutical Industry: Improving Diversity & Inclusion in the Workforce. PhRMA. December 2020. Pg. 20. <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/S-U/TEconomyPhRMA-DIRReportFinal.pdf>

¹⁵ The Biopharmaceutical Industry: Improving Diversity & Inclusion in the Workforce. PhRMA. December 2020. Pg. 21. <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/S-U/TEconomyPhRMA-DIRReportFinal.pdf>

¹⁶ Rebecca Linke, MIT, “Lost Einsteins: The US may have missed out on millions of inventors,” February 2018.

¹⁷ Rebecca Linke, MIT, “Lost Einsteins: The US may have missed out on millions of inventors,” February 2018.

This company partners with the College of Physicians and the program provides mentorship, builds career awareness, and offers an accepting STEM-oriented space.¹⁸ Another member company has a mentorship program where students come to the company's campus once a week for an entire school year and the students are paired with mentors to work together on homework or hands-on science projects that build their interest and confidence in science, offering them a special opportunity to receive individual attention from supportive adults. More than 1,000 students have been mentored since the program began.¹⁹

As part of the strategy to ensure career progression, NIH could consider establishing employee resource groups, mentorship programs, and sponsorship programs targeted specifically at those in their early to mid-careers. PhRMA member companies are utilizing mentorship and networking programs within the workplace to ensure career progression and help prevent women in particular from leaving the workforce. In fact, 94% of PhRMA members utilize employee resource groups (ERGs) as a platform for networking events and mentorship opportunities. One member company specifically has an employee resource group for working parents that offers peer-to-peer mentoring and facilitates connections among employees to help pursue professional success.²⁰ Other companies have created groups specifically for women to create an environment to foster connections, mentorship and development within the workplace and professional development programs for women and multicultural employees who demonstrate strong leadership potential.²¹

d. Barriers inhibiting recruitment and hiring, promotion, retention and tenure.

Innovators and researchers thrive when cultural and institutional barriers within workplaces are minimized and removed. The biopharmaceutical industry has utilized a multipronged approach to making the workplace more diverse and inclusive. Specifically, the biopharmaceutical industry is focusing on education and training to help minimize cultural and institutional barriers. Education initiatives such as unconscious or implicit bias training for organizations throughout the innovative ecosystem is a strategy/model to help overcome and eliminate barriers.

¹⁸ The Biopharmaceutical Industry's Sustained Commitment to Inspiring and Advancing Tomorrow's STEM Workforce. PhRMA. October 2020. Pg. 30. https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/S-U/STEM-Report_Final.pdf

¹⁹ The Biopharmaceutical Industry's Sustained Commitment to Inspiring and Advancing Tomorrow's STEM Workforce. PhRMA. October 2020. Pg. 58. https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/S-U/STEM-Report_Final.pdf

²⁰ The Biopharmaceutical Industry: Improving Diversity & Inclusion in the Workforce. PhRMA. December 2020. <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/S-U/TEconomyPhRMA-DIReportFinal.pdf>

²¹ The Biopharmaceutical Industry: Improving Diversity & Inclusion in the Workforce. PhRMA. December 2020. <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/S-U/TEconomyPhRMA-DIReportFinal.pdf>

An evaluation of 40 years of research on diversity training finds evidence of a positive impact on changing knowledge, attitudes, and behaviors of different populations.²² Notably, the analysis also shows that the most impactful diversity trainings were complemented by other D&I initiatives, were targeted to both awareness and skills development, and were conducted over a significant period of time. PhRMA member companies are proactively training employees to advance diversity and inclusion, especially on subjects such as overcoming unconscious or implicit biases and increasing understanding of and appreciation for cross-cultural collaboration benefits. The NIH could align with the biopharmaceutical companies who are developing cultural competencies, anti-discriminatory behaviors and company-wide trainings for all employees as well as trainings for management-levels specifically.

