2023 Industry Report: The State of Diversity and Equity in Clinical Trials

Executive Summary & Methodology

Enhancing diversity and inclusion in clinical trials has been a long-standing challenge. Current strategies to achieve diversity in clinical trials have proven underwhelming and despite government efforts spanning decades, many groups continue to be underrepresented. With clinical trial diversity now a legal mandate as of December 29, 2022, the need for an effective approach is more critical than ever.

In this comprehensive report, we examine the state of diversity and equity in clinical trials, highlighting the inadequacy of common approaches and advocating for a new, data-driven strategy.

The data & insights reflected in this report were generated from H1's clinical trial data platform, Trial Landscape. Our team of experts analyzed data on nearly 13,000 clinical trials from 11.2 million breast cancer claims and 2020 census data.

To get to the root of the problem, we spotlight the discrepancies between census and claims data, actual patient populations, and trial locations, focusing on breast cancer clinical trials as a compelling case study. We challenge the traditional way of designing clinical trials using surface-level demographic data and underscore the need for transformative changes to improve clinical trial diversity. Our findings stress the importance of a more comprehensive approach that takes into account true patient populations and the unique barriers impeding diverse patient enrollment in trials, centering on data-backed principal investigator (PI) and site selection as keys to success.

With this eye-opening research, we hope to lead the industry towards a future where diversity and inclusion in clinical trials are prioritized, resulting in better and more representative healthcare research.

Why Data-Informed Principal Investigator (PI) and Site Selection are Critical to Achieving Clinical Trial Diversity

Once an aspiration, now a legal mandate, clinical trial diversity can become a reality with the right strategy. As of December 29, 2022, pursuing greater diversity among participants in clinical trials is no longer simply an aspiration — it is a legal mandate. Signed into law by President Biden on that date, the Consolidated Appropriations Act, 2023[1], contains the Food and Drug Omnibus Reform Act of 2022, which requires[2] drug and device sponsors to submit diversity action plans for their phase 3 or other pivotal clinical trials. These legal reforms are consistent with the FDA's 2022 Guidance on Diversity Plans for Underrepresented Racial and Ethnic Populations[3], but add a waiver provision that allows the Food and Drug Administration (FDA) to waive the diversity action plan requirement under certain circumstances.

Even before the passage of this law, many life sciences companies and clinical research organizations (CROs) had begun taking actions to pursue achieving diversity in clinical trials. The results of these efforts, though, have been underwhelming, with only one out of 25 cancer drug developers[4] fairly including racial and ethnic minority patients in their trials. Alzheimer's disease clinical research is another area where companies have struggled[5] to achieve their participant diversity goals.

Decades of government efforts to increase the diversity of clinical trial participants have also fallen short. In a December 2022 report[6], the United States Government Accountability Office wrote:

> "Despite more than three decades of government policies intended to improve clinical trial diversity, certain groups remain consistently underrepresented in cancer clinical trials. Those groups include certain racial and ethnic groups, adolescents and young adults, older adults, women, low-income individuals, and individuals from rural communities."

Did You Know?

Only **one out of twenty-five** cancer drug developers

include racial and ethnic minority patients in their trials.

Based on all of these disappointing results, it seems clear that current strategies are not enough to achieve diversity in clinical trials. What's needed instead is a new approach.

Why Current Approaches to Promoting Clinical Trial Diversity Have Failed

A focus on speedy clinical trial enrollment undermined diversity for too long. Clinical trial diversity was simply not a focus of those administering clinical trials. Even as late as 2022, research centers were more focused on speed than diversity.

> "There are tons of dedicated research centers out there who are just focused on enrolling a patient that meets the protocol," says Stacey Rivkin, Group Vice President of Strategic Insights and Strategy at H1. "They do not care who the patients are. As long as the patients meet the protocol, they're happy to enroll them because they get paid by the patients they enroll."

New Commitment to Clinical Trial Diversity and New Consequences for Failing to Achieve It

In the last few years, though, more and more companies have begun to shift their approach, committing to achieving clinical trial diversity. Merck[7] and Amgen[8] are just two prominent life sciences companies that publicly announced their commitment to clinical trial diversity.

At the same time, the FDA has continued to provide guidance to the industry on the importance of diversity of clinical trial participants. Its most recent guidance on this topic[9], issued in April 2022, advised medical product sponsors to develop Race and Ethnicity Diversity Plans and to seek diversity beyond just race and ethnicity by including other underrepresented populations, including those defined by their socioeconomics status, age, disability, and gender identity.

