Clinical Trial Diversity Statistics 2026 by Race & Age

Published August 1, 2026 35 min read

Clinical Trial Diversity Statistics 2026 by Race & Age

Executive Summary

Diversity in pivotal trials supporting US FDA approvals remains far from proportional in 2026, despite a decade of federal transparency programs and an unresolved implementation timeline for a statutory requirement. This evidence base includes trials conducted both in the United States and internationally; it is not a measure of US-only participant enrollment. The **Food and Drug Administration (FDA)**'s Drug Trials Snapshots program, running continuously since January 2015, reports participant demographics from key clinical trials supporting CDER's original approvals of new drugs (Source: www.fda.gov), yet a peer-reviewed 2025 analysis of 341 pivotal FDA trials conducted between 2017 and 2023 found that only **6%** achieved enrollment aligned with the four largest US racial and ethnic groups' population shares (Source: www.nature.com). Black and Hispanic enrollment actually declined across that period even as Asian and White enrollment held stable or rose (Source: www.nature.com).

The statutory basis for change is the **Diversity Action Plan (DAP)** requirement created by Section 3601 of the Food and Drug Omnibus Reform Act of 2022 (FDORA). The submission requirement will apply to covered studies whose enrollment begins 180 days after FDA publishes final guidance; until then, FDA describes submitted diversity plans as voluntary. The statute requires enrollment goals disaggregated by race, ethnicity, sex, and age, along with a rationale and an explanation of how the sponsor intends to meet those goals (Source: www.govinfo.gov) (Source: vertassets.blob.core.windows.net). FDA issued the implementing draft guidance in June 2024, replacing an earlier 2022 draft (Source: www.govinfo.gov), but a January 20, 2025 executive order directing changes to federal diversity, equity, and inclusion (DEI) programs preceded FDA's removal of the guidance from its website (Source: www.dlapiper.com). A federal judge ordered the pages restored in February 2025 (Source: www.medtechdive.com), yet as of July 2026 the legally mandated final guidance, statutorily due by June 2025, still had not been issued, leaving sponsors uncertain how FDA will ultimately evaluate their plans (Source: www.ajmc.com).

The enrollment gap is widest exactly where disease burden is highest. In pooled heart failure trials, Black patients made up just **4.4%** of participants despite a documented higher incidence of heart failure in Black populations (Source: www.jacc.org) (Source: www.jacc.org). In oncology, a 2026 meta-analysis quantified this mismatch directly: Black cancer patients had an enrollment-to-incidence ratio of just **0.25** and Hispanic patients **0.51**, meaning both groups enroll in trials at roughly a quarter to a half of the rate their cancer incidence would predict (Source: link.springer.com). A systematic review of Alzheimer's disease trials from 1997 to 2023 found median White enrollment of **91.3%** against just **7.2%** for non-Hispanic Black participants and **5.2%** for Hispanic participants (Source: doi.org), despite older Black Americans being twice as likely as older White Americans to have Alzheimer's disease or another dementia (Source: www.alz.org).

Structural barriers compound the disparity: 70% of US counties had no active cancer clinical trial in 2022 (Source: www.healio.com), and Tufts Center for the Study of Drug Development found Black participation running **65%** below general census and disease-population levels in trials supporting approvals from 2007 to 2017 (Source: www.globenewswire.com). Industry and federal responses include NIH's **All of Us** Research Program, which had released data on more than 747,000 participants by June 2026, over three-quarters from historically underrepresented communities (Source: www.nih.gov), and sponsor-level programs such as Genentech's Site Alliance, which enrolled underrepresented patients roughly twice as fast as non-alliance sites (Source: www.fiercebiotech.com). This report examines the current state of that gap in detail, its regulatory context, its variation across race, ethnicity, sex, age, and disease area, and what the evidence suggests for sponsors, sites, and life-science organizations navigating compliance in 2026.

Introduction and Background

Clinical trial diversity, the degree to which the demographic composition of trial participants reflects the population that will ultimately use a medical product, has moved from a research-ethics talking point to a statutory policy priority in the United States. The shift accelerated after Congress passed the **Food and Drug Omnibus Reform Act of 2022 (FDORA)**, which amended the Federal Food, Drug, and Cosmetic Act to establish Diversity Action Plan submission requirements for covered studies; the mandatory submission trigger will apply only after FDA publishes final guidance and the 180-day statutory period has elapsed (Source: www.govinfo.gov). The underlying premise, stated explicitly in FDA's own guidance, is that certain populations are "frequently underrepresented in biomedical research including in clinical studies, even when they have a disproportionate burden for certain conditions or diseases relative to their proportional representation" in the general population (Source: www.govinfo.gov).

This report answers the question "clinical trial diversity statistics 2026" comprehensively: what the enrollment data actually show for race, ethnicity, sex, and age; how enrollment compares with disease burden across major therapeutic areas; what the FDA Diversity Action Plan requires and its uncertain 2026 enforcement status; which structural barriers, from clinical trial "deserts" to site-staff composition, may contribute to persistent gaps; and what named sponsors, regulators, and research programs are doing about it. It draws on federal transparency data, peer-reviewed benchmarking studies, industry association surveys, and named case studies to build a complete, source-verified picture rather than relying on any single dataset or advocacy claim.

The data landscape is unusually well documented for a regulatory topic. FDA's Center for Drug Evaluation and Research (CDER) has published Drug Trials Snapshots since January 2015 for approved new molecular entities and original biologics, reporting participant demographics and trial-location information (Source: www.fda.gov). A five-year aggregate FDA analysis covering 231 published snapshots tallied **292,766** clinical trial participants worldwide, of whom 35% were enrolled at US sites (Source: content.govdelivery.com) (Source: d142khf7ia35oz.cloudfront.net). Peer-reviewed researchers, academic centers, and industry associations including Tufts Center for the Study of Drug Development (CSDD), the Pharmaceutical Research and Manufacturers of America (PhRMA), the Society for Clinical Research Sites (SCRS), and the Association of Clinical Research Professionals (ACRP) have layered additional analysis on top of this federal baseline.

