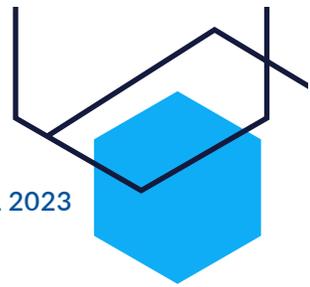




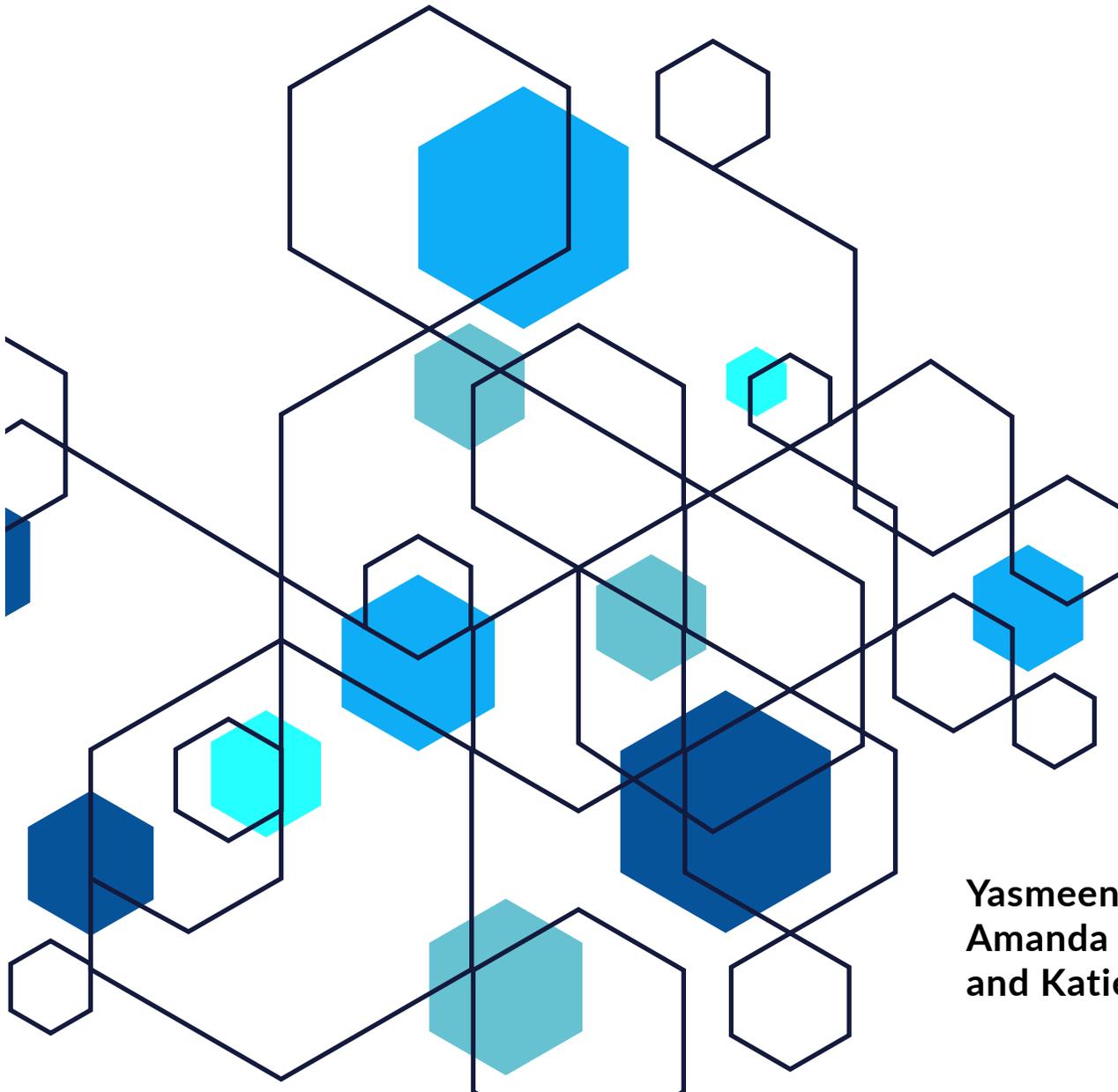
MILKEN
INSTITUTE
FasterCures

APRIL 2023



MAPPING THE JOURNEY

Building a Mutual Understanding for
Health Equity in Clinical Research



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About the Milken Institute

The Milken Institute is a nonprofit, nonpartisan think tank focused on accelerating measurable progress on the path to a meaningful life. With a focus on financial, physical, mental, and environmental health, we bring together the best ideas and innovative resourcing to develop blueprints for tackling some of our most critical global issues through the lens of what's pressing now and what's coming next.

