

Design a Diversity Dashboard

What should I do?

Demonstrate your commitment to diversifying clinical trials by tracking your efforts to increase diversity, equity, and inclusion. Develop a system with metrics to ensure that diverse participant enrollment goals are met. Demonstrated commitment to advancing health equity can lead to sustainable mechanisms for improving the clinical trials process overall and for greater diversity, equity, and inclusion from the entire industry.

Why should I do it?

- Build trust and transparency between participants, Sponsors, and clinical trial teams for long term engagement and commitment to clinical research.
- Demonstrate commitment to eradicating health disparities and advancing health equity.
- Improve credibility as a leader in the clinical trials ecosystem.

Ethical Considerations

Diversity is needed to advance healthcare; therefore all stakeholders need to be accountable. The dashboard is a good way to get a baseline assessment of the diversity of your past and current trials. This will provide insights on how to develop strategies and tactics for a sustainable and effective diversity plan. Use multiple data and information sources to adequately represent multiple populations.

The [Food & Drug Administration](#) (FDA) and [National Institutes of Health](#) (NIH) have encouraged, recommended, and endorsed efforts for diversifying clinical research. The [2023 Omnibus spending bill and DEPICT Act](#) requires sponsors to submit a diversity plan and improve efforts to **promote greater diversity in clinical research**. While this is welcomed, decades-long challenges to diversify or make clinical trial participation more inclusive warrant more significant efforts. One mechanism that can influence actions and lead to progress is **demonstrated accountability**. We recommend that sponsors, clinical trial organizations (CRO), decentralized clinical trials (DCT), and clinical sites hold themselves accountable by implementing their own **tracking system**.

Use Artificial Intelligence/Machine Learning (AI/ML) to analyze Real-World Data/Real-World Evidence (RWD/RWE) to measure your diversity efforts, and use digital platforms or solutions to design a dashboard. See the “[Elements of a Diverse, Equitable, and Inclusive Digital Clinical Trial](#)” for details on using each of these tools.



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Building a Diversity Dashboard

1. Develop a diversity dashboard internally
 - a. Analyze and present data transparently and in a format that you can easily share.
2. Use AI/ML to analyze historical data from previous clinical trials
 - a. Compare proposed enrollment and retention goals to the actual number of participants enrolled and retained by:
 - i. race and ethnicity,
 - ii. Gender,
 - iii. Age,
 - iv. Geographic location,
 - v. Other diversity vectors (disabilities, socioeconomic status, academic attainment).
 - b. Compare enrollment goals to disease epidemiology for the general population, by geographic regions, and relevant to population sizes.
 - c. Mechanisms for participant engagement and other efforts to ensure inclusivity.
 - d. Different time points throughout the clinical trial life cycle.
 - e. Clinical site geographic locations.
 - f. Clinical site team demographics.
 - g. Clinical site workflows and processes, including team training and support for participants.
 - h. Start with these templates:
 - i. [Baseline Characteristics Template: Race, Ethnicity, Region](#)
 - ii. [Cumulative Inclusion Enrollment Report](#)
3. Develop a mechanism to collect and analyze data from current and future clinical trials.
 - a. Collect and analyze all data types listed above
 - i. Determine best methods for collecting comprehensive race and ethnicity data



- b. Collect and analyze additional efforts, including:
 - i. Community partnerships,
 - ii. Inclusive engagement,
 - iii. Clinical site support and training.
 4. Standardize data analysis on diversity efforts throughout your clinical trial cycle and make it a central component of final reports.
 5. Share your analyses and/or dashboard publically to influence others in the industry to follow.
 6. Encourage FDA and clinical trial industry societies and trade organizations to develop a public accountability metric for all clinical trials.
 - a. [Clinical Trial Diversity Score](#).
 - b. [CARER Clinical Trial Diversity Scorecard](#).

Build on Current Demonstrated Commitments

Many clinical trial sponsors have taken a first step by announcing their interests and planned efforts to increase diversity. Now is the time to take the next several steps.

- [Amgen - Clinical Trial Diversity and Representation](#). RISE (Representation in Clinical Research) is an Amgen program dedicated to improving the diversity and representation of participants in the company's clinical trials.
- [Demographic diversity of participants in Pfizer sponsored clinical trials in the United States](#). In order to establish a baseline of diversity in our clinical trials that can be used by us and other sponsors, an analysis of clinical trial diversity was conducted covering race, ethnicity, sex, and age.
- [Demographic diversity of US-based participants in GSK-sponsored interventional clinical trials](#). We investigate the racial and ethnic demographic diversity of US-based participants in GSK-sponsored interventional trials.
- [Genentech - Advancing Inclusive Research](#). Clinical and genetic data enriched by including more representative patient populations will enable us to evolve the promise of personalized healthcare to achieve more accurate diagnoses, improve access to therapies, and optimize treatment outcomes for all patients.
- [GSK - Diversity in Clinical Studies](#). At GSK, we believe our clinical studies must reflect the diversity of populations who are most likely to benefit from our medicines or vaccines.



- [Johnson & Johnson - Our Race to Health Equity](#). Our Race to Health Equity (ORTHE) was launched with the bold ambition that together, we can create a world where the color of your skin is not a determinant of your access to care, quality of care or health outcomes.
- [Takeda's Global Quest for Health Equity](#). Takeda's U.S. Health Equity division is also built on establishing community-based partnerships, sharing knowledge and creating sustainable organizational structures.





References & Resources

1. [Amgen - Clinical Trial Diversity and Representation](#). RISE (Representation in Clinical Research) is an Amgen program dedicated to improving the diversity and representation of participants in the company's clinical trials.
2. [CARER Clinical Trial Diversity Scorecard](#). This instrument was designed to evaluate diversity in the registrational clinical trials for novel new drugs and biological products approved by US FDA.
3. [Demographic diversity of participants in Pfizer sponsored clinical trials in the United States](#). In order to establish a baseline of diversity in our clinical trials that can be used by us and other sponsors, an analysis of clinical trial diversity was conducted covering race, ethnicity, sex, and age.
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5. [GSK - Diversity in Clinical Studies](#). At GSK, we believe our clinical studies must reflect the diversity of populations who are most likely to benefit from our medicines or vaccines.
6. [Johnson & Johnson - Our Race to Health Equity](#). Our Race to Health Equity (ORTHE) was launched with the bold ambition that together, we can create a world where the color of your skin is not a determinant of your access to care, quality of care or health outcomes.
7. [Metrics, baseline scores, and a tool to improve sponsor performance on clinical trial diversity: retrospective cross sectional study](#). This novel approach evaluates trials, products, and sponsors on their fair inclusion of demographic groups in research.
8. [Takeda's Global Quest for Health Equity](#). Takeda's U.S. Health Equity division is also built on establishing community-based partnerships, sharing knowledge and creating sustainable organizational structures.
9. [What gets measured gets done: Time for an industry metric to assess clinical trial diversity](#). Establishing a standardized metric to measure racial and ethnic clinical trial diversity provides several benefits.

