



MILKEN
INSTITUTE
FasterCures

ACHIEVING HEALTH EQUITY

An Action Plan to Address Diversity across
Clinical Trials and Biomedical Research

YASMEEN LONG AND ESTHER KROFAH

ABOUT US

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FasterCures, a center of the Milken Institute, is working to build a system that is effective, efficient, and driven by a clear vision: patient needs above all else. We believe that transformative and life-saving science should be fully realized and deliver better treatments to the people who need them.

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EXECUTIVE SUMMARY

Clinical trials have been used for decades as the primary way by which researchers determine if a new treatment—e.g., a drug or medical device—is safe and effective for human use. Within the biomedical research ecosystem, participants in clinical trials often do not represent the populations bearing the burden of the diseases under study. The COVID-19 pandemic brought issues of inequity into starker focus, as historically underserved communities suffered disproportionately. This disconnect is a product of history, insufficient representation, structural racism, systemic inequality, and a lack of sustained action and leadership in clinical research at the national level.

If the primary objective of biomedical research is to leverage innovation to create healthier communities, extend life, and more effectively treat or cure disease, then these persistent inequities run counter to that goal and create unnecessary barriers to health and wellness. According to the [Food and Drug Administration \(FDA\) 2015-2019 Drug Trials Snapshots Summary Report](#), of all participants in clinical trials, only 7 percent were Black or African American, 13 percent were Hispanic or Latino, and 1 percent identified as American Indian or Alaska Native, in comparison to 76 percent of trial participants identifying as White. According to a Health Affairs blog, "[Clinical Trials in Crisis: Building on COVID-19's Lessons Toward a Better Future](#)" (August 2021), when clinical trials are appropriately diverse and inclusive, they can represent the broader population and increase the health of underrepresented groups such as older adults, rural populations, pregnant or lactating women, and people with limited access to technology. While persistent inequalities constitute an unfortunate reality in health research, it is a fact that we feel can be addressed through a greater understanding of the underlying factors at play, the creation of models that can be adopted and adapted by key players in the biomedical research ecosystem, and the development of concrete actions for change.

To drive needed actions forward in a structured and impactful way, FasterCures convened an advisory working group of experts from academia, industry, policy groups, patient advocacy, and disease-specific patient organizations to dive deeper into these issues. To inform our action report, our team also gleaned the literature across these thematic areas in research and policy. This report is the outcome of these parallel efforts and presents both a tool for understanding the issues facing biomedical research and a concrete action plan with a clear vision. We expect that this report will help key decision makers with influence in biomedical research and innovation to reform the system for the long term.