Two forces make 2026 a pivotal year for this topic. First, the compliance clock on FDORA's Diversity Action Plan mandate has effectively stalled: the statutory deadline for final guidance passed in June 2025 without FDA publishing it (Source: www.ajmc.com), following a politically charged episode in which the guidance was removed from FDA's website under a DEI-related executive order and then restored by court order (Source: www.dlapiper.com) (Source: www.medtechdive.com). Second, the underlying enrollment data continue to show the gap is not closing on its own: the most recent peer-reviewed benchmarking, covering trials through 2023, found enrollment for Black and Hispanic participants trending down rather than up (Source: www.nature.com). The sections that follow lay out the national numbers, the disease-specific disparities, the structural drivers, and the named organizational responses that define where clinical trial diversity in the United States actually stands in 2026.

The Regulatory Framework: FDA Diversity Action Plans and Federal Requirements

FDORA's Section 3601 amended sections 505(z) and 520(g) of the Federal Food, Drug, and Cosmetic Act to create a statutory Diversity Action Plan requirement for covered drug and device studies, while Section 3602 directed FDA to issue implementing guidance (Source: www.govinfo.gov) (Source: www.govinfo.gov). FDA published the resulting draft guidance on June 26, 2024, formally superseding an earlier April 2022 draft that had covered only racial and ethnic diversity plans, not sex or age (Source: www.govinfo.gov). Then-FDA Commissioner Robert Califf framed the requirement plainly: "Participants in clinical trials should be representative of the patients who will use the medical products" (Source: www.prnewswire.com).

The requirement applies to **Phase 3** studies (or other pivotal drug studies) and to covered device studies, including certain studies requiring an Investigational Device Exemption (IDE) and certain non-IDE device studies connected to specified premarket submissions (Source: vertassets.blob.core.windows.net) (Source: vertassets.blob.core.windows.net). A qualifying plan must set **enrollment goals disaggregated by race, ethnicity, sex, and age group** for the clinically relevant study population (Source: vertassets.blob.core.windows.net), and sponsors must justify those goals, particularly where they diverge from the estimated prevalence or incidence of the disease in question (Source: vertassets.blob.core.windows.net). The guidance also lays out criteria and a process for sponsors to request waivers from the submission requirement altogether (Source: www.govinfo.gov).

FDORA itself built in a compliance timeline: Section 3602 directed FDA to publish final guidance no later than nine months after the draft comment period closed, and the mandatory DAP submission requirement becomes legally binding only for studies whose enrollment begins 180 days after that final guidance is published (Source: www.dlapiper.com) (Source: www.dlapiper.com). That timeline has since been disrupted by politics rather than science. On January 20, 2025, a Trump administration executive order directed changes to federal diversity, equity, and inclusion (DEI) programs; FDA subsequently removed the draft DAP guidance from its website (Source: www.dlapiper.com), a move Reuters reported under the headline "US FDA drops web pages on improving clinical trial diversity" (Source: www.reuters.com). A federal judge subsequently ordered FDA and other federal health agencies to restore the removed pages (Source: www.medtechdive.com), and FDA began restoring the 2024 DAP draft guidance on February 12, 2025 following the resulting temporary restraining order (Source: www.agencyiq.com).

Restoration did not fully resolve the uncertainty. When the guidance page reappeared, it carried a disclaimer disputing "gender ideology," tied to a separate executive order unrelated to the DAP's original purpose (Source: www.ajmc.com). By June 2025, the regulatory press was reporting the "Future Of US FDA's Diversity Action Plan Guidance 'Up In The Air' As Statutory Deadline Looms" (Source: insights.citeline.com), and as of a July 29, 2026 analysis, the legally mandated final guidance was still outstanding, leaving sponsors without a settled framework for how FDA would score their diversity plans (Source: www.ajmc.com). Congress has continued to press the issue from a different angle: in mid-2026, House Republicans' FY2027 FDA appropriations bill (H.R. 8646) pushed FDA to continue implementing diversity action plan requirements for late-stage trials while explicitly distancing the effort from DEI framing (Source: www.ajmc.com).

Running in parallel to the DAP saga is FDA's longer-standing transparency mechanism, the **Drug Trials Snapshots** program. Active since January 2015 (Source: www.fda.gov), it reports each approved drug's pivotal trial demographics across female percentage, White, Black, Asian, and Hispanic percentage, age 65-and-over percentage, and US-participant percentage (Source: www.fda.gov). The 2024 summary report covered the 50 novel drugs CDER approved that year (Source: www.fda.gov), continuing an unbroken decade of disclosure that exists independent of whatever happens to the DAP mandate itself.

Table 1 below summarizes this regulatory timeline.

DATE	EVENT	SOURCE
December 29, 2022	FDORA Section 3601 creates statutory Diversity Action Plan requirement; Section 3602 mandates FDA guidance	(Source: www.govinfo.gov
April 2022	FDA issues initial draft guidance on race/ethnicity-only diversity plans (later superseded)	(Source: www.govinfo.gov
June 26, 2024	FDA issues expanded draft guidance covering race, ethnicity, sex, and age Diversity Action Plans	(Source: www.prnewswire.com
January 27, 2025	Executive order pausing federal DEI activity; FDA removes DAP guidance from its website	(Source: www.dlapiper.com
February 12, 2025	Federal court orders restoration; FDA begins restoring the DAP draft guidance	(Source: www.agencyiq.com
June 2025	Statutory deadline for final guidance passes without publication	(Source: www.ajmc.com
Mid-2026	FY2027 FDA appropriations bill (H.R. 8646) urges continued DAP enforcement, distanced from DEI framing	(Source: www.ajmc.com

The table illustrates a statutory framework whose mandatory DAP submission trigger has not yet occurred. FDA's current DAP document remains draft guidance, and FDA has described the plans received to date as voluntary; sponsors can plan proactively, but they are not yet subject to the FDORA DAP-submission mandate (FDA DAP guidance (FDA report to Congress.