About FasterCures

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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INTRODUCTION

Biomedical and clinical research in the United States has a long history of fostering systemic patterns of abuse of people of color. A most egregious example of such abuse occurred over 40 years from 1932 to 1972 in Macon County, Alabama.¹ The clinical study “United States Public Health Service Syphilis Study at Tuskegee” enrolled 600 black men, over 300 of whom were infected with syphilis.² However, in the study, those with syphilis were not informed and were recruited under false information of having “bad blood.” Not only were participants in the study not informed of their diagnoses, but they were also prevented from accessing treatment even after it became widely available.

The atrocities of the syphilis study at Tuskegee were neither the beginning nor the end of abuse in the clinical research enterprise. The history of experimentation and abuse in the American medical system extends more than four centuries. In 1956, at the Willowbrook State School in New York, children with developmental disabilities were intentionally infected with hepatitis.³ The research aimed to further knowledge of the natural progression of the disease and develop a vaccine to inoculate against it. In the 1990s, researchers recruited young African American boys into a study exploring the genetic roots of aggression.⁴ Several rights were violated, including withdrawal from medications, an overnight stay without parents, and the administration of a drug known to increase serotonin levels.

Involuntary medical experimentation takes many forms, and one of the most infamous is Henrietta Lacks. Lacks, a Black tobacco farmer from Virginia, suffered from a rare and aggressive form of cervical cancer.⁵ Shortly before her death, her surgeon kept samples of her cells without her consent. Her cells were the first human cells that could be grown in a laboratory. They were fundamental for studying various cancers, AIDS, polio, and many more crucial medical advances that changed health outcomes for millions of people across the globe. However, neither Lacks nor her family was credited for their contributions; in fact, her family did not know about the use of her cells until more than 20 years after her death.⁶

Grievously, in addition to targeting racial and ethnic minority populations and children for unethical and abusive clinical research, LGBTQIA+ populations have also been targeted for highly unethical clinical research. A landmark example of such research is Humphreys’ Tearoom Trade study of “Impersonal Sex in Public Places.”⁷ The methodology included Laud Humphreys tracking down names and addresses and interviewing men who have sex with men in disguise and conducting all research without his subjects’ consent and without disclosing his role as a researcher.

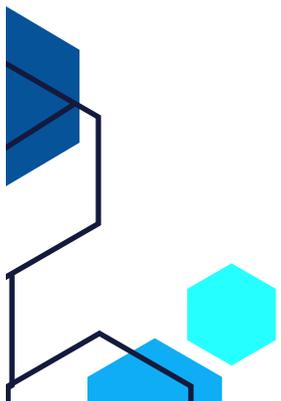
In response to these atrocities, numerous safeguards have been put in place to protect people participating in clinical research.⁸ The National Research Act, passed in 1973 after the horrific reality of the Syphilis Study at Tuskegee was made public, created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to supervise research involving human participants and authorized the development of human research regulations by the National Institutes of Health (NIH) and US Food and Drug Administration (FDA).⁹ The commission published the Belmont Report in 1979, establishing

three core principles for research involving humans: respect for persons, beneficence, and justice.¹⁰ A decade later, the Federal Policy for the Protection of Human Subjects, known as the Common Rule, was published and codified by 15 federal departments and agencies outlining requirements for Institutional Review Boards (IRBs), informed consent, and Assurances of Compliance.¹¹ The Common Rule continues to be revisited, most recently in 2017, as technology and culture evolve to capture the ethical challenges facing clinical research and update the protections guaranteed for participants.¹²

As previously stated in the Institute's report [*Achieving Health Equity: A Multi-Stakeholder Action Plan to Address Diversity across the Clinical Trials Enterprise and the Biomedical Research Ecosystem*](#), if the objective of biomedical research is to spur innovation to create healthier communities, extend life, and more effectively treat or cure disease, then persistent inequities run counter to that goal and create unnecessary barriers to health and wellness. The clinical research system must engage diverse populations to make medical advances available and relevant across populations. One well-known example that became apparent during the COVID-19 pandemic was that pulse oximeters performed less accurately in patients with dark skin tones.¹³ Research linked this to racial disparities in health outcomes, with patients who receive less accurate readings of their oxygen levels receiving less supplemental oxygen during stays in the intensive care unit (ICU). Trials that do not adequately engage and enroll participants of diverse racial and ethnic backgrounds often result in medical tools and interventions that do not work well for all people.¹⁴

The onus for ensuring equitable participation and benefit should not lie only with those who have historically been mistreated but requires collective action from participants, researchers, and all stakeholders involved in clinical research. To facilitate change, we all must purposefully choose to take corrective action. This landscape outline of clinical trials, organized as patients and research developers would encounter them at the most common types of trial sites, serves as a tool to establish a common language and basis of exchange among stakeholders, increase focus on the inclusion of diversity action plans to improve biomedical research, and encourage the further development of equitable research practices with practical recommendations for each type of site.