BACKGROUND

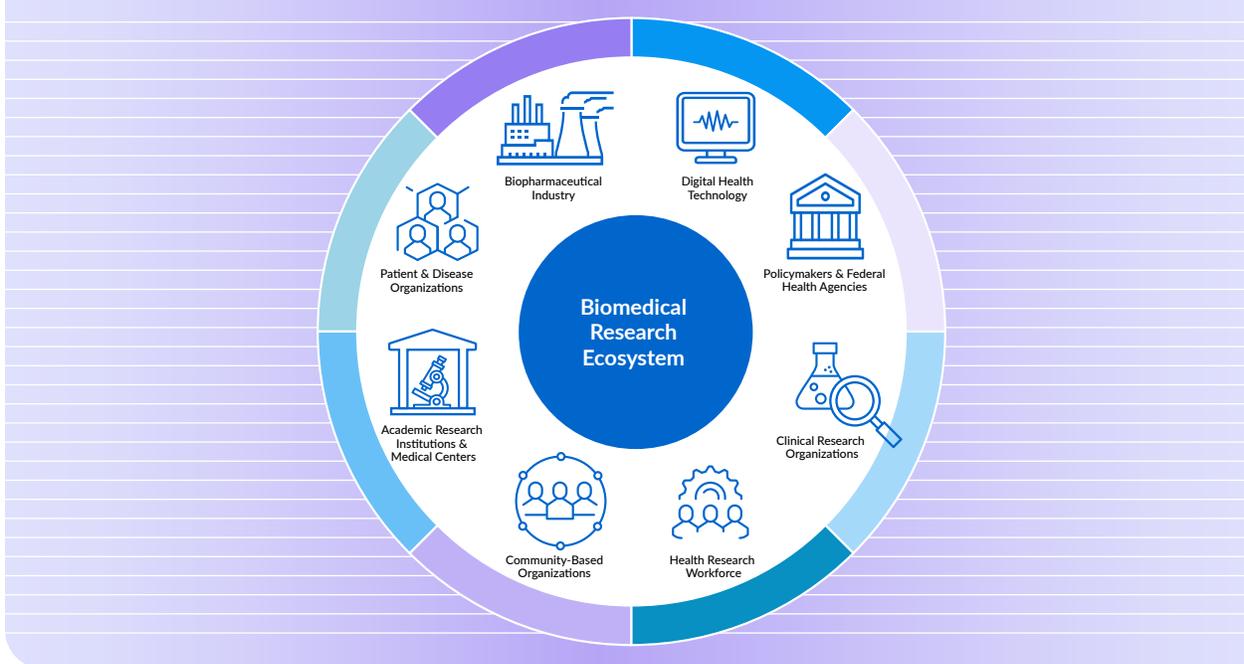
The effects of the COVID-19 pandemic resulted in the highest mortality rates among racial and ethnic minorities. Over 700,000 COVID-19-related deaths had been recorded in the US alone by October 2021.¹ Since the pandemic began in 2020, in the US, Black and Hispanic/Latinx communities have experienced the highest mortality rates. Among all COVID-related deaths in the US, Blacks/African Americans accounted for 30 percent, Hispanics/Latinx for 37 percent,

and Whites for 12 percent.² Initial enrollment in vaccine clinical trials to combat COVID-19 was quite low until leaders within government agencies and other stakeholders pushed for greater representation to encourage vaccine acceptance by these demographic groups. Following the focused recruitment efforts, COVID-19 clinical trials for the Moderna vaccine ultimately enrolled 9.7 percent Black, 20 percent Hispanic, and 79.4 percent White subjects out of a total of 27,817 trial participants.³

When the root causes of the lack of diversity in clinical trial participation are examined, a common theme emerges: a lack of trust that spans generations. This problem has been acknowledged but not addressed for decades. The entry point to clinical trials often stems from interactions with providers in care settings. According to the Institute of Medicine (IOM) 2003 report *Unequal Treatment*, patients solicit the health-care system with various needs and expectations, which include preferences that are socially and culturally determined. However, patients often encounter providers who lack professional training in cultural competency and carry unconscious bias when attempting to meet patients' expectations.⁴ The culture of mistrust in medical research that stems from years of unethical treatment of minority communities has impeded much-needed participation and inclusion of patients on the basis of race and ethnicity, gender, age, and other social and environmental characteristics.⁵ At a workshop on implicit bias, held by the National Academies, Marcella Nunez-Smith, MD, chair of the White House COVID-19 Health Equity Task Force, stated, "Research shows that Black patients are systematically undertreated for pain relative to white patients ... there is implicit bias in the system, and it's led to earned distrust."⁶ The IOM report further states that mistrust of the health-care system and, by extension, of the clinical trials enterprise, stems from a long history of disparities and inequities in the system.

For many minority communities, patients' preferences for treatment of disease can be difficult to separate from mistrust of health professionals because of routine experiences with racial discrimination and a history of segregated and inferior health-care services.⁷ Historical traumas, such as the US Public Health Service Syphilis Study at Tuskegee, as well as daily experiences with both implicit and explicit forms of racism, have created an understandable level of mistrust in Black and Brown communities. However, we should focus on present-day interactions within our health-care system and not only on historical abuses.⁸ Future models for health-care transformation could include a more diverse workforce. In Oakland, California, 1,374 Black men were recruited with financial incentives to a randomized trial evaluating the uptake of preventive measures as it relates to racial concordance with the consulting physician. The study concluded that participants were more likely to accept preventive measures and medical advice from Black physicians, particularly for invasive procedures.⁹

