

LEVERAGING DECENTRALIZED VIRTUAL CLINICAL TRIALS TOWARDS HEALTH EQUITY

INTEGRATING DATA SCIENCE AND
TECHNOLOGY FOR MEANINGFUL INNOVATION

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Executive Summary

Decentralized virtual clinical trials represent a transformative approach to clinical research by allowing patients to engage remotely, thus addressing barriers traditionally limiting trial participation. For underserved and underrepresented communities, including rural, veteran, and communities of color—these trials remove geographic and logistical obstacles that have historically prevented diverse enrollment. Decentralized clinical research solutions emphasizing health equity are needed today—more than ever, to provide communities with access to precision medicine, proactive and predictive health analytics, and the infrastructure to foster long-term health improvements.

Addressing the Challenges in Precision Medicine for Underserved Communities

The shift toward precision medicine and decentralized clinical trials has the potential to revolutionize healthcare, especially in underserved communities that have traditionally faced systemic barriers to quality care. However, challenges such as limited access to healthcare facilities, insufficient health literacy, a lack of diversity in clinical trials, and economic barriers continue to hinder the equitable adoption of precision medicine in these communities. The industry has lacked a focus to address these issues leveraging digital health tools, real-time data analytics, or culturally sensitive community engagement strategies.

For example, a systematic analysis of US-based cancer patient enrollment conducted in 2021 found that 21.5% of patients failed to meet eligibility criteria due to study design and were not offered the opportunity to consider participating in a trial. We must design trials to meet patients and participants where they are rather than design criteria that are restrictive across communities.

Key Challenges

Drug Development & Exclusivity

Research and development of a new drug can cost around \$2.6B USD and can take up to 15 years. As of March 2021, a total of 370K clinical studies were registered globally; however, approximately 90% did not reach completion and market launch.

With almost one hundred and fifty drug patents have or will expire between 2021 and 2025, industry will see invariable downstream effects including an increase in the R&D expenditures and a growing focus on specialty drugs to diversify product portfolios. The pressure for pharmaceutical companies to innovate, in comparison to other industries, is driven by the imperative to manufacture products where they can corner a market, and thus to spend significant amounts on research and development.

Drug manufacturers are increasingly outsourcing large parts of R&D, mostly to clinical research organizations (also contract research organizations), with the main aim of reducing costs. The use of big data in clinical research, such as a predictive modeling platform, is leveraged to use clinical and molecular data to develop safer and more efficient drugs. However, outsourcing R&D, analysis, and trials leads to expedited steps to cut costs and save time, which disproportionately impacts those groups and communities on the margins.

Geographically limited Access to Healthcare Facilities & Providers

Many rural and underserved urban communities lack proximity to comprehensive healthcare facilities, which limits patients' access to preventive care, early diagnostics, and advanced treatment options. According to the Health Resources & Services Administration (HRSA), approximately sixty-two million Americans live in areas classified as Health Professional Shortage Areas (HPSAs), where there are fewer healthcare providers available per capita than needed to meet basic healthcare requirements.

For example, the same cancer patient enrollment study conducted in 2021 found that over 75% of patients were unable to enroll because of the study design or the research site location, with clinical and/or structural barriers preventing over 55% of patients from participating in a trial.

Low Health Literacy & Lack of Awareness of Precision Medicine

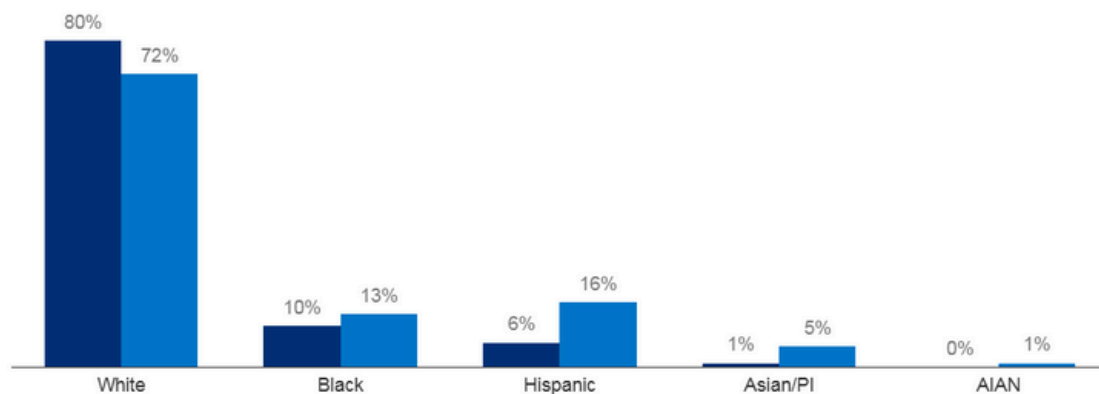
Health literacy – the ability to access, understand, and use information to make informed health decisions – varies widely across different populations. In the United States, over one-third of adults have low health literacy, which disproportionately affects racial and ethnic minorities, older adults, and those with lower socioeconomic status. This lack of awareness and understanding hinders patients' ability to benefit from precision medicine, as many are unaware that genetic and genomic tests could be relevant to their healthcare or that they may be covered by Medicare, Medicaid, or private insurance.