With this tool, we aim to further mutual understanding and foster more meaningful multi-stakeholder engagement. This tool aims to serve as a resource and provide guidance to those generally familiar with clinical research who are interested in driving a more accessible, equitable research enterprise as a basis to understand where, with whom, and when we can most effectively intervene to advance health equity principles. This tool also offers suggestions for achieving health equity at different types of trial sites and gives a deeper understanding of the elements of clinical trials to help stakeholders achieve their health equity goals.



COMMON ELEMENTS FOR CONDUCTING CLINICAL TRIALS

Elements of Trials That Are Largely Independent of Location

Some aspects of clinical trials are largely independent of location. Below we briefly discuss five, sometimes interrelated, trial aspects that can span multiple types of sites.

Study Design

Sites in many locations can run a large variety of study designs. Clinical trials are **interventional**, meaning an investigator assigns a treatment to patients (within a predecided plan, or protocol).¹⁵ Some commonly used interventional trial types include single-arm studies, where all participants get the same treatment, or randomized controlled trials, where the effects of a medical intervention are compared to a control. The control could be a placebo or an existing standard of care. Interventional trials could also use historical comparative data, such as in trials for rare diseases or cases with small numbers of patients, and much information is known about their health outcomes without an intervention. Two increasingly common types of interventional designs are **adaptive or platform trials** (where multiple interventions are compared to each other under one overarching agreement or protocol, and participants might dynamically move to different interventions as more evidence from the trial is generated) and **pragmatic trials** (where the intervention is conducted within routine clinical care).

Another common study design is an **observational study**, where researchers do not directly intervene but instead examine differing effects of treatments chosen by individual providers within the context of usual care. Some types of common observational studies might examine data collected in patient registries, such as for long-term follow-up care after a medical device is implanted (e.g., the Society for Thoracic Surgeons and the American College of Cardiology's Transcatheter Valve Therapy registry monitoring patients' outcomes after heart valve replacement or repair).¹⁶ Observational studies might also examine data from electronic health records (EHRs) or health insurance claims, such as studies done with data from FDA's safety surveillance system [Sentinel](#) (e.g., the World Health Organization's study protocol for COVID-19 vaccine safety).¹⁷

Data Collection

Many types of sites, though not all, collect data for the trials they are running in similar ways. Most sites can perform noninvasive or minimally invasive procedures to collect samples from trial participants (e.g., nose swab, urine collection, blood draw). Most sites also use questionnaires administered on paper at the site or via mobile and computer platforms. Depending on their digital health capabilities and access, many sites can facilitate data gathering from home or through telehealth, such as tests performed by participants in their homes (e.g., blood pressure) or tests performed by digital devices and other sensors (e.g.,

continuous glucose monitoring, interactions with mobile phones). Some sites can contribute information to interventional trials or observational studies by sharing EHRs or insurance claim data.

However, specialized sites are required for invasive procedures or those that use specialized equipment; these types of procedures and related data collection might be limited to community hospitals or large medical centers.

Home Components

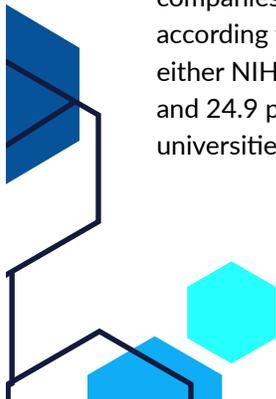
Hybrid or decentralized trials have some elements conducted in medical facilities and some at home, with in-home visits from medical staff or through telehealth. Most trials can have decentralized elements, except for initial trials testing the safety of new treatments or those that require complex, invasive procedures and/or specialized equipment. Many noninvasive or minimally invasive procedures that can be conducted without specialized equipment (for instance, through digital or sensor-driven data collection) can be done in a decentralized or hybrid way. Examples include completing surveys or sharing natural history information digitally, sharing information about whether to participate in a trial (“recruitment” and “consent”), and conducting follow-up discussions with a medical professional. More clinical trials are working to include decentralized elements to lower the burden of participating in clinical trials and increase the number of people and health-care professionals who are able and willing to contribute.¹⁸

Intervention Type

Differing trial sites may allow for varying types of interventions. In general, locations equipped to perform invasive procedures (e.g., private or academic hospitals) can accommodate trials testing surgical procedures or invasive devices. Trials investigating injections, infusions, and biologics that require medical professionals and special training or equipment may take place only in medical centers or hospitals. Oral medications and subcutaneous injections can be accommodated at any trial site or in patients’ homes. Across all interventional trials currently registered in the United States, the majority evaluate drugs or biologics, followed by trials evaluating behavioral or other interventions. Interventional trials testing devices and surgical procedures are less common by comparative volume but growing over time.¹⁹

Sponsor Type

Study sponsors fund operations of clinical trials across a variety of site types, and one particular site can receive funding and conduct trials for multiple funders or funder types. Study sponsors include federal government entities, nonprofit and disease advocacy foundations, large health-care systems, and biopharmaceutical and medical device companies. In the US, from 2021 to 2022, 8,247 clinical trials (phases I-IV) were initiated, according to data from clinicaltrials.gov. Of those, 13.3 percent were federally funded by either NIH or other federal government agencies, 61.7 percent were funded by industry, and 24.9 percent were funded under a sponsor category titled “other,” which encompasses universities, hospitals, cancer centers, and other organizations.