FIGURE 1: STAKEHOLDERS IN THE BIOMEDICAL RESEARCH ECOSYSTEM



Source: Milken Institute (2021)

KEY OVERALL CONSIDERATIONS FOR ACHIEVING DIVERSITY IN CLINICAL TRIALS AND EQUITY ACROSS BIOMEDICAL RESEARCH

To guide the development of our action steps, we have outlined the following key overall considerations to inform the recommendations in this report. In concert with our advisory working group, we identified five primary areas of focus to guide the development of our action steps and consensus vision. The components of this report may not reflect all viewpoints. The following five points form the basis for our recommendations:

1. Identify opportunities to improve participation from underrepresented populations in clinical trials. These communities include racial and ethnic minorities such as African American, Black, Latinx, Asian, American Indian, and Alaska Native; groups with low health literacy; and groups with limited access to high-quality health care.
2. Leverage the authority of federal and regulatory agencies to eliminate standardized processes that perpetuate inequity.
3. Balance value incentives, including financial investments and expansion of community infrastructure to access clinical trials.

4. Take full advantage of digital health technologies, as well as real-world data and evidence, to incentivize change and improve inclusion, engagement, and participation in biomedical research and clinical trials.
5. Prioritize investment in communities and establish an infrastructure for clinical trials where people live, work, play, and worship.

STAKEHOLDER ACTION STEPS AND RECOMMENDATIONS

The following actionable recommendations focus on the role of federal and regulatory agencies, academic research institutions and medical research centers, the biopharmaceutical industry, nonprofit and private research funders, clinical research trial sites, patient advocacy and disease foundations, and community-based organizations. These key stakeholders have the decision-making power to critically address long-standing disparities and inequities in clinical trials and biomedical research. The recommendations are organized by key focus areas and followed by specific action steps. Each of these action steps is organized by categories we believe are critical to address at this time for engagement, funding, data collection, workforce, and accountability.

I. Federal and Regulatory Agencies

These recommendations are focused on the role of federal health agencies such as the National Institutes of Health (NIH), FDA, Health Resources and Services Administration (HRSA), Agency for Healthcare Research and Quality (AHRQ), Centers for Medicare & Medicaid Services (CMS), Office of Management and Budget (OMB), and Government Accountability Office (GAO). These agencies include major funders of biomedical research and health-services research, in addition to offices that conduct regulatory reviews, maintain oversight, and approve product applications. Federal agencies can set policies for national health priorities. Many federal agencies fulfill several functions and serve as regulators to hold research entities accountable.

Action Steps

Engagement

- Develop requirements for researchers to include a plan for community engagement in their grant proposals and regulatory applications.
- NIH and FDA could enlist patient and community advisory councils or boards and develop a patient-centered clinical trials equity task force to increase public awareness of clinical trials and make online clinical trial databases more patient- and participant-friendly.
- Include a requirement for equitable racial and ethnic representation on NIH, FDA, HRSA, and AHRQ grant-review committees.

- Identify regions and locales lacking access to US clinical trials; fund expansion of clinical-trial sites, federally qualified health centers, health-care clinics, and medical centers.
- Conduct a study and report results by a federal agency (e.g., the National Center for Advancing Translational Sciences) on how to expand federal clinical trials capacity to include community-based sites and infrastructure, focusing on building local trial sites and having the research and operational needs to maintain such trial sites.

Funding

- Develop measures to uncover bias in the grant-review processes for biomedical research funded by NIH, FDA, and AHRQ; maintain a commitment to uphold these efforts toward diversity in clinical trials.
- Ensure that scientific funding review committees equitably represent the US population (e.g., by gender and sex, race and ethnicity, age) in the grant-award process and include accountability metrics to secure funding.
- Provide funding to HRSA to expand inclusive clinical trial training and patient-navigation programs (e.g., employ community health workers to support clinical research competency and health literacy, establish programs to build meaningful relationships with community health providers across clinical trial sites, increase trial-site training programs led by NIH).

