



Developing a site plan for diversity enrollment: A practical approach to implementing best practices

October 7, 2022

Today's speakers



Brandon Doyle

Associate Director,
Site Alliances

Parexel



Van Johnson

Vice President of
Commercial Strategy

**Benchmark
Research**



Fabian Sandoval, M.D.

President & CEO,
**Emerson Clinical
Research Institute**



Kim Kundert, RN/BSN

SVP of Site
Development Services

**Total Diversity
Clinical Trial
Management**

Current clinical trials landscape

- › Diverse lived experiences affect health and response to medications
- › Age
- › Biological sex
- › Chronic comorbidities
- › Disabilities
- › Gender identity
- › Geographical location
- › Ethnicity
- › Race
- › Socioeconomic status (SES)

Clinical trial enrollment vs US Census data

2020	Women	White	Black or African American	Asian	*See below	Hispanic	Age 65+	From US
US Census Average	50.8%	76.3%	14.4%	5.9%	3.4%	18.5%	16.5%	100%
Clinical Trial Enrollment Average	56%	75%	8%	6%	11%	11%	30%	54%**
Oncology Trial Enrollment Average	50%	73%	5%	14%	8%	6%	44%	41%**

- * The percentage of all other races combined (American Indian or Alaska Native, Native Hawaiian or other Pacific islander, Other, Unknown/Unreported) makes up to 100% of race category.
- ** The percentage of patients from anywhere else in the world makes up to 100% of geographic category.

Recent US FDA guidance's and Congressional ACTs

- Nov 2020
 - Broadening eligibility criteria and avoiding unnecessary exclusions
 - Make trials less burdensome
 - Adopt practices that enhance inclusiveness
- April 2022
 - Sponsor diversity plan
 - Specify goals for enrollment of underrepresented racial and ethnic participants
 - Plan to enroll and retain diverse populations
 - Describe specific enrollment and retention strategies
- Diverse and Equitable Participation in Clinical Trials ACT
 - Enhance data reporting
 - Provide resources to improve access

Creating a Site Diversity Plan

Baseline of community vs patient database

- What are the demographics of the geographic location of your clinic?
- What are the demographics of your patient database?
- Identify underrepresented patient populations
- Focus and highlight high diversity

Study Staff and PIs

- Hire Study Staff/PIs to be representative of your community demographics
 - Cultural Competency
 - Nuanced language that resonates with a particular community (i.e. McDonald's money)
 - Trust
 - Belonging

- Tuft's CSDD Working Group Study on Staff Diversity in Global Investigative Sites, 2021
 - Strong association was observed between site staff diversity and patient diversity

Site environment and communication

- Sensory cues to create sense of belonging
 - Decor
 - Music
 - Advertisements
 - Television
 - **STUDY STAFF!!!**

Study staff training

- Understanding implicit bias and micro-aggressions
 - Harvard Implicit Association Test (gender, weight, disability, skin-tone, age, sexuality, race, transgender, Asian)
 - <https://implicit.harvard.edu/implicit/>
- Cultural Competency for different communities
 - Black/African American
 - Hispanic/LatinX
 - LGBTQ+
 - People with disabilities

Site outreach and community engagement

- Connect with community leaders who represent the different communities that reside in your site's region
 - Word of mouth referrals
- Participate in local community events
 - Long-term approach
 - Building lasting, trusting relationships
- Expand your access to patients
 - Mobile clinics

Minimizing patient barriers

**Distance to Site or
lack of
transportation**

**Inability to miss
work (work schedule
and financial loss)**

Language barrier

Primary caretaker

Minimizing patient barriers

**Distance to Site or
lack of
transportation**

**Inability to miss
work (work schedule
and financial loss)**

Language barrier

Primary caretaker

➤ Offer
transportation

Minimizing patient barriers

**Distance to Site or
lack of
transportation**

- Offer transportation

**Inability to miss
work (work schedule
and financial loss)**

- Offer early am, evening, or weekend hours
- Provide stipend timely
- Education on benefits of trial*