Elements of Trials That Are Location-Specific

In contrast to elements of trials that are relatively consistent no matter where the trial takes place, there are other trial aspects that vary according to the location type. We consider in this section five types of sites where trials are commonly conducted (Table 1). For each of these site types, we highlight some common places they can be found, typical people involved in conducting the research, the stages of research they can accommodate, the types of organizations that most often collaborate on or fund research at those sites, and actionable recommendations that individuals and organizations can take at those sites to advance health equity (Tables 2–6).

TABLE 1: COMMON TRIAL LOCATIONS

Location	Description
Commercial Clinical Trial Sites	Individual sites or parts of networks that conduct clinical research for commercial funders, typically associated with contract research organizations (CROs) conducting research on behalf of a commercial sponsor; usually conduct multiple clinical trials simultaneously
Academic Trial Sites	Medical centers, hospitals, outpatient clinics, and general clinical research centers associated with a college or university where the associated health system itself, private industry, or government entities typically fund clinical trials
Community Health Centers, Federally Funded Hospitals, and Medical Centers	Community physicians, primary care centers, and Federally Qualified Health Centers typically funded as part of collaborative groups (sometimes quite large with eight or more health systems participating) to conduct trials Funding typically internal or from others in the collaborative group and sometimes from federal government agencies, nonprofit and disease advocacy foundations, or the biopharmaceutical industry
Veteran's Hospitals and Medical Centers	Regional Veterans Affairs (VA) Medical Centers, and VA Rehabilitation Centers conducting trials typically funded by the US Department of Veterans Affairs Office of Research and Development, NIH, research foundations, or nonprofit organizations
Retail/Consumer Pharmacy Sites	Retail outlets and consumer pharmacy locations that provide health services such as health screenings, vaccinations, and urgent care; clinical research typically funded by industry or government entities

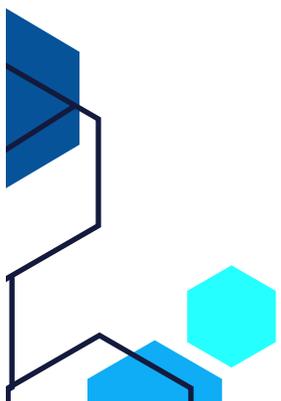


TABLE 2: CHARACTERISTICS OF COMMERCIAL CLINICAL TRIAL SITES

Types of places where these sites can be found	Clinics, hospitals, and other medical sites, often supported by contract research organizations (CROs)
People involved in conducting research at this type of site and how they relate to each other	<p>Principal Investigator (PI), co-PI and clinical project manager work for the trial sponsor or CRO, ultimately responsible for conduct and execution of the trial, data collection, and ensuring adherence to IRB protocols.</p> <p>Clinical research associates or clinical research managers work for the trial sponsor or CRO and facilitate engagement between the site and the sponsor.</p> <p>Site, study, or research coordinators work for the clinical trial site, oversee several clinical trials occurring at the site, and conduct study procedures with patients (e.g., conducting informed consent, taking vitals, administering questionnaires).</p> <p>Study recruitment directors oversee the enrollment of participants in studies and work for the clinical trial site.</p>
Stages of trials typically conducted at this location	Phases I–IV
Types of organizations that might be involved in planning or conducting a trial at this location	<p>Collaborators:</p> <ul style="list-style-type: none"> • Biopharmaceutical and medical device industry • CROs • Nonprofit organizations, including patient advocacy and disease-specific foundations • Academic institutions and universities, individually or as part of a research network • Large private health systems • Clinical trial laboratories • Federal health and research agencies <p>Funders:</p> <ul style="list-style-type: none"> • Biopharmaceutical and medical device industry • Nonprofit organizations, including patient advocacy and disease-specific foundations • Large private health systems • Federal health and research agencies
Recommendations for achieving health equity	<p>Increase engagement strategies and develop integrative structures to ensure uptake of patient and community perspectives in trial development.</p> <p>Encourage collaboration between biopharma-sponsored researchers and patient advocacy organizations and embed requirements for patient engagement to guide research and drug-development decisions.</p> <p>Build collaborations with community organizations as part of standard operating procedures and quality measures across key performance indicators for clinical trial design, recruitment, enrollment, and study execution.</p> <p>Establish partnerships with community leaders to ensure financial benefits and returns on community value and investment, in support of development and infrastructure for local community-based research.</p> <p>Invest in 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.</p> <p>Invest in all CROs to identify clinical trial sites that meet the geographic, cultural, and access needs of underrepresented populations.</p>