Underrepresentation in Clinical Research

Despite efforts to improve diversity in clinical trials, minority groups remain significantly underrepresented. There is typically only around 10% overall participation from minority populations and an even lower proportional representation from women. For instance, while African Americans represent around 13% of the U.S. population, they cumulatively accounted for only 10% of clinical trial participants from 2000 to 2020. This lack of participation limits the generalizability of clinical research findings, as treatments developed without diverse genetic data may be less effective for minority populations. Furthermore, a recent FDA guidance report emphasizes the importance of diversity in clinical trials for creating effective, equitable treatment options.

Racial and Ethnic Distribution of Enrollees in U.S.-Based Clinical Trials Compared to Total Population

■ Median Share of Enrollees in U.S.-Based Trials by Race/Ethnicity, 2000-2020 ■ Total Population Based on 2010 U.S. Census



NOTE: Race and ethnicity reporting of enrollees is not standardized across clinical trials. Persons of Hispanic origin are generally categorized as Hispanic; in some cases, persons of Hispanic origin may also be included in other racial categories. AIAN refers to American Indian and Alaska Native people, Asian/PI refers to Asian and Native Hawaiian or Pacific Islander people.

SOURCE: Turner, B. E., Steinberg, J. R., Weeks, B. T., Rodriguez, F., & Cullen, M. R. (2022). Race/ethnicity reporting and representation in US clinical trials: a cohort study. *The Lancet Regional Health-Americas*, 11. 2020 Census Illuminates Racial and Ethnic Composition of the Country. • PNG

KFF

Source: **Racial and Ethnic Disparities in Access to Medical Advancements and Technologies**. KFF. 2024.

Economic Barriers to Access

Economic instability and high out-of-pocket costs present substantial barriers to accessing advanced medical care in underserved communities. Even with insurance, many patients face high deductibles, co-pays, or limitations in coverage for certain precision medicine tests. Although some genetic and genomic tests are covered by Medicare and Medicaid, patient and provider awareness remain low, leading to missed opportunities for early intervention. Studies show that minority and low-income patients often forgo preventive care due to cost concerns, exacerbating health disparities.

Data Infrastructure & Digital Storage

Implementing precision medicine relies heavily on robust data infrastructure, as it requires the collection, storage, and analysis of large-scale genetic and phenotypic data. However, underserved communities often face challenges related to the digital divide, including limited access to high-speed internet, insufficient digital literacy, and outdated technology infrastructure. For precision medicine to be successful, these communities need access to digital health tools and data management systems.

Mistrust in Healthcare & Clinical Research

Historical abuses in medical research, such as the Tuskegee Syphilis Study, have fostered deep-seated mistrust in healthcare among minority communities. This mistrust has been identified as a significant barrier to clinical trial participation and precision medicine adoption. Addressing this requires culturally sensitive outreach and transparency prioritized through educational programs, community partnerships, and efforts to build trust between patients and researchers.

Complexities of Genomic Data Interpretation

Genomic data is inherently complex, requiring specialized expertise for proper analysis and integration with other health records. Many healthcare providers lack the training or resources to interpret genomic data, leading to missed opportunities for personalized interventions. This challenge must be addressed by integrating genomic data directly into Electronic Health Records (EHRs) to enable more seamless care coordination between healthcare providers and supporting timely, evidence-based interventions.



A Decentralized Trial Model for Underserved Communities

The decentralized trial model prioritizes patient accessibility and engagement by reducing in-person requirements, leveraging digital tools, and using real-time data integration for actionable insights. Key components include:

Remote Patient Monitoring (RPM)

- ▶ *RPM tools allow for continuous monitoring of patient data from any location, capturing essential biomarkers and diagnostics in real-time. This capability addresses gaps in care by providing immediate data on patients' conditions, facilitating prompt intervention and ensuring participants stay engaged in the trial process.*

AI-Driven Data Analytics

- ▶ *AI-powered data analytics platforms can be integrated into the virtual trial environment. These solutions would analyze patient data for predictive insights and identify trends in real-time, helping guide patient treatment decisions and alerting providers to risks. This is particularly crucial for underserved populations who may not have regular access to healthcare facilities, enabling early detection and targeted interventions.*