National Clinical Trial Enrollment by Race, Ethnicity, Sex, and Age

The clearest national baseline comes from FDA's own five-year aggregate analysis of Drug Trials Snapshots data. Across 231 published snapshots totaling 292,766 global participants, US sites contributed 102,596 participants, 35% of the total (Source: pmc.ncbi.nlm.nih.gov). Within that pooled data, Black or African American participants were enrolled at a mean of 16.3%, actually slightly above their 13.4% US Census share (Source: pmc.ncbi.nlm.nih.gov). Asian participants, by contrast, were substantially underrepresented at a mean of 1.6% against a 5.9% Census share (Source: pmc.ncbi.nlm.nih.gov), White participants were slightly overrepresented at 78.3% versus a 76.3% Census share (Source: pmc.ncbi.nlm.nih.gov), and Hispanic or Latino participants were underrepresented at a mean of 15.3% against an 18.5% Census share (Source: pmc.ncbi.nlm.nih.gov). These pooled Snapshot figures describe participants at US sites in trials supporting FDA approvals from 2015 through 2019; they should not be read as directly comparable with disease-specific, study-level proportionality analyses, which use different trial samples, populations, and methods. This same five-year FDA report found that female participation was notably higher at US sites (56%) than in the global pooled trial population (49%) (Source: d142khf7ia35oz.cloudfront.net), that US participants skewed younger than participants enrolled outside the United States (Source: d142khf7ia35oz.cloudfront.net), and that Black or African American participants were specifically underrepresented within the 65-and-older age bracket, at a rate 6 percentage points lower than in younger cohorts (Source: d142khf7ia35oz.cloudfront.net).

More recent data suggest the picture has not improved and, on some measures, has worsened. A 2025 peer-reviewed study analyzing 341 Phase 3 pivotal trials supporting FDA approvals from 2017 to 2023 found that only **6%** achieved enrollment aligned with the population distribution of the four largest US racial and ethnic groups. Because the dataset includes both US-based and internationally conducted trials, this benchmark does not measure US-only enrollment (Source: www.nature.com). Among trials supporting drugs approved in 2023 specifically, only **23%** had representative Black enrollment (Source: www.nature.com) and only **30%** had representative Hispanic enrollment, compared with **81%** for Asian participants (Source: www.nature.com). The same study found Black and Hispanic participant enrollment declining over the study period while Asian and White enrollment increased or held stable (Source: www.nature.com), and it found trials with US-based recruitment sites enrolled more Black participants than internationally recruited trials (Source: www.nature.com), underscoring how much geography, not just eligibility criteria, shapes the final demographic mix.

Health Affairs research corroborates the stagnation. Comparing trials before, during, and after FDA's earlier 2015 five-year diversity action plan, researchers found Black patients remained inadequately represented, at a median of just **one-third** the enrollment that proportional representation would require, regardless of when the trial started (Source: www.healthaffairs.org). The same analysis found fewer than **20%** of drugs studied had

treatment benefit or side-effect data reported specifically for Black patients, a gap that did not narrow over the study period (Source: www.healthaffairs.org).

Sex-based representation has its own long, uneven history. Congress wrote inclusion of women and minorities in NIH-funded research into federal law through the 1993 NIH Revitalization Act (Source: orwh.od.nih.gov), reversing a legacy 1977 FDA policy that had actively recommended excluding women of childbearing potential from Phase 1 and early Phase 2 drug trials in the wake of the thalidomide tragedy (Source: orwh.od.nih.gov). Yet current data still show a shortfall in some fields. A cross-sectional analysis of cardiovascular trials from 2017 to 2023 found women made up only **41.0%** of 1,396,104 participants (Source: jamanetwork.com), and an earlier 2010 to 2017 analysis of cardiovascular trials found women made up just **38.2%** of 862,652 adults enrolled (Source: pubmed.ncbi.nlm.nih.gov). A landmark historical NEJM analysis of NHLBI-funded cardiovascular studies from 1965 to 1998 found female enrollment (54%) actually exceeded the female share of cardiovascular disease prevalence in the general population (49%), though that pattern reversed once single-sex studies were excluded from the analysis (Source: www.nejm.org).

Age representation shows a parallel gap at the older end of life. A 38-year analysis of the SWOG cancer cooperative group's 45,670 patients found only **30.6%** were aged 65 or older (Source: doi.org), even though approximately **60%** of US cancer diagnoses occur in that same age group (Source: doi.org). FDA's own 2024 Drug Trials Snapshots analysis found only **36%** of participants enrolled in cancer drug programs were 65 or older (Source: www.fda.gov). A separate PLOS ONE cross-sectional review of the wider trial registry found that only **1.4%** of 80,965 interventional trials focused exclusively on elderly patients (Source: journals.plos.org), and a JAMA Network Open cross-sectional study of 229,558 participants across 166 trials supporting 44 new drug and biologic approvals from 2010 to 2019 found the oldest adults specifically remained underrepresented despite representing a large share of the treated population (Source: www.ovid.com). At the opposite end of the age spectrum, a pediatric oncology study found only **19.9%** of estimated US pediatric cancer patients aged 0 to 19 enrolled in Children's Oncology Group trials between 2004 and 2015 (Source: journals.plos.org).

Sponsor-level data tell a similar story. A 10-year analysis of Amgen's US clinical trials found 31,619 participants across 258 trials were 74% White, 17% Black, 3% Asian, and less than 1% American Indian or Alaska Native (Source: link.springer.com) (Source: link.springer.com), while male representation became disproportionately higher than female representation specifically between 2016 and 2020 (Source: link.springer.com).

Table 2 below consolidates this national demographic picture against US Census benchmarks.