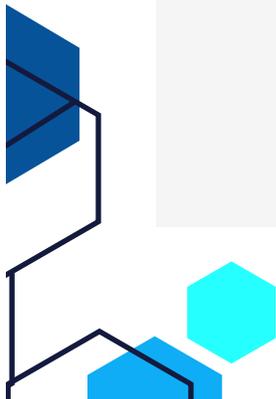


TABLE 3: CHARACTERISTICS OF ACADEMIC TRIAL SITES

Types of places where these sites can be found	<p>Medical centers, hospitals, and outpatient clinics</p> <p>General clinical research centers</p>
People involved in conducting research at this type of site and how they relate to each other	<p>PIs and Co-PIs design, conduct, and oversee the research aspects of clinical trials.</p> <p>Clinical research coordinators report directly to PI, facilitate day-to-day operations, and coordinate the trial's conduct (such as staffing and training, regulatory compliance, or financial reporting).</p> <p>Program coordinators and research program managers oversee the handling and entry of data collected for the trial to ensure they are accurate, organized, and well-maintained.</p> <p>Study biotechnicians, phlebotomists, and specimen collection processors help collect samples from trial participants.</p> <p>IRBs, Office of Human Research Protections, and Office of Sponsored Research Programs review plans for clinical trials before they begin and periodically after they start to ensure the research is ethical and safe and protects the rights and welfare of participants. The Office of Sponsored Research Programs serves as the liaison between research sponsors and the PI. Although IRB officers do not interface with study participants, the IRB's role in equitable and ethical research is critical.</p> <p>Clinical research nurses care for patients participating in clinical trials, give the investigational treatment to patients, monitor their outcomes, collect samples and data, and report any changes in how the study protocol is carried out.</p>
Stages of trials typically conducted at this location	Preclinical and phases I-IV
Types of organizations that might be involved in planning or conducting a trial at this location	<p>Collaborators:</p> <ul style="list-style-type: none"> • CROs • Biopharmaceutical and medical device industry • Nonprofit organizations, including patient advocacy and disease-specific foundations • Academic institutions and universities • Clinical trial laboratories • Large private health systems • Federal health and research agencies
Types of organizations that might be involved in planning or conducting a trial at this location (cont.)	<p>Funders:</p> <ul style="list-style-type: none"> • Biopharmaceutical and medical device industry • Nonprofit organizations, including patient advocacy and disease-specific foundations • Academic institutions and universities • Academic clinical researchers, individually or as part of a research network • Large private health systems • Federal health and research agencies
Recommendations for achieving health equity	<p>Collaborate with industry in developing a clinical trials education and communications campaign to disseminate and promote clinical trials to underrepresented and underserved communities and potential trial participants.</p> <p>Ensure that research plans, recruitment materials (e.g., informed consent, study outreach fliers), and protocols are codesigned with patient advocates and community members to achieve equity in research programs.</p> <p>Academic community partnerships should address the barriers that impede patients and communities from accessing trials by developing relationships with community leaders and health centers to advance community outreach. To ease access to a trial, PIs could identify the most impactful factors.</p> <p>Translate recruitment materials to the languages colloquially spoken in diverse communities.</p> <p>Require PIs to incorporate study evaluation metrics and milestone checks to confirm that the clinical research program achieved its goals for clinical trial diversity and to provide transparent reporting if goals are not met.</p> <p>Follow and implement policy guidance for inclusive diversity action plans in clinical research (e.g., FDA guidance for submitting diversity plans in clinical trials).</p>