Even though such guidance documents are not binding on drug developers, the FDA in March 2022 rejected[10] a drug application because it was based on a homogeneous population made up of only Chinese patients.

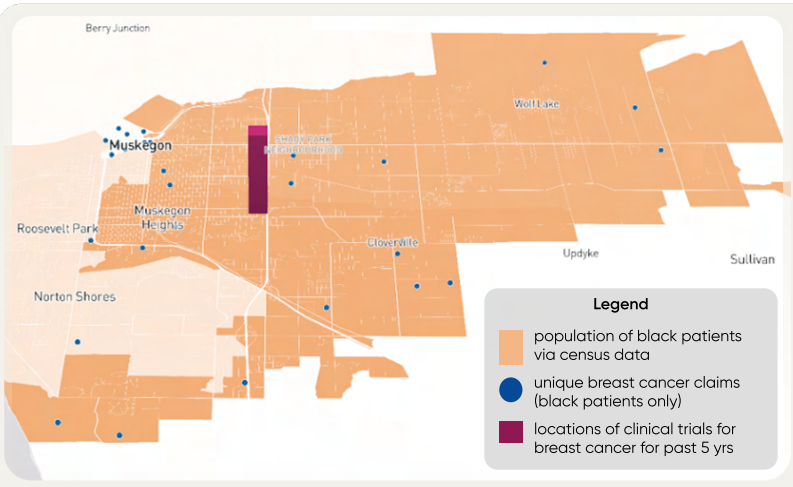
Now, with diversity action plans a binding, legal requirement, drug and device developers can expect similar adverse actions for failing to achieve clinical trial diversity.

> H1 Senior Director of Product Management for Clinical Trials, Adam Wycoff, echoed this perspective: "Clinical operations teams are trying to go really fast. The faster they get their trial done, the faster their drug goes to market, the faster they make money on the drug. It's a game of speed."

Why Census Data Is Not Enough

Despite the commitment of the FDA and life sciences companies to increasing clinical trial diversity, many study sponsors have continued to fall short of their goals because their approach to achieving diversity is flawed.

One approach study sponsors commonly use is combining U.S. census data with claims data to identify areas within the country where both a particular disease of interest and a racial or ethnic minority coincide. For example, as of July 2018, U.S. census data shows that 79.1% of those in the City of Detroit are African American. If claims data also indicated there are a lot of breast cancer patients in the City of Detroit, then perhaps a study sponsor would try to establish a study center within Detroit to increase representation of African American women in a breast cancer clinical trial.



Source: H1 clinical trials platform*

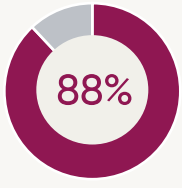
Diversity and Disparate Access to Trials

In the communities around Grand Haven and Grand Rapids, Michigan, according to census data, this map show the amount of breast cancer trials/the amount of unique breast cancer claims and the location of clinical trials for the past five years - there is a clear disconnect.

Challenges to This Approach

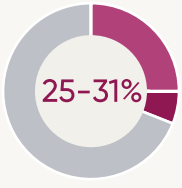
Just because a population lives in a particular area doesn't mean that this population is treated at the nearest clinical center.

For example, African Americans make up about



of the Middle East Baltimore neighborhood[11] where Johns Hopkins Hospital is located.

Despite this, African Americans account for only about

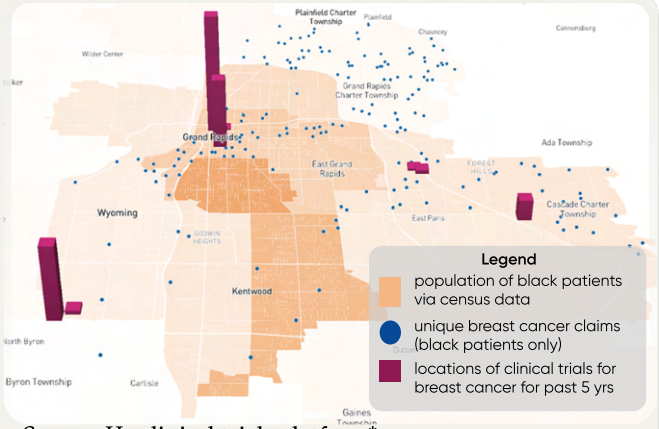


of the patients treated in the Hopkins hospital system.

As a result, choosing a site based on local demographics may not result in the specific patient population enrollment one expects.