GROUP	US CENSUS SHARE	2015-2019 FDA PIVOTAL TRIALS (MEAN)	2023-APPROVAL TRIALS, % REPRESENTATIVE
Black / African American	13.4% (Source: pmc.ncbi.nlm.nih.gov)	16.3% (Source: pmc.ncbi.nlm.nih.gov)	23% of trials representative (Source: www.nature.com)
Hispanic / Latino	18.5% (Source: pmc.ncbi.nlm.nih.gov)	15.3% (Source: pmc.ncbi.nlm.nih.gov)	30% of trials representative (Source: www.nature.com)
Asian	5.9% (Source: pmc.ncbi.nlm.nih.gov)	1.6% (Source: pmc.ncbi.nlm.nih.gov)	81% of trials representative (Source: www.nature.com)
White	76.3% (Source: pmc.ncbi.nlm.nih.gov)	78.3% (Source: pmc.ncbi.nlm.nih.gov)	Stable / increasing over time (Source: www.nature.com)

The table juxtaposes two non-comparable measures: US-site pooled enrollment in trials supporting approvals from 2015 to 2019, and the share of 2023-approval trials meeting a representativeness threshold in a later dataset that includes international recruitment. It therefore cannot establish a cross-period change in enrollment or parity for any group.

Diversity Versus Disease Burden by Therapeutic Area

Aggregate national statistics understate the problem in the specific disease areas where underrepresentation intersects with the highest disease burden. Four therapeutic areas illustrate this most starkly: oncology, cardiovascular disease, diabetes, and Alzheimer's disease.

In **oncology**, a JCO Oncology Practice analysis of FDA approval trials from 2012 to 2021 found older adults made up only 19% of participants, Asian patients 9.6%, Black patients just 3%, and Latino patients just 3% (Source: ascopubs.org). A more recent 2026 meta-analysis quantified the mismatch between enrollment and cancer incidence directly using an enrollment-incidence ratio (EIR): Black participants had an EIR of just **0.25** and Hispanic participants an EIR of **0.51**, meaning each group enrolls at roughly a quarter to a half of the rate its cancer incidence would predict (Source: link.springer.com). Earlier data from 2008 to 2018 FDA approvals found Black and Hispanic patients represented just 3.1% and 6.1% of oncology trial participants respectively (Source: link.springer.com). A real-world US cohort study covering 2017 to 2022 across five common cancers found overall trial participation of just 4.4% among Black patients and 4.2% among Latinx patients, compared with 7.2% among White patients (Source: pmc.ncbi.nlm.nih.gov), and the same study found the gap between Black and White participation widened specifically during the COVID-19 era compared with before the pandemic (Source: pmc.ncbi.nlm.nih.gov). The disease-burden mismatch behind these numbers is well documented by the American Cancer Society: Black men have a 67% higher prostate cancer incidence rate than White men but are more than twice as likely to die of the disease (Source: www.cancer.org), and Black women have a 38% higher likelihood of dying from breast cancer despite a 5% lower likelihood of diagnosis (Source: www.cancer.org). Site-level survey data from SCRS found African Americans, 13% of the US population, typically account for only about 5% of oncology trial participants (Source: myscrs.org).

In **cardiovascular disease**, a 2026 JACC abstract analyzing 233 major cardiovascular randomized controlled trials from 1986 to 2024 found average non-White representation of just **24.6%** and, critically, no significant improvement in the 2020 to 2024 period compared with 1986 to 2019 (Source: www.jacc.org) (Source: www.jacc.org). A JAMA Cardiology "Call to Action" from the Heart Failure Collaboratory stated bluntly that "despite bearing a disproportionate burden of heart failure (HF), Black and Hispanic individuals have been poorly represented in HF clinical trials" (Source: pmc.ncbi.nlm.nih.gov). The pooled global PARADIGM-HF and PARAGON-HF heart failure trials illustrate the point at scale: Black patients made up only **4.4%** of the combined study population, versus 78.1% White and 17.5% Asian (Source: www.jacc.org), even though JACC: Heart Failure notes plainly that "Black people have a higher incidence and prevalence of heart failure (HF) than White people" (Source: www.jacc.org). Not every heart failure trial shows this pattern: the PIONEER-HF trial of acute decompensated heart failure, which intentionally targeted Black American patients, enrolled a cohort that was 36% Black (Source: www.jacc.org), demonstrating that representative enrollment is achievable when it is designed as a study objective from the outset rather than left to default recruitment practices.

In **diabetes**, a meta-epidemiological review of type 2 diabetes randomized controlled trials from 2000 to 2020 found that in industry-funded trials specifically, the participation-to-prevalence ratio for White participants was 1.95 while the ratio for racialized participants was just **0.36** (Source: link.springer.com). This mismatch is especially consequential given that Hispanic or Latino individuals are 17% more likely, and non-Hispanic Black individuals 60% more likely, to have type 2 diabetes than non-Hispanic White individuals (Source: www.frontiersin.org). The HHS Office of Minority Health reports that in 2021, Hispanic and Latino adults were 81% more likely than US adults overall to develop diabetes-related kidney failure (Source: minorityhealth.hhs.gov), a disease-burden gap that a 0.36 participation-to-prevalence ratio does little to close.

In **Alzheimer's disease**, a systematic review of 71 US-based Phase 3 trials with published results from 1997 to 2023 found nearly half (49.3%) did not report patient race or ethnicity at all, and among those that did, median White enrollment stood at **91.3%**, against median enrollment of just **7.2%** for non-Hispanic Black participants and **5.2%** for Hispanic participants (Source: doi.org). Reporting practices and representation showed little improvement across the full 26-year study window. This gap sits against a documented disease-burden reality: the Alzheimer's Association reports that older Black Americans are twice as likely as older White Americans to have Alzheimer's disease or another dementia (Source: www.alz.org), with 21.3% of Black Americans aged 70 and older living with Alzheimer's disease specifically (Source: www.alz.org).

Table 3 below summarizes the representation-versus-burden mismatch across these four therapeutic areas.

