

Support and Train Clinical Trial Site Staff

What should I do?

Set clinical trial teams up for success and alignment with your goals for diversity, equity, and inclusion. Use the recommendations and resources to create a training program for your clinical site team. Clinical sites need support and resources to successfully implement digitized clinical trials and execute your diversity, equity and inclusion strategies.

Why should I do it?

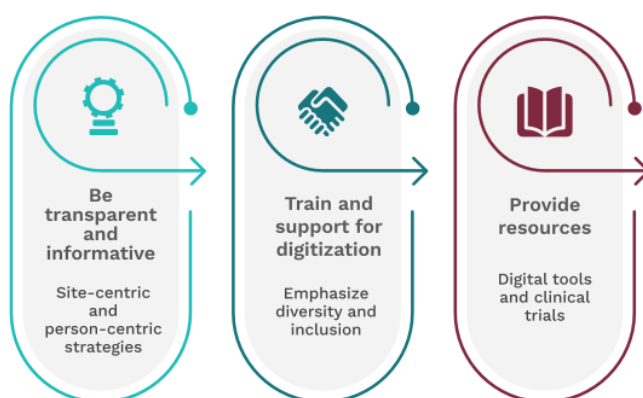
- Reduce burdens for participants and clinical trial teams by streamlining processes and including participants as partners.
- Build trust and transparency, and strengthen relationships between Sponsors and clinical trial teams.
- Increase compliance and participant adherence.
- Improve outcomes with more robust data collection.
- Increase and improve patient engagement and retention.
- Increase access and awareness for participants to clinical trial participation.
- Increase awareness for participants on clinical trial participation value and process.

Ethical Considerations

Support for clinical site teams will be critical for executing strategies for digitizing clinical trials and for improving diversity, equity, and inclusion. It is imperative that clinical sites have adequate information, training, and support. The recommendations and resources here serve as a starting point to help you develop training and support for your clinical teams.

To reinforce your strategies for diversity, equity and inclusion, especially with adding digital tools, you need to **provide support and training for clinical site staff**. Clinical trial success can be thought of as a coin; one side is **person-centricity** and the other side of the coin is **site-centricity**. Considerations on how best to support site staff will be critical to **ensuring clinical trial compliance** and collecting sufficient data to adequately assess the treatment’s **safety and efficacy**, and the ultimate success of your trial. Consider using these resources to develop a training program.

Several digital tools can be utilized to create training and offer continuous training for site staff; these include Artificial Intelligence/Machine Learning (AI/ML), Real World Data/Evidence (RWD/RWE), on demand videos, virtual visits, and other digital solutions. See the “[Elements of a Diverse, Equitable, and Inclusive Digital Clinical Trial](#)” for details on using each of these tools.



Recommendations on How to Support Clinical Site Teams

1. Be **transparent and informative**:
 - a. Implement a **site-centric strategy**
 - b. Share your **digital clinical trial strategy** and person-centric approach
 - c. Share your **enrollment and retention goals**, engagement plan, and overall diversity plan
 - d. **Share resources** from the “[Specific Actions to Enroll and Retain Diverse Participants workbook](#)”
 - e. **Identify** any **gaps** in knowledge or training, or additional areas that your clinical site teams would like specific training or information
2. **Train and support** for digitized clinical trials with an emphasis on increasing diversity and inclusion:

- a. Inform clinical trial teams about your plans for a digitized clinical trial
 - b. Share how **digitization** will enable **streamlined operations** and reduced administrative burdens
 - c. Share how **digitization** will **increase diversity** across demographics and geography, and allow staff to work on building strong relationships with participants
 - d. **Share** details on the different digital tools, use “[Elements of a Diverse, Equitable, and Inclusive Digital Clinical Trial](#)”
 - e. Work with site staff to **identify** the **best digital tools/products** to use that will fit well into participants' lives,
 - f. Consult the [Toolkits for Inclusive Digital Product Deployment and Development](#) from the Digital Health Measurement Collaborative Community ([DATAcc](#)) **resources**
 - g. Work with site teams to develop a **change management** strategy
3. **Provide** additional **resources** that your clinical trial team may need:
- a. Use AI/ML to analyze RWD/RWE on clinical site operations to **increase efficiencies**
 - b. Implement a digital platform for **online, on demand training**
 - c. Build this in **collaboration** with your clinical teams
 - d. Include **training** on diversity, equity, and inclusion
 - e. Provide **budget allocations** for implementing change management and hiring more staff that are representative of the participant populations of interest
 - f. Meet with clinical teams regularly to **review and evaluate** progress