Data Collection

- FDA could address barriers inhibiting accurate data collection on race and ethnicity in their reporting requirements. FDA centers could ensure accurate data on race and ethnicity in their reporting structure across all therapeutics, devices, and biologics.
- Ensure equitable data collection at clinical trial sites, including the use of real-world data (RWD) and real-world evidence (RWE), to allow agencies such as FDA to integrate these data better in regulatory policy decisions, including the review of Investigational New Drug (INDs) and Biologics License Application (BLA) processes.
- Leverage data collection, including RWD and RWE, at trial sites to explore health inequities as well as safety and efficacy in the drug approval process and in regulatory application data at clinical trial sites.
- Require data models at FDA to collect data and incorporate RWD and RWE into clinical trial data-collection protocols; ensure that data models and algorithms include subpopulations of racial and ethnic groups.
- Increase the use of RWD and RWE in decision-making to improve the quality of clinical trial data analytics supporting regulatory policies based on ensuring racial and ethnic diversity across all drug and product development.

Workforce

- Federal agencies, such as the Department of Education and NIH, should support policies to increase diverse and equitable admissions and enrollment of students into academic degree and fellowship programs, and develop mentorship programs to fund the development of underrepresented groups in biomedical research.

Accountability

- Promote regulatory bodies, such as Institutional Review Boards (IRBs), to ensure the inclusion of requirements for equitable racial and ethnic representation in participant recruitment and enrollment and in access to opportunities to participate in clinical trials. A mandate would broaden the reach of policies requiring clinical research to serve the minority communities that manifest the widest health disparities.
- The OMB and GAO should study the socioeconomic and environmental barriers that limit the participation of underrepresented communities in clinical trials.
- CMS should establish a reimbursement model for health care providers participating in clinical trials, allowing for a permanent add-on payment if coverage for clinical trials is used as a continuum of care when other treatments are unavailable, including in quality improvement payment programs.

II. Academic Research Institutions and Medical Research Centers

Academic clinical research institutions and academic health systems have unique connections to the communities they serve. Academic clinical researchers should determine what is most important to the community when designing and conducting a particular study and disseminating the results in the community.

Action Steps

Engagement

- Academic research centers could partner and collaborate with industry in developing a clinical trials education and communications campaign to disseminate and promote clinical trials to all patient communities and potential trial participants.
- Ensure that research plans and protocols are codesigned with patient advocates and underrepresented community members, to align research outcomes with broader impact and benefit to them.
- Academic community partnerships should address the barriers that impede patients and communities in accessing trials, by developing relationships with community leaders and health centers to expand community outreach. To ease access to trials, principal investigators could identify those factors most important to the communities.

- Develop inclusive patient and research navigation programs employing community health workers or promotoras, lay health workers, and health educators to support capacity building, outreach, cultural competency, and health literacy in clinical research.

Funding

- Require funding for community-engaged research to facilitate collaboration among principal investigators, research staff, and community leaders. Funding could also be provided directly to community partners rather than only to academic institutions, and NIH could require community partners as co-PIs.

Data Collection

- Academic institutions can assume responsibility for collecting patient/participant data on race, ethnicity, and language preference.

Workforce

- Expand leadership pipeline opportunities in an ongoing effort to recruit a diverse pool of talented biomedical researchers and innovators, by supporting undergraduate and graduate student fellowship opportunities.
- Identify the barriers inhibiting recruitment, tenure, and promotion, including the barriers that research scientists from underrepresented groups face in hiring and promotion within the academic research workforce.
- Examine where biases exist in research trainee sponsorship and highlight opportunities for collaboration with academic research institutions and medical centers.
- Ensure diverse faculty promotions, equitable and inclusive workforce training programs, and professional development opportunities.
- Create new degree and professional programs and/or evaluate existing programs to ensure that health equity is incorporated in curricula with a focus on clinical research and trial development.