A 2020 report on PhRMA members' efforts to increase D&I in the workforce demonstrates these efforts.²³ For example, one PhRMA member company redesigned its D&I training to be inclusive of topics such as unconscious bias, physiological safety, and supporting an "Upstander" mindset, which denounces all acts of racism, discrimination, and violence that initiates positive actions that promote meaningful, cultural change, and reinforces a safe environment of belonging via internal and external communications.

Beyond explicit training designed to raise awareness of unconscious bias and different cultures, advance anti-discriminatory behaviors, and other related areas, numerous member companies promote training among their underrepresented employees to help support their career advancement and develop cohorts of leaders. This can help increase the number of diverse managers and leaders within the industry. The NIH could consider deploying and implementing trainings and development opportunities like these if they have not yet done so.

e. Successful actions to improve representation, equity and inclusion and/or reduce barriers within the internal workforce and across the broader funded biomedical research enterprise.

The biopharmaceutical industry has made a significant, sustained commitment to enhancing the country's STEM education and diverse talent pipeline. The biopharmaceutical industry's sustained commitment to support STEM education includes:²⁴

- Industry financial support totaled \$204 million in the last 5 years.
- 7.4 million students have been reached by industry-sponsored STEM programs.

²² The Biopharmaceutical Industry: Improving Diversity & Inclusion in the Workforce. PhRMA. December 2020. <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/S-U/TEconomyPhRMA-DIReportFinal.pdf>

²³ The Biopharmaceutical Industry: Improving Diversity & Inclusion in the Workforce. PhRMA. December 2020. <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/S-U/TEconomyPhRMA-DIReportFinal.pdf>

²⁴ The Biopharmaceutical Industry's Sustained Commitment to Inspiring and Advancing Tomorrow's STEM Workforce. PhRMA. October 2020. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/S-U/STEM-Report_Final.pdf

- 25,000 teachers have been reached by industry-sponsored STEM programs.
- Companies and their foundations awarded nearly 2,500 STEM education grants.
- 70+ STEM programs initiated by PhRMA members in the last 5 years.
- Just over half of the reported STEM education programs are intentionally designed to engage underrepresented populations.

The innovative biopharmaceutical industry is working to broaden participation of historically underrepresented groups in STEM so that the American STEM talent pool, workforce, and biomedical researchers can better reflect our nation’s diverse population. This includes engaging all demographic groups in STEM education and experiential learning and ensuring STEM classrooms are representative of the nation. These initiatives demonstrate that sustained and consistent action by the NIH will be necessary to make progress in developing a diverse STEM workforce for the future. The industry recognizes that it will be critical to partner with the public sector to ensure progress across the biomedical research enterprise and hopes these examples will be useful as NIH develops its plan.

IV. POLICY AND PARTNERSHIPS

a. Best practices or proven approaches to build new or enhance existing partnerships and collaborations between investigators and research-intensive institutions.

PhRMA believes that advancing the inclusion of diverse populations, including racial and ethnic populations, in clinical trials relies on having trusted partners working with community-based clinical trial infrastructure. This is important to identify barriers to enrollment of underrepresented demographic subgroups in clinical trials and employ strategies to encourage greater participation, while also ensuring an efficient drug development process.²⁵ PhRMA believes that partnerships with multiple stakeholders and targeted and sustained initiatives are required to provide solutions to these challenges.

PhRMA recommends that NIH collaborate and partner with biopharmaceutical companies, together with patient advocacy organizations, FDA and other regulatory authorities, academia and other stakeholders to continue to work towards finding ways to increase diversity in clinical trial participation. For example, PhRMA member companies have employed a range of tools and strategies to enhance clinical trial awareness and increase trial diversity, such as real-time recruitment tracking dashboards, new investigator training programs, and partnerships with minority advocacy groups. However, PhRMA also recognizes that there is more work to be done. PhRMA believes that multi-stakeholder initiatives are required to provide solutions to these challenges and suggests that NIH partner with stakeholders to work together to identify and share potential best practices to advance clinical trial diversity. PhRMA suggests that a list of potential best practices includes strategies to increase trust and decrease stigma towards the medical profession, as well as to minimize barriers to clinical trial participation, while also

²⁵ Enhancing the Diversity of Clinical Trial Populations - Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry, Final Guidance. FDA. November 2020. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial>

addressing recruitment and retention of diverse populations. This should also include possible measures of success and tracking progress. PhRMA requests that NIH share best practices with stakeholders in the clinical trial ecosystem, especially academic sites and NIH run co-operative groups.