Resources to Create Clinical Site Team Trainings

- [Center for Information and Study on Clinical Research Participation](#). Educational materials, including brochures, videos and webinars to help professionals better understand research participants and educational materials to help patients better understand clinical research.
- [Clinical Trial Staff Diversity and Cultural Humility](#). Online Collaborative Institutional Training Initiative (CITI) training on how clinical trial staff diversity



and cultural humility can yield diverse subject recruitment and improved study outcomes.

- [CTTI Investigators and Sites](#). Sponsors, Contract Research Organizations (CROs), and site teams can use CTTI's recommendations and resources to learn how to recognize previous training and experience, identify gaps in knowledge and skills, and improve understanding to achieve higher quality clinical trials.
- [Digitally Enabled Clinical Trials: A Practical Guide](#). It is essential for both sponsors and sites to be early adopters of digital trials. This article will examine the benefits and challenges of digital clinical trials and identify key considerations for sponsors and sites.
- [Diversity, Equity, and Inclusion in Clinical Trials](#). The Association of Clinical Research Organizations (ACRO) created these Principles to demonstrate its shared commitment to advancing diversity, equity and inclusion in clinical trials and bring focus to taking actions toward advancing a more inclusive clinical research ecosystem.
- [Diversity, Inclusion, and Equity in Clinical Research](#). Innovative and practical measures to increase diverse and inclusive representation in the clinical research enterprise.
- [Equity, Diversity and Inclusion Research Site Self-Assessment](#). The ASCO-ACCC Equity, Diversity, and Inclusion (EDI) Research Site Self-Assessment is designed to help research sites and networks do an internal review of policies, programs, and procedures and identify evidence-based strategies to improve EDI in their clinical trials.
- [Health Literacy in Clinical Research](#). A helpful way to learn about clear communications and plain language in clinical research.
- [How Can We Increase Public Awareness of Clinical Trials?](#) Outlines the biggest barriers to awareness of clinical research, the roles healthcare practitioners and clinical trial advocates can play in the education of prospective patients, and the most effective ways of improving clinical trial awareness.
- [Just ASK Increasing Diversity in Cancer Clinical Research Training Program](#). This training program is an online implicit bias training program intended for all members of the cancer research team.
- [PhenX Social Determinants of Health \(SDOH\) Assessments Collection](#). Researchers are encouraged to use this collection to examine the role of SDOH and other factors related to health inequities that enable effective interventions to reduce health disparities.
- [Promoting inclusion in clinical trials — a rapid review of the literature and recommendations for action](#). Based on the literature, it makes 15 recommendations that, if implemented, may help improve inclusion within clinical trials and clinical research more generally.



- [Strategies to improve diversity, equity, and inclusion in clinical trials](#). A description of steps taken to address disparities in a cancer clinical practice and proposed actions at the patient, provider, community, and institution levels to improve DEI in clinical trials.
- [Talking to Your Patient About a Clinical Trial](#). Talking with prospective participants about enrollment in a clinical trial is not always easy and there are few evidence-based strategies to help.
- [Understanding Health Disparities Series](#). National Institute on Minority Health and Health Disparities (NIMHD) online resource to provide educational information and resources on topics and concepts originated by and/or impacting minority health and health disparities research.