Accountability

- Prioritize research plans and the development of recruitment materials (e.g., informed consent, study outreach fliers) under IRB authority in academia to include an equity lens for communities of interest targeted for medical research in the protocol approval process. Translate recruitment materials to the languages colloquially spoken in diverse communities.
- IRBs and research administration offices could ensure that the requirements for the study protocol-approval process involve a diversity and inclusion plan for health equity in clinical research design. Research and administration offices should hold PIs accountable for ensuring that clinical research programs are inclusive in site selection, enrollment, and study execution.

- Require PIs to incorporate study evaluation metrics, milestone checks, and monitoring to confirm that the clinical research program achieved its goals for clinical trial diversity in the design and conduct of the research, and to provide transparent reporting if goals are not met.

III. Biopharmaceutical Industry

Biopharmaceutical and biotech companies can invest in communities by working with them as collaborators and building their trust in clinical trials. Strategies to finance community investment for research infrastructure can include a multi-stakeholder approach. The use of public-private partnerships to expand community-based infrastructure for clinical trial sites is imperative to achieve diversity in trials that better represent minority and underrepresented populations.



Action Steps

Engagement

- Support the building of academic, industry, and commercial clinical-trial site infrastructure in underrepresented communities and incorporate engagement practices into standard operating procedures and quality measures.
- Increase engagement strategies and develop integrative structures to ensure uptake of patient and community perspectives in trial development.

- Ensure that patient and community engagement generally occurs at an early stage in R&D and allows for meaningful input; ensure, too, that such engagement is perceived as a means to support the marketing of, and recruitment to, the study.
- Initiate community engagement early in the planning process to obtain feedback on protocol design, subject eligibility/ineligibility criteria, and outcome measures.
- Biopharma-sponsored PIs could collaborate with patient advocacy organizations and embed requirements for patient engagement to guide research and drug-development decisions. This collaboration should be part of standard operating procedures and quality measures across key performance indicators for clinical trial design, recruitment, enrollment, and study execution.
- Establish partnerships with community leaders to ensure financial benefits and returns on community value and investment, in support of community development and infrastructure for local community-based research.

Data Collection

- Explore using telehealth and electronic health visits as a potential means to ensure novel equitable data collection plays a significant role in clinical trial diversity.
- Identify and address gaps in accurate data collection by demographics, race, and ethnicity.

Funding

- Provide financial support to fund undergraduate and graduate student fellowships, as well as apprenticeships, to develop a diverse pipeline of researchers; create partnerships with historically Black colleges and universities and minority-serving institutions.
- Invest in contract research organizations (CROs) owned and led by underrepresented racial and ethnic groups—specifically Black and African American, Hispanic and Latinx, and American Indian and Alaska Native populations; invest in all CROs to identify clinical trial sites.

Workforce

- Address any lack of diversity and inclusion in members of board governance, C-suite executives, and senior leadership teams in positions of authority in the workforce pipeline and throughout the biomedical research industry.
- Invest in expanding the pipeline of PIs who are underrepresented by race and ethnicity to increase diversity across industry within biopharma and clinical research sites.
- Sponsor junior PIs and invest in loan forgiveness programs, college and university fellowship programs, and mentorship opportunities; create leadership training programs and focus on inclusive eligibility criteria and allyship.

IV. Nonprofit and Private Research Funders

Nonprofit and private funders, such as philanthropies and investment firms, can provide the capital needed to expand infrastructure and support efforts for increasing diversity in clinical trials by funding health programs and promoting biomedical innovation. The use of public-private partnerships to develop community-based infrastructure for clinical trial sites is imperative to achieve diversity in clinical trials that better represent minority and underrepresented populations.

Action Steps

Engagement

- Leverage multi-stakeholder collaborations across the clinical research and public health and policy sectors, such as local public health agencies and community foundations.
- Across nonprofit and philanthropic funders, partnerships should involve engaging and collaborating with local community business leaders and patient groups.