V. RESEARCH AREAS

a. **Significant research gaps or barriers to expanding and advancing the science of health disparities/health inequities research and proposed approaches to address them.**

PhRMA applauds the NIH for seeking stakeholder input on the areas and types of engagement NIH should prioritize in the coming years and the potential mechanisms that can be used to implement them. PhRMA supports NIH's efforts "to advance racial equity, diversity, and inclusion within all facets of the biomedical research workforce, and expand research to eliminate or lessen health disparities and inequities,"²⁶ including efforts focusing on outreach and communication, as well as research and collaboration.

PhRMA and its members request that NIH supports and partners in efforts to advance training of clinical trial personnel from diverse backgrounds who can assist in increasing access and enhancing educational efforts on medical product development. Clinical trial investigators with diverse racial and ethnic backgrounds can serve as a trusted source of information on medical product development to underrepresented demographic populations. Moreover, these clinical trial investigators also have significant knowledge of the barriers to clinical trial participation among certain underserved populations and can serve as trusted messengers.

PhRMA and its members believe it is important to work with multiple stakeholders in the clinical trial ecosystem to better serve historically underserved populations. By diversifying clinical trial populations, we can better reflect the broad patient population that will use a medicine once it is approved and thereby help improve health outcomes. In 2020, PhRMA and its member companies launched the first ever industry-wide principles on clinical trial diversity. The goal of these principles is to enhance education about the role of clinical trials, increase awareness of clinical trials, expand diversity in clinical trials by reducing barriers to clinical trial access and participation, use real world data to enhance information on diverse populations, and increase information about diversity and inclusion in clinical trials. PhRMA looks forward to working in partnership with NIH and academic researchers to help advance these principles.

VI. FURTHER IDEAS

a. **Additional ideas for bold, innovative initiatives, processes or data-driven approaches that could advance the diversity, inclusion, and equity of the biomedical research workforce and/or promote research on health disparities.**

²⁶ Request for Information (RFI): Inviting Comments and Suggestions to Advance and Strengthen Racial Equity, Diversity, and Inclusion in the Biomedical Research Workforce and Advance Health Disparities and Health Equity Research (NOT-OD-21-066). <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-066.html>

While the biopharmaceutical industry understands that innovative medicines are only successful if they can reach the patients who need them, many of the challenges in accessing healthcare are often outside of the patient’s control. As part of its commitment to health equity and advancing inclusive research, one PhRMA member company commissioned a landmark study of more than 2,000 patients in the U.S. to better understand how they perceive and interact with the healthcare system. Initial findings illuminate these inequities with new clarity, revealing a crisis of trust in the healthcare system among medically disenfranchised communities.

NIH has a critical public health mission to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to help enhance health, lengthen life, and reduce the burdens of illness and disability. As part of its efforts, NIH could consider increasing its research focus on how different populations respond differently to health interventions. In particular, there is a critical need for more information about how varying intrinsic (e.g., genetics, age, sex) and extrinsic (e.g., socioeconomic status, culture, drug-drug interactions, diet, medical practice) factors affect how individuals respond to medicines and other medical interventions.

VII. CONCLUSION

PhRMA thanks NIH for seeking comments on this important topic. PhRMA strongly agrees and supports the work of NIH to help ensure scientific discoveries truly benefit all, incorporating diverse skill sets, viewpoints, and backgrounds, including collaboration with multiple stakeholders. PhRMA looks forward to further collaboration to advance transparent patient-centric approaches to drug development that may address important health concerns of racial and ethnic populations that are underrepresented or underserved in the medical product development process.

Respectfully submitted,

/s/

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