THERAPEUTIC AREA	POPULATION EXAMINED	TRIAL REPRESENTATION MEASURE	DISEASE-BURDEN CONTEXT
Oncology	Black patients	EIR 0.25 (Source: link.springer.com); 3% of trial population (Source: ascopubs.org)	67% higher prostate cancer incidence, 2x more likely to die (men) (Source: www.cancer.org)
Cardiovascular	Black patients; non-White participants	4.4% Black participants in pooled **global** HF trials; not directly comparable with US disease-burden measures (Source: www.jacc.org); 24.6% non-White average, 1986-2024 (Source: www.jacc.org)	In the US, Black people have higher HF incidence and prevalence than White people (Source: www.jacc.org)
Diabetes	Racialized participants	PPR 0.36 in industry-funded trials (Source: link.springer.com)	Black patients 60% more likely to have T2D (Source: www.frontiersin.org)
Alzheimer's	Black, Hispanic patients	7.2% Black, 5.2% Hispanic vs. 91.3% White (Source: doi.org)	Black Americans 2x more likely to have dementia (Source: www.alz.org)

The pattern across all four disease areas is consistent: the groups with the highest documented disease incidence, prevalence, or mortality are the same groups most underrepresented in the trials generating the evidence base for treating that disease, a structural mismatch that FDA's own guidance explicitly names as the policy rationale for the Diversity Action Plan requirement (Source: www.citeline.com).

Analysis of Key Segments: Geographic Access, Trial Deserts, and Site-Level Barriers

Demographic underrepresentation in clinical trials is inseparable from where trials are physically located. An ASCO-affiliated analysis found that **70%** of US counties had no active cancer treatment trial in 2022, and those counties represented 74% of the country's total land area (Source: www.healio.com). The urban-rural gap is stark: **86%** of nonmetropolitan counties had no cancer clinical trial at all, compared with 44% of metropolitan counties (Source: www.healio.com).

Geographic exclusion is measurable at a finer grain, too. A 2025 census-tract study found approximately **40.9 million** US adults, 12.5% of the population, resided in what researchers term clinical trial "deserts" for gastrointestinal cancers specifically, and populations in these deserts had higher poverty rates than populations near trial sites (Source: pubmed.ncbi.nlm.nih.gov). The Milken Institute's geographic mapping of Phase 2 and 3 trial sites found that counties more than 60 miles from a trial site tend to have lower incomes and education levels, less internet access, and higher rates of disability, and that agricultural counties and American Indian reservations are disproportionately far from trial access points (Source: milkeninstitute.org).

Site-level workforce composition appears to be a meaningful lever. Tufts CSDD's global study of investigative site staff found a strong association between the racial and ethnic diversity of site staff and the diversity of enrolled patients (Source: arma.ac.uk), a finding echoed in industry practice: Genentech's Site Alliance, discussed further below, reported that its network of sites, selected in part for their ability to reach underrepresented communities, enrolled those patients roughly twice as fast as non-alliance sites (Source: www.fiercebiotech.com).

Industry and professional associations have documented both the barriers and their own responses. A PhRMA-commissioned survey of member companies found **97%** of respondents reported taking specific measures to address clinical trial access issues for underserved communities (Source: cdn.aglty.io), and PhRMA's own diversity principles, adopted by its Board of Directors, describe "addressing the systemic issues that deter mainly Black and Brown communities" from participating in research (Source: phrma.org). ACRP has separately pointed to the COVID-19 vaccine trials as a symptom of the broader problem, noting that the pivotal Pfizer and Moderna vaccine trials enrolled populations that were more than **70% white** (Source: acrpnet.org). SCRS's 2023 Site Landscape Survey, drawing on approximately 550 respondents, most representing research sites, tracked diversity and inclusion alongside financial health and technology adoption as a core theme for the clinical research site community (Source: myscrs.org).

Together, these findings identify geographic access, site-staff diversity, and site-selection practices as evidence-supported contributors to differences in trial access and enrollment. They do not establish the relative importance of those factors, individual willingness to participate, or the effect of any particular site-network model. Sponsors may therefore consider site selection and community partnership alongside eligibility criteria when designing recruitment strategies.

Data Analysis and Evidence: Historical Trends and Industry Benchmarking

The most rigorous historical benchmark comes from Tufts CSDD's analysis of pivotal trials supporting US drug approvals from 2007 to 2017. That study found Black participants were the single most underrepresented subgroup, with participation rates running **65%** below their levels in the general census and disease populations they were meant to reflect (Source: www.globenewswire.com), while Asian participants were over-represented and Hispanic/Latinx participants under-represented over the same decade (Source: www.globenewswire.com). Crucially, only **37%** of all pivotal trials in that decade even reported ethnicity data at all, and sex representation skewed in the opposite direction from race, with women under-represented by 7.3 percentage points and men over-represented by 7.5 percentage points (Source: www.globenewswire.com).

Placed side by side, the Tufts 2007-2017 benchmark, the Health Affairs analysis spanning FDA's 2015 diversity action plan, and the Nature Communications Medicine analysis of 2017-2023 trials collectively describe a decade and a half in which national policy attention increased sharply but measured Black and Hispanic enrollment did not meaningfully improve, and by some measures worsened after 2020 (Source: www.nature.com). This is consistent with the cardiovascular-specific finding that non-White representation showed no significant improvement between 2020-2024 and the prior 1986-2019 period (Source: www.jacc.org).

Part of the explanation is economic. Tufts CSDD's updated 2024 estimate of the direct cost of a Phase 2 or 3 clinical trial puts it at approximately $40,000 per day, with a single day of delay now worth roughly $500,000 to $800,000 in lost prescription drug or biologic sales, a dramatic increase from the outdated $4 to $5 million per-day-of-delay industry estimate that had circulated since 1993 (Source: csdd.tufts.edu) (Source: pubmed.ncbi.nlm.nih.gov), which Tufts characterized as "a gross misestimation for more than 25 years." Every added day spent building a more representative recruitment pipeline therefore carries a real, quantifiable opportunity cost that sponsors must weigh against the scientific and regulatory value of representative data, a tension the still-unfinished Diversity Action Plan guidance leaves unresolved for 2026 planning purposes.