Language barrier

Primary caretaker

Minimizing patient barriers

Distance to Site or lack of transportation

- Offer transportation

Inability to miss work (work schedule and financial loss)

- Offer early am, evening, or weekend hours
- Provide stipend timely
- Education on benefits of trial*

Language barrier

- Hire multi-lingual staff
- Translate study materials

Primary caretaker

Minimizing patient barriers

Distance to Site or lack of transportation

- Offer transportation

Inability to miss work (work schedule and financial loss)

- Offer early am, evening, or weekend hours
- Provide stipend timely
- Education on benefits of trial*

Language barrier

- Hire multi-lingual staff
- Translate study materials

Primary caretaker

- Offer to watch children

Measuring success



Establish a baseline

- › Measure & document demographics by % of patient database
- › Research & document demographics by % of community
- › Establish goals to increase certain demographics by x%
- › Complete Diversity Site Assessment Tool (DSAT)



Track Progress

- › Monitor demographic enrollment of each trial
- › Monitor demographic growth of patient database every 6 months
- › Evaluate progress to established goals every 3 months
- › Retake DSAT every 6 months

**DIVERSITY PLAN
PROJECT/SITE LEVEL**

INDICATION:	PROTOCOL #:	PRINCIPAL INVESTIGATOR NAME:	SITE #:
--------------------	--------------------	-------------------------------------	----------------

Indication prevalence among minority populations

- Utilize scholarly articles, medical journals, websites (<https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=1&lvlid=1>) to educate site staff on prevalence of disease among underserved and minority patients.

Section A. Investigator Site Subject Availability Assessment

Based on the above findings, indicate below the anticipated target enrollment by race/ethnicity

<input type="checkbox"/> Black/African American	<input type="checkbox"/> Hispanic
<input type="checkbox"/> Asian	<input type="checkbox"/> Non-Hispanic
<input type="checkbox"/> White	
<input type="checkbox"/> American Indian or Alaska Native	
<input type="checkbox"/> Native Hawaiian or Pacific Islander	

It is important that the estimated number of subjects the site says it can deliver be realistic and evidence based.

Section B. Source of Subjects- internal vs. external

Identify specific sources of underserved or minority patient populations:

Internal Database Recruitment

Source	Estimated number of patients	Planned outreach method	Planned outreach timing
Research database			
Practice database			
Routine visits			
Lab result review			
Medication refill review			

External Recruitment

Source	Estimated number of patients	Planned outreach method	Planned outreach timing
Physician referrals			
Pharmacy referrals			

**DIVERSITY PLAN
PROJECT/SITE LEVEL**

INDICATION:	PROTOCOL #:	PRINCIPAL INVESTIGATOR NAME:	SITE #:
--------------------	--------------------	---	----------------

Local pharmacies			
Community Outreach			
Patient advocacy groups			
Community health clinics			
Social Media			
Advertising			
Other*			

**Add rows as needed*

Section D. Increase Enrollment and Retention by Removing Barriers

- Provide transportation to research site (Uber, Taxi, bus fare)
- Offer childcare
- Extend office hours to accommodate working patients (evenings, early mornings, or weekends)
- Provide stipends timely and in a convenient method
- Translate recruitment and study materials for research site to have at study start
- Educate on clinical trial benefits

Section E: Site Recruitment Implementation Plan

Use this section to note the implementation plan, and later, any updates to the implementation plan. Note which sponsor-created recruitment materials the site will use, including quantities and languages, if applicable.

- Review of internal database/EMR for therapeutic indication with breakdown by race/ethnicity if possible.
- Outreach to referring physicians within minority communities with study details as they relate specifically to the patient population of that clinic. (Brochures, flyers, educational materials displaying inclusive artwork/pictures)
- Develop awareness of upcoming events within communities that you intend to reach (5Ks, church events, farmers markets, concerts, etc.) and arrange attendance by site staff.

Questions?



Thank you