Traveling for Care & Trials

In this view, there is a high volume of black patients but a limited number of trials, which again means patients are either traveling elsewhere from where they live or not seeking care. "While census data shows a significant number of black patients in this geographic area - we do not see many breast cancer claims. Either individuals affected by breast cancer are not seeking treatment or are seeking treatment outside of where they live and work in and around Grand Rapids, Michigan.



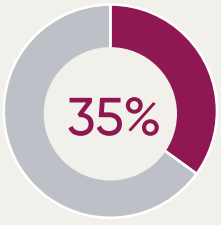
Source: H1 clinical trials platform*

Moreover, U.S. Census Bureau data do not necessarily reflect the proportion of the population by ethnicity that may be impacted by a specific disease. A recent GSK study[12] found that in four disease areas (asthma, COPD, HIV, and influenza) census data differed from the epidemiological data.

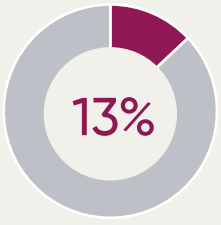
For example, U.S. Census Bureau data indicates that 13.4% of the total US population is Black/African American while the prevalence of asthma among this group in the U.S. is 17%, and the prevalence of COPD among this group is 7.1%. Similarly, census data indicates 18.5% of the population is Hispanic/ Latinx while the prevalence of different diseases among this group varies (asthma 14.4%; COPD 6.5%, HIV 35.7%; and influenza 10.4%).

The study also showed that GSK trial enrollment for each condition differed by race and ethnicity. Enrollment in clinical trials of African Americans for asthma (22.6%) exceeded both census (13.4%) and epidemiologic (17%) levels.

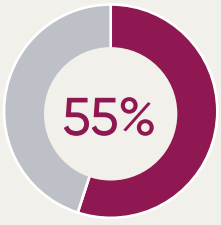
In HIV trials, enrollment of African Americans was at



markedly exceeding census levels of



but underrepresenting the epidemiologic levels of



There are many other potential barriers to diverse patient enrollment that you must address, including patient distrust or unawareness about the clinical research, inability to come in for regular clinical visits, and the overall high burden of trial participation. These problems with a census-based approach to addressing clinical trial diversity necessitate a more sophisticated solution.

Data-Informed PI and Site Selection

Instead of looking only at census and claims data, clinical study sponsors and their feasibility teams should also look at potential primary investigators' (PIs') race, languages spoken, patient population, clinical trial experience, affiliations, and publications.

For example, if you're trying to enroll more hispanic patients in a trial for a type 2 diabetes treatments, you may find that Dr. Maria Rodriguez speaks Spanish, treats many hispanic patients with type 2 diabetes, has run clinical trials in the past with success, and has even published on the importance of health disparities in type 2 diabetes. All of these factors suggest Dr. Rodriguez would be an ideal PI. You would then want to check what hospitals Dr. Rodriguez is affiliated with before selecting a site. If she is only affiliated with Acme Health System, you wouldn't want to choose City Hospital Center as your site. You would also want to review social determinants of health data to help inform your overall patient recruitment strategy.

> For instance, if this data reveals that over 70% of Dr. Rodriguez's patients only have a high school education, your clinical feasibility team might want to carry out targeted marketing and education campaigns based on the populations health literacy.

H1's Work with Clinical Study Sponsors Validates this Approach

H1 has taken the above approach to PI and site selection with a variety of clinical study sponsors. Using Trial Landscape, part of H1's suite of solutions that enable drug development and adoption, we've helped clinical feasibility teams achieve their clinical trial diversity goals. Trial Landscape provides the comprehensive data these teams need to evaluate potential PIs and sites.

200,000+

doctors in the H1 platform have self identified their race

150,000+

doctors in the platform have indicated their languages spoken.

“If you're trying to get Hispanic or Black patients into your trial, what works very effectively is selecting doctors that look and speak like those patients,” says H1 Director of Product Marketing Alexandra Moens.

Doctors that look like your target patients and speak the same language as them can overcome the potential distrust these patients might have about clinical research.

“Something that we've heard a couple of times from patients is that they would not have participated in a trial if their doctor was not the same race,” says Moens. “These patients say, ‘because he looks and speaks like me, he understands the way that I think. He understands the kind of community that I'm in and truly addresses the kind of concerns and questions I have.”

H1 can surface data on:

- PIs
- Patients
- PIs that have completed trials
- How many trials PIs have conducted
- What phases those trials are in
- Publications
- Trial sites that successfully recruited & completed similar trials

You can also see doctors’ publication data. This information proved beneficial to a company that H1 was helping with enrolling more black patients in a Crohn’s disease trial. Using Trial Landscape, the company uncovered a doctor who wrote a paper about disparities in the care of black inflammatory bowel disease, a topic exactly on point with their planned study.