Structural, non-financial barriers add to the picture. FDA's own five-year Drug Trials Snapshots aggregate confirmed almost **300,000** patients participated in trials supporting 2015-2019 approvals, with 35% enrolled from the United States (Source: content.govdelivery.com), a figure that puts the tens of millions of Americans living in clinical trial deserts, discussed in the prior section, into sharper relief: a substantial share of the domestic population physically cannot reach the infrastructure that produces the participation numbers regulators track. Taken together, the economic and geographic evidence identifies several potential constraints on more representative enrollment. It does not establish whether site investment, staff recruitment, eligibility-criteria reform, or other interventions is most effective in a given study population.

Case Studies and Real-World Examples

NIH All of Us Research Program

The National Institutes of Health opened national enrollment for the **All of Us Research Program** on May 6, 2018, with an explicit goal of building a diverse cohort of more than 1 million participants to advance precision medicine (Source: www.nih.gov). By June 2021, three years after launch, NIH reported that more than **80%** of participants came from communities historically underrepresented in biomedical research (Source: allofus.nih.gov). The program's 2024 genomic data release of 245,388 whole genome sequences reported that **77%** of participants came from historically underrepresented communities (Source: www.nature.com), and a JAMA Cardiology analysis of the cohort through June 2022 found non-Hispanic Black or African American participants numbered 73,348, or **20.5%** of that analytic subset, overrepresenting their Census share (Source: pubmed.ncbi.nlm.nih.gov). By June 2026, NIH reported data covering more than **747,000** participants, including over 535,000 whole genome sequences, describing the program as the largest integrated genomics and health database in the world (Source: www.nih.gov). All of Us illustrates that federally funded, purpose-built diversity recruitment at a national scale can substantially outperform the diversity metrics typical of pharmaceutical sponsor-run trials, though the program is a research cohort rather than an interventional drug trial, a distinction that limits direct comparison.

Genentech Site Alliance

Genentech, part of Roche, launched its **Site Alliance** program in 2021 to build long-term relationships with clinical trial sites capable of reaching historically underrepresented patient populations. Three years later, in August 2024, Genentech reported that Site Alliance sites enrolled underrepresented patients roughly **two times faster** than other sites (Source: www.fiercebiotech.com). In roughly a quarter of the clinical studies in which Site Alliance oncology sites participated, they were the sole recruiter of Black or Hispanic/Latinx patients across the entire study (Source: www.fiercebiotech.com), a striking indicator of just how concentrated diverse enrollment can be in a small number of purpose-selected sites when the rest of a trial's site network is not built with representation as an explicit criterion.

Novartis Beacon of Hope Initiative

Novartis launched its **Beacon of Hope** initiative as a 10-year commitment to address health and education inequities tied to clinical trial access. In July 2023, the company expanded the program, adding new technology partners to support Centers of Excellence at Historically Black Colleges and Universities (HBCUs), describing the effort as part of "our 10-year commitment to co-create programs that address health and education inequities" (Source: www.novartis.com). The initiative reflects a broader industry pattern of sponsors investing in academic and educational infrastructure, rather than only in individual trial recruitment, on the theory that a more diverse pipeline of clinical investigators and research staff will translate into more diverse enrollment over time, a theory consistent with the Tufts CSDD finding linking site staff diversity to patient diversity (Source: arma.ac.uk).

Columbia-Pfizer Clinical Trials Diversity Initiative

Columbia University and Pfizer established the **Columbia-Pfizer Clinical Trials Diversity Initiative** in September 2021, with Pfizer providing a three-year, **$10 million** grant to help establish and expand the program (Source: www.cuimc.columbia.edu). Pfizer's own clinical trials diversity page acknowledges the underlying problem the initiative was built to address: Black Americans make up roughly **13%** of the US population but only **5%** of clinical trial participants (Source: www.pfizer.com), a gap consistent with the SCRS oncology-specific survey figure cited earlier and with the Health Affairs finding of one-third proportional enrollment. The initiative pairs an academic medical center's community relationships with a large sponsor's clinical development pipeline, a model that Bristol Myers Squibb pursued at even larger scale through its **$100 million** program with National Medical Fellowships, launched in November 2020 to train 250 new racially and ethnically diverse clinical investigators (Source: news.bms.com).

Roche/Genentech Columvi Complete Response Letter: A Regulatory Enforcement Case

Not every case study is a success story, and one 2025 regulatory episode illustrates how seriously FDA can weigh population representativeness even without final Diversity Action Plan guidance in place. On May 20, 2025, an FDA advisory committee voted **8 to 1** that results from Roche's Phase 3 Starglo trial were not applicable to a US patient population (Source: www.fiercepharma.com). The trial had enrolled 48% of its patients in Asia, with 34% from China alone, while US patients made up only **9%** of the total trial population (Source: www.fiercepharma.com). On July 18, 2025, FDA followed through by issuing Genentech a complete response letter for glofitamab (Columvi) plus chemotherapy in diffuse large B-cell lymphoma, directly citing the Starglo population-representativeness concerns raised by the advisory committee (Source: www.oncologynewscentral.com). The case demonstrates that population representativeness concerns can affect real regulatory outcomes for sponsors regardless of exactly where the Diversity Action Plan guidance process stands, since FDA reviewers and advisory committees can and do apply representativeness scrutiny under existing statutory authority independent of the still-pending final DAP guidance.

Gilead Yeztugo (Lenacapavir): Diversity by Design in HIV Prevention

One 2025 approval illustrates how a trial program can recruit participants in populations central to its public-health objective. FDA approved Gilead's twice-yearly lenacapavir, marketed as **Yeztugo**, for HIV pre-exposure prophylaxis on June 18, 2025, based on the PURPOSE 1 and PURPOSE 2 trial program, which Gilead describes as demonstrating superiority "among a broad and geographically diverse range of cisgender men and gender-diverse people" (Source: www.gilead.com). The PURPOSE 1 trial, conducted primarily among cisgender women in sub-Saharan Africa, a population carrying a disproportionate share of the global HIV burden, recorded zero HIV infections among the **2,134** participants who received the drug (Source: www.gilead.com). The program stands in direct contrast to the Starglo case above: where Starglo's geographic concentration became a liability during FDA review, PURPOSE 1's deliberate recruitment among the population most affected by the disease became a central part of the approval narrative, illustrating that disease-burden-aligned trial design can function as a scientific and regulatory asset rather than merely a compliance obligation.