Electronic Health Record Integration

- ▶ *By integrating with major EHR platforms like Epic and Cerner, healthcare systems can ensure a seamless data flow between the systems and patient records, reducing redundancy and enabling comprehensive views of patient history. This capability would enhance data accuracy and allow for collaborative care between local providers and specialists.*

Patient-Centric Study Design

- ▶ *Digital consent, secure messaging, and interactive dashboards support a user-friendly experience, designed with literacy and technology-accessibility considerations. For underserved communities, this ensures engagement remains consistent and accessible, even for patients with limited digital experience.*

Addressing Barriers to Clinical Trial Participation

Many factors impact clinical trial participation in underserved communities, such as mistrust in medical research, limited awareness of trial availability, and logistical challenges like transportation. A well-designed decentralized model alleviates these concerns through:

- ▶ *Culturally Sensitive Outreach and Education: Providing educational materials and recruitment messaging that resonate with cultural values builds trust and awareness of clinical trial benefits. Materials explaining the safety, purpose, and potential outcomes of trials address misinformation and create a foundation for trust between patients and researchers.*
- ▶ *Reducing Financial and Logistical Burdens: Ensuring trials are accessible to participants at no cost would empower payors to pre-authorize costs. Addressing common logistical barriers, such as transportation, would enable telemedicine options and remote follow-up mechanisms.*

Enhancing Data Diversity & Health Equity

Data from diverse populations remains vital in developing precision medicine solutions. By increasing participation from marginalized communities, decentralized trials will generate data reflective of a broader population, ensuring the development of interventions that are effective across demographic groups.

- ▶ *Data Inclusivity for Improved Population Health: The insights gained from diverse participant data will allow for the development of population health models that better represent real-world demographics, directly supporting improved outcomes for these communities. Furthermore, de-identified aggregated data can drive health policy recommendations, leading to systemic improvements.*

The Impacts of Decentralized Clinical Research

The adoption of decentralized clinical trials (DCT) and virtual healthcare solutions promise substantial economic and social benefits for underserved communities, local economies, and the broader healthcare ecosystem. Making clinical trials and healthcare solutions more accessible, addresses socioeconomic challenges, enhances community health, and contributes to workforce development.

Enhancing Equity & Reducing Costs

A focus on precision medicine and decentralized trials within underserved communities directly addresses health disparities, improving outcomes for populations that often suffer higher rates of chronic disease and unmet health needs. The long-term economic benefits of this model include:

Preventing Chronic Disease Progression

- ▶ Early interventions made possible through genomic screening and ongoing health monitoring, the DCT model prevents conditions from becoming more severe, which universally reduces long-term healthcare costs. Detecting genetic predispositions to diseases allows for proactive management- a less costly and more effective path than treating advanced disease stages.

Improving Productivity & Reducing Absenteeism

- ▶ For marginalized communities, chronic health issues often result in reduced productivity and increased absenteeism. By implementing precision medicine and decentralized clinical trials, patients will proactively manage or avoid chronic conditions altogether. This has broader social and economic impacts by enabling a more stable workforce and reducing dependency on social support programs.

Reducing Disparities with Data-Driven Policy

- ▶ Data collected from decentralized clinical trials offers insights into specific health trends and needs within underserved communities and provides valuable input for shaping healthcare policy. This data also supports research institutions and public health agencies in understanding disease prevalence and risk factors among different demographics, enabling better-informed public health initiatives.

Empowering Community Health Through Education & Awareness

A fundamental aspect of this approach is empowering patients and providers with the knowledge and tools to take charge of their health. This empowerment has profound economic and social implications:

Increased Health Literacy & Community Engagement

- ▶ Outreach and education efforts foster greater health literacy and help communities understand the value of genomic testing, preventive care, and precision medicine. This is particularly important in populations where misinformation or a lack of trust in the healthcare system exists. Improving health literacy fosters community resilience and enable individuals to make informed health decisions that positively impact long-term health outcomes.

Providing Individuals & Families with Proactive Health Management

- ▶ Through decentralized trials, patients can receive screenings that identify genetic predispositions, enabling family members to take preventive steps as well. This community-centric approach not only improves individual outcomes but also strengthens family and community ties.

Educational Collaboration for Skills & Knowledge Transfer

- ▶ Partnering with community colleges, universities, workforce and industry to support internships, apprenticeships, and training programs offers a pathway to specialized skills development. By integrating clinical trial management, genomic data analysis, and precision medicine training, decentralized clinical trials facilitate the development of a skilled, local healthcare workforce that can sustain community health initiatives and contribute to future research and innovation.