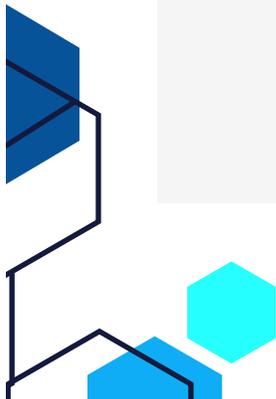


TABLE 4: CHARACTERISTICS OF COMMUNITY HEALTH CENTERS AND FEDERALLY FUNDED HOSPITALS AND MEDICAL CENTERS

Types of places where these sites can be found	<ul style="list-style-type: none"> • Community physician/primary care centers • Federally Qualified Health Centers (FQHCs) • Veterans Affairs hospital centers
People involved in conducting research at this type of site and how they relate to each other	<p>Primary care physicians are primarily responsible for a patient’s care inside or outside a clinical trial. They may serve as a co-PI of a clinical trial and contribute to trial design and conduct directly, or they may coordinate with the trial PI separately without being directly involved in the clinical trial.</p> <p>Clinical research nurses and health technicians care for patients participating in clinical trials, give the investigational treatment to patients, monitor their outcomes, collect samples and data, and report any changes in how the study protocol is carried out.</p> <p>Research program managers and program coordinators oversee the operations and procedures, and handling and entry of data collected for the trial to ensure they are accurate, organized, and well-maintained.</p>
Stages of trials typically conducted at this location	Phases II–IV
Types of organizations that might be involved in planning or conducting a trial at this location	<p>Collaborators:</p> <ul style="list-style-type: none"> • Other health systems, either private or government-funded • Academic or government-funded research networks • Nonprofit and disease advocacy foundations <p>Funders:</p> <ul style="list-style-type: none"> • Federal agencies • Other health systems, either private or government-funded • Nonprofit and disease advocacy foundations • Biopharmaceutical industry
Recommendations for achieving health equity	<p>Build relationships (such as public-private partnerships) with investors, philanthropy, and the business industry to support expanding the infrastructure to make clinical trials accessible to underrepresented communities at primary care and community health-care facilities.</p> <p>Leverage the support of community-based organizations and local businesses to build patient and community advisor coalitions.</p> <p>Provide education and training to the patient and clinical trial participant communities in research content agreed upon by various stakeholders.</p>

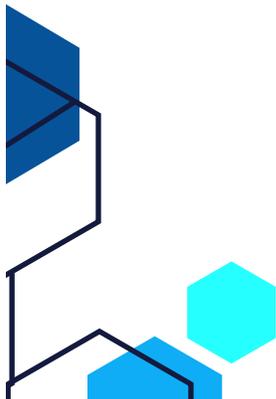


TABLE 5: CHARACTERISTICS OF VETERANS' HOSPITALS AND MEDICAL CENTERS

Types of places where these sites can be found	<p>Regional VA medical centers</p> <p>VA medical systems</p> <p>VA rehabilitation centers</p>
People involved in conducting research at this type of site and how they relate to each other	<p>Study coordinator/program manager oversees the operations of the research program and entry of data collected for the trial to ensure they are accurate, organized, and well-maintained. Clinical research pharmacists are responsible for the investigational product, including receiving, documenting, preparing, dispensing, administering, and counseling.</p> <p>Pharmaceutical project managers or clinical research coordinators report directly to PI, facilitate day-to-day operations, and coordinate the trial's conduct (such as staffing and training, regulatory compliance, and financial reporting).</p> <p>Clinical research assistants frequently interact with patients in the conduct of a trial, working on trial aspects such as recruiting participants, conducting interviews, reviewing and analyzing other related research, and collecting data.</p> <p>VA Central Institutional Review Boards review plans for clinical trials before they begin and periodically after they start to ensure the research is ethical and safe and protects the rights and welfare of participants. The Office of Research and Development serves as the liaison between research sponsors and the PI.</p>
Stages of trials typically conducted at this location	<p>Early phase I-IV, mostly phase II studies</p>
Types of organizations that might be involved in planning or conducting a trial at this location	<p>Collaborators:</p> <ul style="list-style-type: none"> • VA health centers • US Department of Veterans Affairs, Office of Research and Development • Academic institutions and universities • Private hospital systems • Biopharmaceutical and medical device industries • US Department of Defense • Mental illness research, education, and clinical centers • US Army Medical Research and Development Command • Nonprofit research corporations associated with the VA <p>Funders:</p> <ul style="list-style-type: none"> • US Department of Veterans Affairs, Office of Research and Development • Regional Veterans Affairs medical centers • NIH • Research foundations • Nonprofit research corporations associated with the VA
Recommendations for achieving health equity	<p>Implement a requirement for letters of intent submitted to the VA Cooperative Study Program (CSP) to explain, using an equity lens, how a study will center veterans and clinical practice directly.</p> <p>Promote the importance of gender and racial diversity within the executive committee of CSP studies to ensure equity is a priority from the development to the execution of a clinical trial.</p> <p>Establish partnerships with community-based organization leaders to ensure financial benefits and returns on community value and investment, in support of community development and infrastructure for local community-based research</p> <p>Leverage the support of community-based veterans' organizations to build patient advisor coalitions.</p> <p>Develop measures to uncover bias in the grant-review processes for biomedical research funded by the VA. Maintain a commitment to uphold these efforts toward diversity in clinical trials.</p>