Funding and Data Collection

- Institutional investors can drive change, applying environmental, social, and governance (ESG) research criteria (e.g., Sustainalytics, MSCI Index) around capacity building and infrastructure development; they may leverage trial safety data to make investment decisions about diversity and inclusion in clinical trials and biomedical research.
- Funders could align incentives that will value underrepresented communities as expert resources and collaborators, and will include community-based stakeholders to evaluate the requirements for meaningful community member involvement.
- Financing priorities for research and investment in community clinical trial site infrastructure could be a method to demonstrate the value of community expertise and partnership.

Workforce

- Increase financial support and mentorship opportunities for professional workforce development in community-based clinical research; research foundations can also invest in diverse recruitment of PIs, in addition to their own investment in PIs and in setting up a development pipeline.
- Sponsor fellowship and professional workforce-development training programs to build local clinical research staff and capacity at community sites.

Accountability

- Prioritize underrepresented communities when funding health programs, particularly the communities that confront barriers to accessing clinical trials and limitations in health systems.

- Take action to eliminate barriers and disparities causing limitations related to physical, environmental, social, and economic determinants, or access to employment or financial capital.
- Include investment evaluation metrics for diverse representation in trials as a measure of accountability.

V. Clinical Research Trial Sites

Clinical research sites are where participants are enrolled in a clinical trial. Many trials conducted by industry are executed by CROs and commercial sites representing industry-funded trials that also contribute to closing the diversity gaps in clinical trial enrollment. Partnering with patient advocates and community leaders, CROs can apply community engagement methods and build relationships to support communities at the local level, including primary care facilities and community health centers.



Action Steps

Engagement

- Engage with diverse clinical research team members, including managers, academic researchers, and PIs across the clinical research enterprise.
- Establish collaborations to agree on common ground for achieving racial and ethnic diversity in data collection endpoints. Leverage these collaborations toward increasing participation and representation in trials for the diseases affecting the least-represented populations.
- Build partnerships with community-based health organizations and with health-service providers.
- Clinical-research program staff and study investigators at CROs and commercial trial sites, and academic research centers could include in their research plans a requirement for education and training with regard to culturally and linguistically relevant research-study recruitment materials codeveloped with local community members.
- Partner with public health communications organizations to develop culturally competent awareness campaigns about new and emerging clinical trials.

Data Collection

- Make telehealth and electronic visits available to access clinical trials and leverage digital health technologies and innovations, including novel, equitable data-collection methods.

Workforce

- Ensure diversity and inclusion among clinical research program staff, including clinical trial coordinators, research managers, and trial site staff who represent the populations under study.
- Ensure the inclusion of professionally trained clinical researchers who are aligned with the patient and research-participant community.

Accountability

- Develop patient- and community-informed roadmaps to help co-designers and study volunteers locate research studies; engage community expertise to lead the development of relevant recruitment and enrollment materials.
- Develop accessible mechanisms that ensure collaboration with leaders of qualified community-based organizations to benefit the entire clinical trial recruitment practice.

VI. Patient Advocacy, Disease Foundations, and Community Health Organizations

Patient advocacy and disease foundations and community health organizations are often the closest representatives of patients with particular conditions; they gather data and information relevant to their community's needs. Patient and community organizations can report on lived experience with a health condition to guide funding decisions or lend their expertise to inform health-policy decisions. Community health organizations support and provide health care to the local community. They can advocate for what matters most to them, including how to access and enroll in a clinical trial or share best practices for meaningful engagement methods.

Action Steps

Engagement

- Build relationships to support expanding the infrastructure to make clinical trials accessible to underrepresented communities at primary care and community health-care facilities.
- Leverage the support of community-based organizations, leaders, and local businesses to build patient and community advisor coalitions.

Workforce

- Prioritize the use of community health programs and direct attention to developing inclusive clinical trial training and patient-navigation programs, deploy the community health worker/promotores workforce to support capacity-building for clinical research competency.
- Develop opportunities for CHWs and lay health workers to build meaningful relationships with health-care providers across community health centers (CHCs) and clinical trial sites.