Fostering a Sustainable Model for Health Equity

The decentralized clinical trials model represents a sustainable approach to health equity, creating long-term benefits for both the healthcare ecosystem and the communities it serves. By focusing on inclusivity and accessibility, this model can demonstrate how a decentralized solution is not just an adaptation of traditional clinical trials but a transformative platform for health equity. Benefits to community sustainability include:

Building Trust in Healthcare

- ▶ For many underserved communities, historical inequities and limited access to care have fostered mistrust in the healthcare system. A patient-centered, accessible model actively works to rebuild trust, showing these communities that healthcare can be inclusive and responsive to their needs. This trust translates to higher engagement rates, more reliable data collection, and, ultimately, a healthier population.

Strengthening Public Health Resilience

- ▶ By generating community-level health data and population health insights, organizations performing these trials can inform public health policies that directly respond to local needs, making these communities more resilient to future health crises. This model is especially relevant for pandemic preparedness, where local health infrastructure and real-time data can significantly improve response times and targeted intervention strategies.

Economic Resilience Through Healthier Communities

- ▶ Healthier communities contribute to economic resilience. When individuals have better access to preventive and personalized healthcare, they experience fewer disruptions in employment, maintain higher productivity, and have less financial strain from medical expenses. This ripple effect fosters stable local economies and creates a feedback loop where economic stability enables continued investment in community health initiatives.

Economic Development & Job Creation

Bringing critical healthcare services directly into communities that traditionally lack access to advanced diagnostics and specialized care stimulates local economies through:

Job Creation & Workforce Development

- ▶ *Implementing decentralized clinical trials in underserved areas generates demand for healthcare roles such as telehealth coordinators, data management specialists, community health workers, mobile lab technicians, and patient liaisons. These roles not only provide employment opportunities but also equip individuals with skills in emerging areas of healthcare and digital health technology. By partnering with local training centers and educational institutions, organizations can help build a pipeline of trained professionals, thus creating sustainable job opportunities within these communities.*

Economic Stimulation Through Partnerships

- ▶ *Partnering with local vendors, pharmacies, mobile diagnostic units, and community health organizations enhances regional economies. Using local suppliers for trial-related equipment, medications, and transport needs directs investment back into the community and ensures economic benefits are both immediate and ongoing.*

Investment in Digital Infrastructure

- ▶ *The need for reliable connectivity, telehealth capabilities, and secure data storage encourages local investments in digital infrastructure. Collaborations with local internet service providers, tech companies, and municipalities to enhance connectivity can bridge the digital divide, enabling these communities to access broader telehealth, remote education, and economic development opportunities. Over time, this infrastructure improvement can have a multiplier effect, making remote work, online education, and other digital services more accessible.*

Outcomes of Holistic Community Engagement & Empowerment

Decentralizing clinical trials does more than transform healthcare delivery; it becomes an economic driver, a trust-building tool, and a foundation for equitable health outcomes in historically underserved communities. By reducing barriers to participation, stimulating local economies, and empowering individuals with proactive health knowledge, this model creates immediate and lasting impact. The opportunity to partner with these communities extends beyond medical testing—it represents a commitment to fostering resilience, equity, and opportunity, generating a legacy of healthier, economically stable communities that can thrive for generations to come.

The Phronetik Clinical Trial Model

Phronetik®, a minority-owned, woman-owned, and service-disabled veteran-owned business, is uniquely positioned to bridge the healthcare gap for marginalized communities accessing precision medicine services. To expand the capabilities and reach into marginalized communities, Phronetik offers an engagement strategy for decentralized clinical trials to partner with local providers, community organizations, and health systems to embed the model into existing care networks. We believe in:

Government & Payor Collaboration

- ▶ *Engaging with state and federal agencies, as well as Medicaid and Medicare, to secure funding for trial costs and expand coverage for precision medicine in underserved areas.*

Community Partnership Initiatives

- ▶ *Engaging with state and federal agencies, as well as Medicaid and Medicare, to secure funding for trial costs and expand coverage for precision medicine in underserved areas.*

Education Campaigns

- ▶ *Targeted campaigns to increase awareness and understanding of trial benefits among patients and providers, focusing on the safety, impact, and accessibility of decentralized trials.*

Conclusions

In the modern technological era, it is paramount that science and industry leverage a decentralized clinical trial model that enables and harnesses technology to address longstanding disparities in access, particularly for historically underserved communities. It is critically important to meet patients and trial participants where they are—geographically, demographically, and socioeconomically, to achieve equitable representation and improved outcomes.

By using a range of innovative solutions including real-time analytics and EHR integration, Phronetik pioneers a clinical trial model that is accessible, inclusive, and effective. Through this initiative, Phronetik aims to transform patient outcomes, contribute to equitable research, and provide a replicable model for health equity across the industry.



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