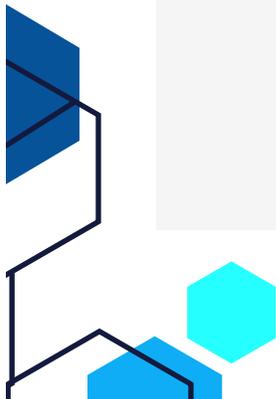
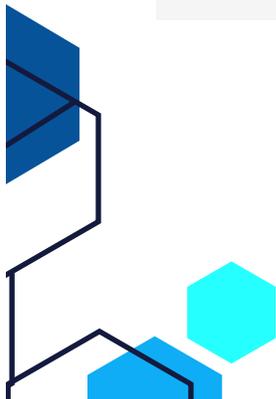


TABLE 6: CHARACTERISTICS OF RETAIL OUTLET AND CONSUMER PHARMACY SITES

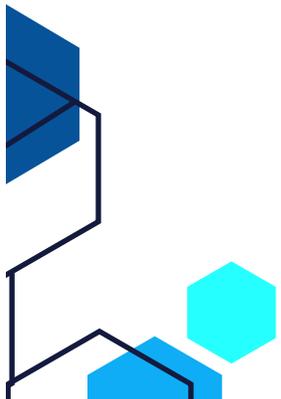
Types of places where these sites can be found	Retail pharmacy locations, most likely those providing health services such as health screenings, vaccinations, and urgent care
People involved in conducting research at this type of site and how they relate to each other	<p>Clinical research pharmacist is responsible for the investigational product, which includes receiving, documenting, preparing, dispensing, administering, and counseling.</p> <p>Recruitment director is responsible for the scientific review, screening and analysis of protocols, and recruitment study opportunities.</p> <p>Nurse practitioner serves as a sub-investigator for the research site and ensures all elements of the studies are completed in compliance with standard operating procedures.</p> <p>Clinical study manager is responsible for managing relationships with the study sponsor, principal investigator, and other stakeholders.</p> <p>Clinical study coordinator is responsible for managing clinical trial operations regionally, including communications with medical centers, IRBs, vendors, and sponsors, as well as daily operations of sites.</p> <p>Clinical operations coordinator is responsible for supporting clerical activities of the clinical operations and nursing staff. The clinical operations coordinator interacts with patients, plan representatives, and providers.</p>
Stages of trials typically conducted at this location	<p>Observational and phase IV studies</p> <p>Potentially hybrid decentralized trials where samples could be collected in or coordinated through retail settings</p>
Types of organizations that might be involved in planning or conducting a trial at this location	<p>Collaborators:</p> <ul style="list-style-type: none"> • Health systems, either private or government-funded • Academic or government-funded research networks • Federal government agencies • Large research universities • The commercial sector, partnering with communities and community health sites • Nonprofit foundations <p>Funders:</p> <ul style="list-style-type: none"> • Biopharmaceutical and medical device industries • Health-care systems • Academic institutions and universities
Recommendations for achieving health equity	<p>Include in research plans a requirement for education and training with regard to culturally and linguistically relevant research-study recruitment materials codeveloped with local community members.</p> <p>Partner with public health communications organizations to develop linguistically relevant research awareness campaigns about new clinical trials.</p> <p>Develop accessible mechanisms (e.g., community advisory boards, committees, or councils) that ensure collaboration with leaders of qualified community-based organizations to benefit the entire clinical trial recruitment practice.</p>



THE ROLE OF DECENTRALIZED AND HYBRID CLINICAL TRIALS

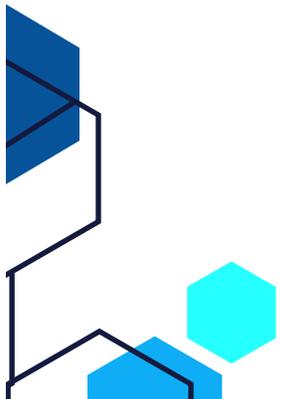
Across all clinical trial sites, an opportunity exists to embed elements of trial decentralization through hybrid models. As COVID-19 spread throughout 2020, contract research organizations and other organizations performing clinical research were forced to turn to technology to continue patient monitoring and engagement in the face of social distancing guidelines, implementing practices such as virtual study visits using telemedicine, clinical supplies shipped directly to patients' homes, electronic consent technologies, and wearable devices enabling remote data collection.²⁰

Hybrid clinical trials have the potential to minimize the burden of time and transportation costs associated with participating in a clinical trial. Previous research has established that underrepresented populations that are often excluded from clinical research are more likely to be affected by geographical barriers, therefore making hybrid decentralized trials a potential key factor in the effort to increase clinical trial diversity and equity.²¹ However, it is equally important to note potential downfalls of hybrid models of clinical research. In fact, increases in decentralized trials may have an adverse effect on participant diversity and equity due to inequities in broadband access and smartphone usage in the US population.²² Around 10 percent of the US population does not have access to either a smartphone or broadband internet, with this number only increasing for minoritized populations.²³