References & Resources

1. [3 Ways to Future-Proof Digital Clinical Trials](#). The industry is progressing toward a digital trial environment that connects patients, sites, and sponsors to drive seamless execution and flow of data across stakeholders. Doing so can increase trial speed and reduce costs by 25%.
2. [ASCO Clinical Trial Resources Library](#). Provides a repository of resources related to conducting and managing clinical trials.
3. [ASCO Research Community Forum](#). Site to access resources related to the conduct of clinical trials and to connect with research colleagues about needs and best practices.
4. [Center for Information and Study on Clinical Research Participation](#). Educational materials, including brochures, videos and webinars to help professionals better understand research participants and educational materials to help patients better understand clinical research.
5. [Clinical Trial Staff Diversity and Cultural Humility](#). Online Collaborative Institutional Training Initiative (CITI) training on how clinical trial staff diversity and cultural humility can yield diverse subject recruitment and improved study outcomes.
6. [CTTI Investigators and Sites](#). Sponsors, CROs, and site teams can use CTTI's recommendations and resources to learn how to recognize previous training and experience, identify gaps in knowledge and skills, and improve understanding to achieve higher quality clinical trials.
7. [DATAcc](#): The Digital Health Measurement Collaborative Community uses interdisciplinary expertise, data, and use cases to develop and demonstrate best practices and advance harmonized approaches to speed the use of digital health measurement to improve health outcomes, health economics, and health equity.
8. [DATAcc Toolkits for Inclusive Digital Product Deployment](#). We all know that we “should” be more inclusive in our approach to healthcare delivery and research. It's now time to show the field “how” we can do this when we use digital health measures.
9. [DATAcc Toolkit for Inclusive Digital Product Development](#). This toolkit provides the supporting tools and research that you need to take you from making the business case for an inclusive approach to success at every step of the process.
10. [Digitally Enabled Clinical Trials: A Practical Guide](#). It is essential for both sponsors and sites to be early adopters of digital trials. This article will examine the benefits and challenges of digital clinical trials and identify key considerations for sponsors and sites.
11. [Diversity, Equity, and Inclusion in Clinical Trials](#). The Association of Clinical Research Organizations (ACRO) created these Principles to demonstrate its shared commitment to advancing diversity, equity and inclusion in clinical trials and bring focus to taking actions toward advancing a more inclusive clinical research ecosystem.
12. [Diversity, Inclusion, and Equity in Clinical Research](#). Innovative and practical measures to increase diverse and inclusive representation in the clinical research enterprise.



13. [Health Literacy in Clinical Research](#). A helpful way to learn about clear communication and plain language in clinical research.
14. [How Can We Increase Public Awareness of Clinical Trials?](#) Outlines the biggest barriers to awareness of clinical research, the roles healthcare practitioners and clinical trial advocates can play in the education of prospective patients, and the most effective ways of improving clinical trial awareness.
15. [New Year. New You? Using Change Management for Digital Clinical Trial Transformations](#). Organizational change takes a long time and requires consistent planning and resources.
16. [PhenX Social Determinants of Health \(SDOH\) Assessments Collection](#). Researchers are encouraged to use this collection to examine the role of SDOH and factors related to health inequities that enable effective interventions to reduce health disparities.
17. [Promoting inclusion in clinical trials — a rapid review of the literature and recommendations for action](#). Based on the literature, it makes 15 recommendations that, if implemented, may help improve inclusion within clinical trials and clinical research more generally.
18. [Strategies for Successful Site Selection in Clinical Trials](#). Essential strategies for identifying the appropriate sites, analyzing historical site performance and feasibility, and implementing better communication and tools across stakeholders to maximize time, resources, and funds associated for each clinical trial.
19. [Strategies to improve diversity, equity, and inclusion in clinical trials](#). A description of steps taken to address disparities in a cancer clinical practice and proposed actions at the patient, provider, community, and institution levels to improve DEI in clinical trials.
20. [Talking to Your Patient About a Clinical Trial](#). Talking with prospective participants about enrollment in a clinical trial is not always easy and there are few evidence-based strategies to help.
21. [Tips For Clinical Trial Sponsors To Cultivate Meaningful Relationships With Sites](#). Sponsors can influence site choices by creating a positive sponsor-site relationship from the onset.
22. [Understanding Health Disparities Series](#). National Institute on Minority Health and Health Disparities (NIMHD) online resource to provide educational information and resources on topics and concepts originated by and/or impacting minority health and health disparities research.

