



Checklist for Increasing Patient Diversity and Access to Clinical Trials

Special Thanks to our Co-Authors:

Keith Wright, Florence Healthcare

Janet Mathews, Drexel University

Jen Brown, Medical College of Wisconsin

Zoé Felicié, PPD

Matt Maxwell, Alcanza Clinical Research

Nancy Sacco, SiteBridge Research, Inc.

Amy Krueger, Bon Secours Mercy Health

Lindsey Guirgues, Bon Secours Mercy Health

Checklist for Increasing Patient Diversity and Access to Clinical Trials:

Introduction

In the pursuit of advancing clinical research and ensuring equitable access to the cutting edge therapies, it is imperative for all stakeholders within the clinical research industry—be they Sponsors, Contract Research Organizations (CROs), or Research Sites—to prioritize the enrollment of diverse patient populations. We, members of the Florence Site Enablement League, have been hard at work developing a comprehensive checklist designed to guide and empower these stakeholders in their efforts to enhance diversity and inclusivity within clinical trials. By adhering to the references and recommendations in this checklist, stakeholders can not only broaden the representation of patients participating in trials but also extend access to potentially life-saving treatments to individuals from historically marginalized or underrepresented communities. Embracing diversity in clinical research not only aligns with ethical imperatives but also fosters the generation of robust, generalizable data that ultimately benefits patients worldwide. Through concerted action guided by this checklist, stakeholders can collectively contribute to a more equitable and effective landscape of medical research and healthcare delivery.



Checklist for Increasing Patient Diversity and Access to Clinical Trials:

1. Diversity Planning:

- Develop a comprehensive diversity and inclusion plan.
- Set specific, measurable goals for diverse participant recruitment.
- Include diversity as a key performance indicator in trial planning.

Resources:

[Diversity Initiative Overview](#)

FDA- [Diversity Plans to Improve Enrollment of Participants from Underrepresent...](#)

Science 37- [How to Meet the FDA's Diversity Guidance](#)

MRCT- [Diverse Participant Engagement Strategies](#)

2. Community Engagement:

- Establish partnerships with local community organizations and leaders.
- Conduct informational sessions in diverse communities to educate about clinical trials.
- Prioritize community education as a method of recruitment
- Address cultural sensitivities and language barriers through effective communication.

Resources:

Dr. Sharon A Brangman- [Achieving diversity in study populations](#)

FDA- [Diversity Plans to Improve Enrollment of Participants from Underrepresent...](#)

Scott Gray- [Diversity in Clinical Trials: Going Beyond Why to How](#)

Science 37- [How to Meet the FDA's Diversity Guidance](#)

Mayo Clinic- [Community-Engaged Approaches for Minority Recruitment Into...](#)

3. Site Selection:

- Choose trial sites in geographically diverse locations.
- Consider the demographic composition of the area when selecting sites.
- Prioritize sites with a history of successfully recruiting diverse populations.

Resources:

Science 37- [How to Meet the FDA's Diversity Guidance](#)

MRCT- [Diverse Participant Engagement Strategies](#)

4. Patient Education:

- Develop educational materials in multiple languages.
- Use plain language and visual aids to enhance understanding.
- Provide information about the importance of diversity in clinical trials.

Resources:

ACRP- [How to Make Clinical Trials More Diverse and Inclusive](#)

MRCT- [Diverse Participant Engagement Strategies](#)

Checklist for Increasing Patient Diversity and Access to Clinical Trials:

5. Cultural Competency Training:

- Provide training for trial staff on cultural competence and sensitivity.
- Ensure staff is knowledgeable about diverse cultural practices and beliefs.

Resources:

Science 37- [How to Meet the FDA's Diversity Guidance](#)

6. Patient Advocacy Involvement:

- Collaborate with patient advocacy groups focused on diverse populations.
- Seek input from these groups in trial design and participant engagement strategies.