Accountability

- Educate and train the patient and clinical trial-participant communities in clinical research content agreed upon by various stakeholders.
- Eliminate barriers to allow patients and communities access to clinical trials according to their needs.
- Collaborate with clinical research site teams in implementing procedures to include patient advocates and community engagement methods to inform drug- and product-development processes.
- CHCs could become a means of making clinical trials more accessible to underrepresented communities. Development may include working with federal agencies (e.g., NIH, HRSA, AHRQ) to develop a federal, community-site, clinical trials training program.

CONCLUSION

During the COVID-19 pandemic, and despite a growing awareness of systemic inequities in health care and medical research, many communities continued to experience disproportionate health disparities and inequalities. Historical mistrust of health systems and medical research on the part of underrepresented groups is a contributing factor. Diverse representation in clinical trials helps to explain the benefits and risks of treatments to underrepresented populations in racial and ethnic subgroups.¹⁰ More effort is required from all stakeholders across the biomedical research and innovation ecosystem to build trust systematically and overcome a generation of neglect of health priorities among underrepresented communities. An important action step that we must prioritize is the establishment of a nationally coordinated US community-based clinical trials network. Investment in the appropriate infrastructure, resources, and workforce development, together with the inclusion of community engagement, could meaningfully augment efforts to achieve diversity across the clinical trials enterprise.

More health challenges lie ahead as a result of the COVID-19 pandemic; however, these action steps and recommendations could coalesce around a starting point in the development of a coordinated, multi-stakeholder clinical trials network, issuing a call to action. Federal agencies have a large part to play in aligning the appropriate financial and value incentives as part of this effort. Development of a unified strategy and plan across biomedical research and innovation, as well as collaboration with patient organizations and underrepresented communities, must be recognized as the key priority in devising new models for conducting clinical trials now and in the future.

APPENDIX

Glossary of Abbreviations

AHRQ: Agency for Healthcare Research and Quality

BLA: Biologics License Application

CDC: Centers for Disease Control and Prevention

CHC: community health center

CHW: community health worker

CMS: Centers for Medicare & Medicaid Services

FDA: Food and Drug Administration

GAO: Government Accountability Office

HRSA: Health Resources and Services Administration

IND: Investigational New Drug

IOM: Institute of Medicine (now known as the National Academy of Medicine)

IRB: Institutional Review Board

NIH: National Institutes of Health

OMB: Office of Management and Budget

RWD: real-world data

RWE: real-world evidence

Definition of Terms¹¹

Clinical Research: Clinical research is a component of medical care and health research designed to provide information to further the understanding of human health, preventing and treating illness, and promoting population health.

Clinical Trial: Study of therapeutic interventions to evaluate effects on human outcomes, principally safety and efficacy.

Community: A configuration of individuals, families, or groups united by values, characteristics, interests, location, and/or social relations.

Health Disparities: Differences in health and life expectancy among specific population groups or social groups as measurable by incidence, prevalence, and burden of disease; morbidity and other adverse conditions; and mortality.

Health Equity: The state in which individuals enjoy equal rights and opportunities to attain their full health potential without disadvantage due to any socially defined circumstance.

Participants: Human study volunteers; medical information and biological materials obtained from human subjects; data derived from volunteers, who may be healthy, have specific conditions, or be members of the general public or of populations under study.

Principal Investigator: The scientist leading a clinical research team drawn from varied disciplines and with one or more of a range of academic qualifications.

Research Funders/Sponsors: May include private donors and/or public-sector funding organizations (e.g., NIH, pharmaceutical companies, medical device manufacturers, biotechnology firms, universities, private foundations, and national societies, among others).

Research Organizations: Can include academic health centers, private research institutes, survey research organizations, federal government intramural research programs, and contract research organizations.

Social Determinants of Health: Environmental conditions where people live, learn, work, play, worship, and age that affect health, functioning, quality-of-life outcomes, and risks.

Stakeholders/Consumers: May include individuals, investors, health insurers, managed-care organizations, health-care systems, organized medicine, voluntary health agencies, patient advocacy groups, purchasers and providers of health care, and public health systems.

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