CONCLUSION

Our series of call to action issue briefs on [diversity in clinical trials](#) and [health equity](#) inform health researchers, industry, and policy stakeholders to facilitate increased diversity in trials and engagement with communities for equitable research and development of medical interventions. FasterCures believes that a key part of building an inclusive and equitable clinical trials enterprise is including the expertise of local communities and patient advocates in codesigning research materials and encouraging efforts to increase diversity in biomedical research. Diverse representation in clinical trials may help to inform the benefits and risks to underrepresented populations, including racial and ethnic subgroups.²⁴ Diverse representation can also increase unique and unexpected findings that pave the way for discoveries that improve outcomes in the future and, most importantly, facilitate access to clinical research as a common good to improve the quality and efficacy of care for all people. With the addition of this tool, FasterCures aims to strengthen equitable interactions in policy efforts and further prepare a truly inclusive clinical trial ecosystem.



EXAMPLE OF A STUDY PATIENT'S CLINICAL TRIAL JOURNEY

Address the barriers that impede patients and communities from accessing trials by developing relationships with community leaders and health centers.

Sponsors and PIs should identify the barriers to access and support closing gaps to participation.

PEOPLE INVOLVED IN STUDY PLANNING AND COMMUNITY OUTREACH:

Study participant or patient arrives at study site

PEOPLE INVOLVED IN RESEARCH:

Study participant or patient meets program coordinator, who administers informed consent form and discusses questions together

Implement policy guidance for inclusive clinical research, such as FDA requirements for diversity action plans.

Translate recruitment materials to the languages colloquially spoken in diverse communities.

Ensure that research plans, recruitment materials, and protocols are codesigned with patient advocates and community members, to achieve equity in research programs.

PEOPLE INVOLVED IN DATA COLLECTION:

Study participant or patient meets clinical research nurse/coordinator to fill out survey and/or complete specimen collection

...or utilizes electronic surveys, medical device monitoring, telehealth or other digital platforms

INTERVENTION TYPE:

Study participant or patient receives the treatment being studied from clinical research nurses

...or completes hybrid components done at home (telehealth or home health checkups, remote monitoring)

PATIENT'S ACTIVE ROLE IN STUDY IS FINISHED

Incorporate study evaluation metrics and milestone checks to confirm that the clinical research program achieved its goals.

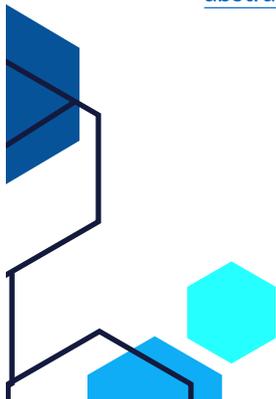
Maintain ongoing communication and share study results with study participants, patients, and their health-care providers.

Recommendations for Health Equity

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ACKNOWLEDGMENTS

The authors are grateful to Kinnari Harjivan, former intern at FasterCures, for her initial research and assistance with this effort and to the Health Equity and Diversity in Clinical Trials Advisory Working Group at FasterCures.

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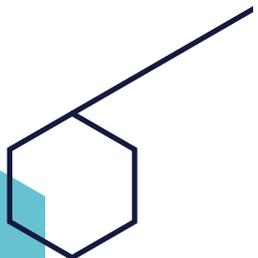
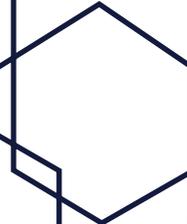
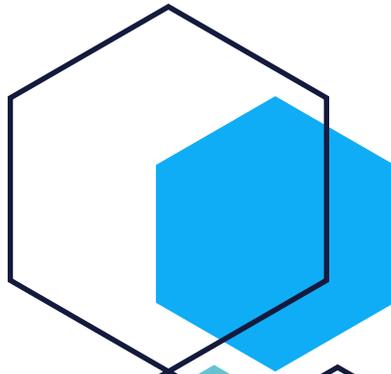
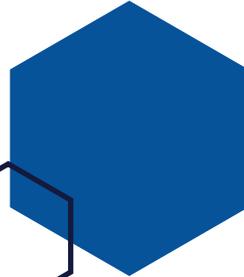
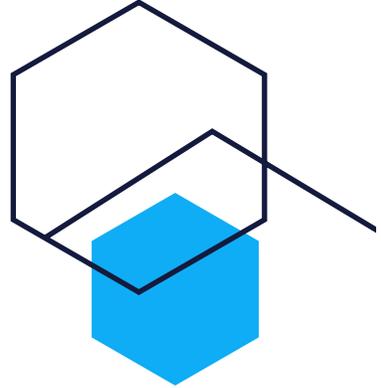
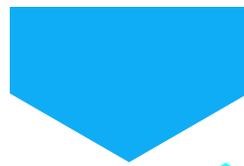
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