

Medidata AI Intelligent Trials Diversity Module

At Medidata, our vision is to be a catalyst in the life sciences industry, building solutions that enable Access for All and power greater diversity in clinical trials. We believe that improvements to access, awareness, and inclusion are not only possible but essential.

Improving diversity in clinical trials is ultimately an issue of health equity and success will occur when we break barriers and challenge norms to provide comprehensive treatments, quality services, strengthened community partnerships, and optimized patient experiences. We are stronger together.

Motivation for More Diversity The Right Way of Doing Things

The life sciences industry has an obligation to improve diversity in clinical trials. In April 2022, the FDA released draft guidance to improve enrollment in clinical trials for underrepresented racial and ethnic populations in the United States. This gap between patients recruited and those affected by the disease could be undermining efficacy outcomes. Increasing diversity in clinical trials leads to:

- Better science
- Representative outcomes
- More equity

HOW OUR DATA IS DIFFERENT:

Cross-industry sponsor and CRO data: allows holistic insights into what you can expect at the indication, country and site-level

Standardized and analysis-ready demographic and operational data: enabling you to understand both operational and diversity performance, together, and bring diversity into your feasibility process

Actionable, granular site level data: provides you critical insights into what sites can help you enroll quickly and ensure that you have a diverse patient population)

Our Solution

Intelligent Trials Diversity module provides insights that allow you to take action to improve study diversity during the planning stages. This enables you to make qualified decisions about site selection to find sites that not only will perform well operationally, but have also demonstrated the ability to recruit diverse patients.

DIVERSITY MODULE CAPABILITIES

- Baseline and benchmark the diversity of your trials in a specific indication vs. industry trials to identify gaps and reasonable diversity goals
- Provide actionable insights into how to improve the diversity of your trials by identifying sites that are more likely to perform well operationally AND recruit diverse patient populations

WHAT METRICS ARE WE USING TO CAPTURE DIVERSITY?

- Diversity is captured via 4 main demographic variables: age, sex, race, and ethnicity
- Analysis is done at the indication level, and can be further narrowed down by phase, country, and all the way down to a specific site

OUR DATA:

With the industry's largest scientific and operational dataset, Medidata AI provides a unique and integrated view of site-level performance and demographic data. This allows you to identify sites that enroll fast and a diverse population.

27,000 +
STUDIES RUN

8,000,000+
TRIAL SUBJECTS

1,000,000+
STUDY-SITES

150+
COUNTRIES

Medidata AI has gone through the process of standardizing our clinical and operational data. This data is surfaced in our Intelligent Trials solution to provide our customers the unique ability to derive relevant insights for enrollment planning. Sponsors and CROs have the ability to filter and sort through a site list in a particular indication, and choose the best performing sites while simultaneously evaluating **site experience, operational performance, and diversity metrics.**

Use Case: Diversity Benchmarking for a Large Sponsor

SITUATION

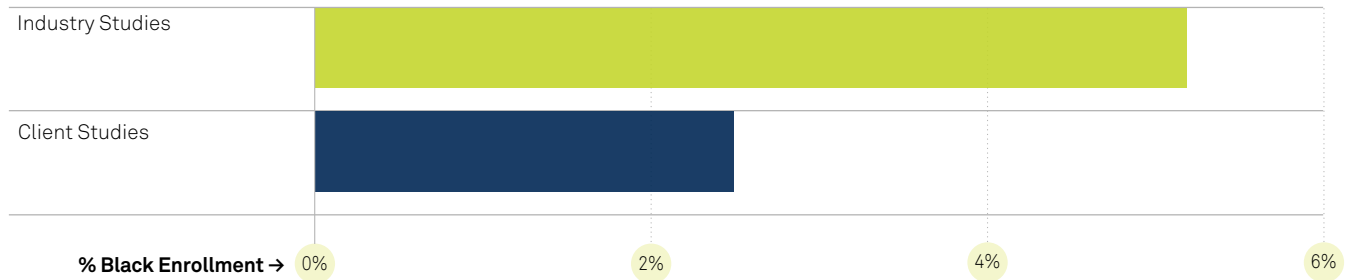
A large sponsor asked the Intelligent Trials team to benchmark diversity in their clinical trials, and help them identify how they were performing vs. industry to help them start setting goals. They also wanted to understand how to improve diversity in their trials with data-driven site selection.

APPROACH

1. Baseline and benchmark sponsor's study diversity against industry performance
 - Industry vs. client rates diversity in sex, age, race, and ethnicity
 - Industry vs. client rates of diversity by phase and country
 - Global vs. U.S. view
2. Analyze site-level diversity and gain insights into appropriate sites for this indication
 - Data extract with site list and site level metrics for sex, age, race, and ethnicity
 - Insights on best performing sites for recruiting certain demographics

RESULT

INDUSTRY HAD ~2X BLACK PARTICIPANT ENROLLMENT VS. CLIENT



Our data and analytics showed the sponsor that they had a significant gap vs. industry. In fact, they were recruiting half as many Black participants as other industry studies.

Site level analysis - Race

Site #	Site Name	Site City	Site Country	# Studies	# Enrolled Participants	% Black Participants
1	masked	Atlanta	United States	6	41	30% - 40%
2	masked	New Haven	United States	9	62	30% - 40%
3	masked	Hasselt	Belgium	4	19	30% - 40%
4	masked	Matthews	United States	14	74	20% - 30%
5	masked	Hattiesburg	United States	14	72	20% - 30%

In order to help the sponsor improve the diversity of their trial in this particular indication, we provided insights into which industry sites they could leverage. This image shows the top five sites that enrolled between 20-40% black participants into industry studies.