Implications and Future Directions

Three trends will shape how clinical trial diversity statistics evolve through the rest of 2026 and beyond. First, the regulatory status of the Diversity Action Plan requirement remains unresolved: the statutory deadline for final guidance passed in June 2025, the guidance itself has been entangled in a DEI-related executive order dispute and subsequent court-ordered restoration, and congressional appropriators are now pushing FDA to keep implementing the requirement while explicitly separating it from DEI politics (Source: www.ajmc.com). Sponsors planning Phase 3 programs in 2026 and 2027 face genuine uncertainty about what a compliant Diversity Action Plan will ultimately need to contain, even though the underlying statutory obligation under FDORA has not been repealed.

Second, the Roche/Genentech Columvi case shows that representativeness scrutiny is not contingent on the DAP guidance being finalized. FDA advisory committees and review divisions retain authority to question whether trial populations, wherever they were enrolled globally, support a claim about a US patient population, and sponsors running geographically concentrated trials outside the United States should expect that scrutiny to continue regardless of the DAP guidance's administrative status. The Gilead Yeztugo case, by contrast, suggests that sponsors who build disease-burden-aligned recruitment into a trial's original design, rather than retrofitting it after the fact, are positioned to turn representativeness into a competitive and regulatory advantage rather than a late-stage risk.

Third, the sponsor-level and academic initiatives profiled above, Genentech's Site Alliance, Novartis's Beacon of Hope, the Columbia-Pfizer and Bristol Myers Squibb-National Medical Fellowships programs, and NIH's All of Us Research Program, collectively suggest that measurable improvement in trial diversity is achievable when it is designed as an explicit program objective with dedicated funding and site infrastructure, rather than left to emerge from standard recruitment practices. The persistent gap documented across national, disease-specific, and geographic data in this report indicates that voluntary programs alone have not closed the mismatch at a system-wide level; the Nature Communications Medicine finding that Black and Hispanic enrollment actually declined from 2017 to 2023 suggests the gap could widen further without either binding regulatory pressure or substantially larger investment in the site-level infrastructure changes shown to work.

For life-science organizations managing the operational side of this compliance question, the challenge increasingly resembles a data and systems problem as much as a clinical one: enrollment goals must be tracked, disaggregated by race, ethnicity, sex, and age, against real-time site-level recruitment data, and reconciled with disease-prevalence benchmarks that sponsors must be prepared to justify to FDA. Life-science technology and advisory firms have begun positioning around exactly this operational layer. IntuitionLabs, a life-sciences and AI consultancy and Veeva Vault CRM X-Pages partner, describes its regulatory compliance work as building systems with "built-in compliance with FDA, EMA, and global regulations" (Source: intuitionlabs.ai), and its advisory practice explicitly offers "advisory services for maintaining compliance with industry regulations" alongside broader digital transformation and data engineering work for pharmaceutical and life-science organizations (Source: intuitionlabs.ai). As enrollment-tracking and diversity-reporting requirements grow more data-intensive, this kind of consultancy support for integrating trial-management, CRM, and regulatory-reporting systems is likely to become a more prominent part of how sponsors and CROs operationalize whatever final Diversity Action Plan framework FDA ultimately publishes.

Frequently Asked Questions (FAQs)

What is the FDA's Diversity Action Plan requirement? It is a statutory requirement created by Section 3601 of the Food and Drug Omnibus Reform Act of 2022. It will require covered Phase 3 (or other pivotal) drug studies and covered device studies to submit a plan setting enrollment goals disaggregated by race, ethnicity, sex, and age, along with a rationale and an explanation of how the sponsor intends to meet those goals, once the final-guidance timing trigger is met (Source: www.govinfo.gov) (Source: vertassets.blob.core.windows.net).

How diverse are US clinical trials in 2026? Results vary by trial sample and geography. In a study of pivotal trials supporting FDA approvals from 2017 to 2023, which included US and international recruitment, only 6% achieved enrollment aligned with the four largest US racial and ethnic groups' population shares (Source: www.nature.com), and Black and Hispanic enrollment declined over the study period (Source: www.nature.com).

Which racial or ethnic groups are most underrepresented in clinical trials? Asian participants are the most underrepresented relative to Census share in pooled national pivotal-trial data (1.6% versus a 5.9% Census share) (Source: pmc.ncbi.nlm.nih.gov), while Black and Hispanic patients are the most underrepresented relative to disease burden in specific high-burden areas such as oncology, cardiovascular disease, and Alzheimer's disease (Source: link.springer.com).

What percentage of US clinical trial participants are Hispanic or Latino? In FDA's pooled 2015-2019 pivotal trial data, Hispanic or Latino participants averaged 15.3% of enrollment against an 18.5% US Census share (Source: pmc.ncbi.nlm.nih.gov), and among drugs approved in 2023 specifically, only 30% of trials achieved representative Hispanic enrollment (Source: www.nature.com).

Are women adequately represented in clinical trials? It varies by field. Overall national pivotal-trial data show closer-to-parity representation, but specific disease areas such as cardiovascular disease show persistent underrepresentation, with women making up only 41.0% of a 1.4-million-participant pooled 2017-2023 cardiovascular trial cohort (Source: jamanetwork.com).

Is the FDA still enforcing clinical trial diversity requirements in 2026? FDORA established a Diversity Action Plan submission requirement, but FDA's guidance remains draft and the submission requirement has not yet commenced. FDA says plans submitted to date are voluntary; the statutory trigger applies to covered studies whose enrollment begins 180 days after publication of final guidance (Source: www.ajmc.com).