Resources:

FDA- [Diversity Plans to Improve Enrollment of Participants from Underrepresent...](#)

Science 37- [How to Meet the FDA's Diversity Guidance](#)

Mayo Clinic- [Community-Engaged Approaches for Minority Recruitment Into...](#)

Project Muse- [Defining and Measuring Community Engagement and Community...](#)

7. Inclusive Outreach:

- Use diverse channels for recruitment, including social media, community events, and local media.
- Leverage patient registries to identify potential participants from diverse backgrounds.

Resources:

ACRP- [How to Make Clinical Trials More Diverse and Inclusive](#)

Julie M. Vose, MD- [Minority Enrollment to Clinical Trials: Road to Increased Access...](#)

Mayo Clinic- [Community-Engaged Approaches for Minority Recruitment Into...](#)

8. Flexible Trial Design:

- Consider flexible inclusion and exclusion criteria to accommodate diverse patient characteristics.
- Account for variations in disease prevalence among different demographics.

Resources:

[Diversity of Participants in Clinical Trials](#)

FDA- [Achieving Diversity, Inclusion, and Equity in Clinical Research Webinar](#)

Science 37- [How to Meet the FDA's Diversity Guidance](#)

Checklist for Increasing Patient Diversity and Access to Clinical Trials:

9. Accessible Locations and Facilities:

- Ensure that trial sites are easily accessible by public transportation.
- Provide facilities that are accommodating and culturally sensitive.

Resources:

ACRP- [How to Make Clinical Trials More Diverse and Inclusive](#)

Science 37- [How to Meet the FDA's Diversity Guidance](#)

Julie M. Vose, MD- [Minority Enrollment to Clinical Trials: Road to Increased Access...](#)

10. Financial Assistance:

- Offer financial assistance for transportation and lodging for participants.
- Collaborate with insurers and sponsors to reduce financial barriers for diverse populations.

Resources:

FDA- [Achieving Diversity, Inclusion, and Equity in Clinical Research Webinar](#)

11. Data Collection and Reporting:

- Collect and analyze demographic data to monitor diversity.
- Regularly report on recruitment progress to sponsors and regulatory bodies.

12. Continuous Evaluation and Improvement:

- Conduct ongoing assessments of diversity strategies.
- Adjust strategies based on feedback and outcomes to continually improve recruitment.

Resources:

Science 37- [How to Meet the FDA's Diversity Guidance](#)

13. Regulatory Compliance:

- Stay informed about regulatory requirements related to diversity in clinical trials.
- Ensure compliance with guidelines and regulations promoting diversity.

Resources:

FDA- [Postmarketing Approaches to Obtain Data on Populations Underrepresented...](#)

Checklist for Increasing Patient Diversity and Access to Clinical Trials:

14. Diverse Investigator Pool:

- Encourage and support diversity among principal investigators and site staff.
- Promote opportunities for underrepresented groups to participate in clinical research.

Resources:

Science 37- [How to Meet the FDA's Diversity Guidance](#)

15. Patient Retention Strategies:

- Implement strategies to improve retention among diverse participants.
- Address specific concerns or challenges faced by participants from different backgrounds.

Resources:

ACRP- [How to Make Clinical Trials More Diverse and Inclusive](#)

FDA- [Achieving Diversity, Inclusion, and Equity in Clinical Research Webinar](#)

Science 37- [How to Meet the FDA's Diversity Guidance](#)

16. Public Awareness Campaigns:

- Launch public awareness campaigns about the importance of diverse participation in clinical research.
- Highlight success stories of individuals from diverse backgrounds who have participated in trials.

Resources:

FDA- [Diversity Plans to Improve Enrollment of Participants from Underrepresent...](#)

Science 37- [How to Meet the FDA's Diversity Guidance](#)

Project Muse- [Defining and Measuring Community Engagement and Community...](#)

17. Feedback Mechanisms:

- Establish mechanisms for participants to provide feedback on their trial experience.
- Use feedback to make real-time adjustments and enhance participant satisfaction.
- By systematically addressing each point on this checklist, sponsors, CROs, and sites can contribute to more inclusive and representative clinical trials.

Resources:

Science 37- [How to Meet the FDA's Diversity Guidance](#)

Other Resources and Tools:

[ASCO-ACCC Equity, Diversity, and Inclusion Research Site Self-Assessment](#)