To find PIs and their affiliated sites on Trial Landscape, clinical study feasibility teams simply enter their custom criteria into Trial Landscape’s easy-to-use interface, and the system generates the answers they’re after.

Helping a Top 20 Pharma Company Find Diverse PIs

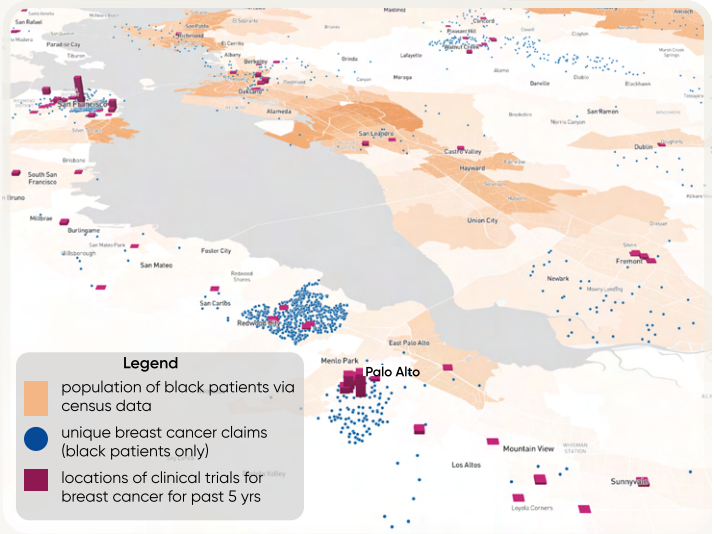
A top 20 pharma company asked H1 to help with the challenging task of identifying all new investigators and sites to use for a study, excluding all 180 sites they’d worked with in the past. The company wanted a diverse group of PIs who treat diverse patients. Despite the wide swath of sites that their parameters eliminated, H1 “exceeded their expectations in uncovering PIs and sites that were completely new to them,” explains Rivkin.

Working with CROs

While choosing the right PIs and study sites is foundational to success in enrolling a diverse cohort of patients, clinical study investigators must also remove other potential barriers to participation, such as patients lacking the time or means of accessing clinical trial sites.

Southern California

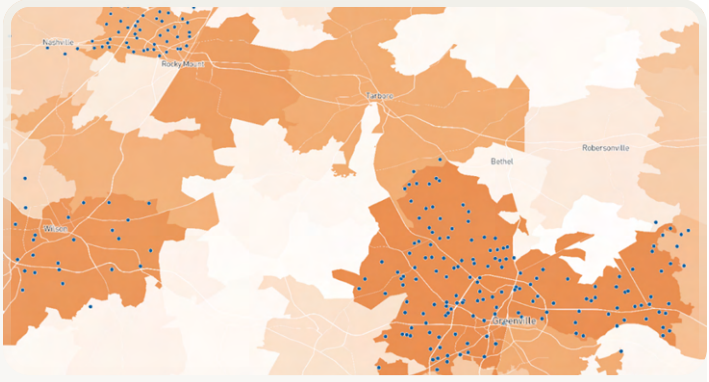
H1's data surfaces some interesting points. The trials are limited to a few metropolitan areas, but not near where the breast cancer claims are. If you look north of Palo Alto, you can see trials where there are very few claims for black breast cancer patients. Maybe pharma can rethink identifying potential investigators for breast cancer in geographies outside of Palo Alto, giving more patients access and opportunity to participate in trials.



Source: H1 clinical trials platform*

This is What Good Looks Like When It Comes to Care Access

In rural Pennsylvania, there is a high volume of black patients in the region but also a high number of claims, which means people are getting access to the care they need, where they live.



Source: H1 clinical trials platform*

That's why H1 partners with clinical research organizations and other companies that help overcome these barriers with solutions such as e-consent as well as remote clinical monitoring and data collection.

Working Together Towards More Diverse and Inclusive Clinical Research

H1 is helping the life sciences industry revolutionize clinical trial diversity and representation. Leveraging our deep clinical trial and diversity data insights at the site, PI, patient, and indication level - organizations can build plans to meet their specific goals.

Working together, H1 and internal expertise teams can create a new state of diversity and equity in clinical trials — one that meets our ideals of providing effective and equitable healthcare solutions for all.

We invite you to learn more. Visit h1.co.

References

*H1's Trial Landscape Clinical Trial Intelligence Platform

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