What is a clinical trial "desert"? It refers to a geographic area, often measured at the census-tract or county level, with no accessible clinical trial site nearby. One 2025 study found 40.9 million US adults, 12.5% of the population, lived in trial deserts for gastrointestinal cancers alone (Source: pubmed.ncbi.nlm.nih.gov), and 70% of US counties had no active cancer trial in 2022 (Source: www.healio.com).

How does clinical trial diversity vary by disease area? It varies by disease, study geography, eligibility criteria, recruitment sites, and the demographic measure reported. This report presents oncology, cardiovascular disease, diabetes, and Alzheimer's disease as examples, but their representation and disease-burden measures are not all directly comparable.

Why does FDA require Diversity Action Plans instead of leaving enrollment voluntary? FDA's guidance states that certain populations are frequently underrepresented in biomedical research "even when they have a disproportionate burden for certain conditions or diseases relative to their proportional representation," which is the explicit statutory and scientific rationale Congress and FDA cite for making diversity planning mandatory rather than voluntary for covered pivotal trials (Source: www.govinfo.gov).

Conclusion

Clinical trial diversity statistics in 2026 describe a system under real but unevenly applied pressure to change. FDORA created a statutory framework for Diversity Action Plans, but FDA states that the DAP submission requirement has not yet come into effect because final guidance has not been published. A decade of FDA Drug Trials Snapshots data has made enrollment gaps unusually visible and quantifiable. Yet the most recent peer-reviewed benchmarking shows that the gap widened rather than closed for Black and Hispanic participants specifically, even as national attention to the issue intensified. Evidence of representation gaps and disease-burden mismatches is consequential in oncology, diabetes, and Alzheimer's disease; cardiovascular findings should be interpreted with attention to whether the trial and comparator share the same geographic scope.

What has changed measurably is the response infrastructure: NIH's All of Us Research Program has built a diverse national research cohort at unprecedented scale, and sponsor-level programs such as Genentech's Site Alliance and Novartis's Beacon of Hope have reported progress in reaching underrepresented communities. For sponsors and sites, representative recruitment and transparent demographic tracking can strengthen the relevance of clinical evidence. That practical value is distinct from the statutory DAP submission requirement, which FDA says has not yet come into effect.

Tags: clinical trial diversity, clinical trial diversity statistics, fda diversity action plan, clinical trial enrollment by race, minority participation in clinical trials, clinical trial disparities, fdora, clinical trial diversity 2026

IntuitionLabs - Industry Leadership & Services

North America's #1 AI Software Development Firm for Pharmaceutical & Biotech: IntuitionLabs leads the US market in custom AI software development and pharma implementations with proven results across public biotech and pharmaceutical companies.

Elite Client Portfolio: Trusted by NASDAQ-listed pharmaceutical companies.

Regulatory Excellence: Only US AI consultancy with comprehensive FDA, EMA, and 21 CFR Part 11 compliance expertise for pharmaceutical drug development and commercialization.

Founder Excellence: Led by Adrien Laurent, San Francisco Bay Area-based AI expert with 20+ years in software development, multiple successful exits, and patent holder. Recognized as one of the top AI experts in the USA.

Custom AI Software Development: Build tailored pharmaceutical AI applications, custom CRMs, chatbots, and ERP systems with advanced analytics and regulatory compliance capabilities.

Private AI Infrastructure: Secure air-gapped AI deployments, on-premise LLM hosting, and private cloud AI infrastructure for pharmaceutical companies requiring data isolation and compliance.

Document Processing Systems: Advanced PDF parsing, unstructured to structured data conversion, automated document analysis, and intelligent data extraction from clinical and regulatory documents.

Custom CRM Development: Build tailored pharmaceutical CRM solutions, Veeva integrations, and custom field force applications with advanced analytics and reporting capabilities.

AI Chatbot Development: Create intelligent medical information chatbots, GenAI sales assistants, and automated customer service solutions for pharma companies.

Custom ERP Development: Design and develop pharmaceutical-specific ERP systems, inventory management solutions, and regulatory compliance platforms.

Big Data & Analytics: Large-scale data processing, predictive modeling, clinical trial analytics, and real-time pharmaceutical market intelligence systems.

Dashboard & Visualization: Interactive business intelligence dashboards, real-time KPI monitoring, and custom data visualization solutions for pharmaceutical insights.

Leading Claude & ChatGPT AI Enablement and Training: Help biotech and pharmaceutical teams adopt Claude and ChatGPT through practical training, governed workflows, use-case development, and implementation designed for regulated environments.

AI Consulting & Training: Comprehensive AI strategy development, team training programs, and implementation guidance for pharmaceutical organizations adopting AI technologies.

Contact founder Adrien Laurent and team at intuitionlabs.ai/contact for a consultation.

DISCLAIMER

The information contained in this document is provided for educational and informational purposes only. We make no representations or warranties of any kind, express or implied, about the completeness, accuracy, reliability, suitability, or availability of the information contained herein.

Any reliance you place on such information is strictly at your own risk. In no event will IntuitionLabs.ai or its representatives be liable for any loss or damage including without limitation, indirect or consequential loss or damage, or any loss or damage whatsoever arising from the use of information presented in this document.

This document may contain content generated with the assistance of artificial intelligence technologies. AI-generated content may contain errors, omissions, or inaccuracies. Readers are advised to independently verify any critical information before acting upon it.

All product names, logos, brands, trademarks, and registered trademarks mentioned in this document are the property of their respective owners. All company, product, and service names used in this document are for identification purposes only. Use of these names, logos, trademarks, and brands does not imply endorsement by the respective trademark holders.

IntuitionLabs.ai is North America's leading AI software development firm specializing exclusively in pharmaceutical and biotech companies. As the premier US-based AI software development company for drug development and commercialization, we deliver cutting-edge custom AI applications, private LLM infrastructure, document processing systems, custom CRM/ERP development, and regulatory compliance software. Founded in 2023 by Adrien Laurent, a top AI expert and multiple-exit founder with 20 years of software development experience and patent holder, based in the San Francisco Bay Area.

This document does not constitute professional or legal advice. For specific guidance related to your business needs, please consult with appropriate qualified professionals.