Empower with Information and Education

What should I do?

Create an empowering experience for participants. Ensure that participants have all the resources and tools they need to fully participate, before implementing clinical trial processes. This includes tools for inclusive participation and participant education.

Why should I do it?

→ Increase and improve patient engagement and retention.

→ Reduce burdens for participants and clinical trial teams by streamlining processes and including participants as partners.

→ Increase compliance and participant adherence.

→ Improve outcomes with more robust data collection.

→ Build trust and transparency between participants, Sponsors and clinical trial teams for long term engagement with clinical trials and research.

→ Increase access and awareness for participants to clinical trial participation.

→ Increase awareness for participants on clinical trial participation value and process.

Ethical Considerations

As digital technology use grows, it will be important to ensure that all populations have adequate knowledge on how to use these technologies and how they affect their lives. This will be important for clinical trials as more digital health technologies become integrated into the clinical trial process. Participants must fully understand the role digital technology will play. This will ensure adequate participation for complete data collection and interpretation for safety and efficacy outcomes. The resources referenced here serve as a starting point to help you develop and customize educational materials for your participants.

Equity and inclusivity require that you **ensure all participants can participate fully**. This will be critical for clinical trial compliance and collecting sufficient data to adequately assess the treatment's safety and efficacy, and the ultimate success of your trial. There is a need for information sharing and educating participants. Determine and customize a program for your participants.

Several digital tools can be utilized to create an empowering experience by educating participants. These include: on demand videos, virtual visits and other digital solutions. Use these tools to create an online/virtual program to educate participants.

See the "Elements of a Diverse, Equitable, and Inclusive Digital Clinical Trial" for details on using each of these tools.

Jump to:

- Resources to Tackle the Digital Divide

- Resources to Demystify Clinical Trials

- Additional Sources for Information to Share with Participants

Resources to Tackle the Digital Divide

Many groups **do not have adequate access** to affordable or reliable internet, or the **skills necessary** to fully comprehend and/or effectively use **digital technology** products and services. This digital divide affects people across demographics, including race, ethnicity, age, socioeconomic status, and academic attainment.

A first step in **bridging this divide** is **providing training** and **resources** to those most in need, to increase digital literacy.

The **resources below** can assist with developing a **digital literacy training program** or can be used as-is. They cover general digital and digital health literacy topics.

> **Digital literacy** is "the ability to **use information and communication technologies** to find, evaluate, create, and communicate information, requiring both cognitive and technical skills." – the American Library Association.

1. Materials cover topics on **designing digital literacy programs** for participants, training community members on digital health literacy, and videos and handouts on different components for digital literacy.

    a. Digital Health Literacy Curriculum

b. Health Online: Finding Information You Can Trust Curriculum Material

c. Learn Internet Skills Online: Free Online Learning Modules

d. Why is Digital Literacy So Important to Health?

e. Free Digital Health Literacy Posters

f. Digital Health Literacy Resources for Libraries

2. Digital Inclusion 101. Video introduction to digital inclusion and resources to train community members.

3. Digital Learn.Org. Materials on computer and internet literacy that can be used to customize a training plan for community groups and specific training modules that individuals can complete independently.

4. Learn My Way. Resources and courses for self-paced learning.

5. Techboomers.com. Education on basic computer skills and other resources for older adults and others needing assistance with learning how to use digital technologies.

6. See the "Digital Assessment Readiness" tool in the "Plan for Diverse, Equitable, and Inclusive Engagement" resource.

Resources to Demystify Clinical Trials

Many diverse populations, who have been underserved by healthcare and underrepresented in research, **do not fully comprehend the clinical trials system**. This has been a great source of **mistrust and hesitancy** to participate. Participant **education** will be critical to **developing a more robust, equitable clinical trial system**. Use these resources to **customize education** for your clinical trial.

1. Accelerating Clinical Trials Best Practices for Recruitment and Retention. This manual takes the participant journey as an organizing principle for optimizing clinical trial design.

2. Clinical Research Glossary. This glossary is a list of research words and their meanings; use this to learn more about words used in research studies.

3. Clinical trial resources for patients. Videos and other resources explaining the clinical trial process and answers to FAQs.

4. ClinicalTrials.gov. Provided by the U.S. National Library of Medicine, this is a registry of privately and publicly funded clinical studies conducted around the

world. Information is provided for participants and researchers.

5. [Clinical Trials Information for Patients and Caregivers](). This resource from the National Cancer Institute provides information on the entire clinical trial life cycle from helping participants find a trial to safety, and how to talk to their providers.

6. [Clinical Trials: What Patients Need to Know](). An introduction on clinical trials and trial participation.

7. [Digital Health Literacy](). Materials cover topics on designing digital literacy programs for participants, training community members on digital health literacy, and videos and handouts on different components for digital literacy.

8. [Digital Inclusion 101](). Video introduction to digital inclusion and resources to train community members.

9. [Digital Learn.Org](). Materials on computer and internet literacy that can be used to customize a training plan for community groups and specific training modules that individuals can complete independently.

10. [Learn My Way](). Resources and courses for self-paced learning.

11. [Techboomers.com](). Education on basic computer skills and other resources for older adults and others needing assistance with learning how to use digital technologies

12. [Understanding the patient journey](). This is an overview of the participant clinical trial experience. While written for health care providers the information included will be valuable for participants and their support group.

Additional Sources for Information to Share with Participants

The following are **additional references** and **resources** that you can **share** with your participants, **Integrate** into your **educational materials** for participants, or share with clinical teams. These can be **customized** to your specific clinical trial or digital tools and products.

1. [CDC Health Literacy](). This is an extensive library of resources for developing health literacy enrichment programs. The resources are designed for health communicators, public health professionals, and community leaders who seek information and tools on health literacy research, practice, and evaluation.

2. [Center for Information and Study on Clinical Research Participation](), Inc. (CISCRP). Provides educational resources, programs, and services to increase

awareness and understanding of the clinical research process for patients and their families; and promote engagement and partnership between clinical research professionals, patients, and the public.

3. [Clinical Trials Internet Resources](#). This is a compilation of online resources for participants and clinicians to learn more about clinical trials in general, avenues for participation, and disease specific advocacy groups.

4. [End User Bill of Rights](#). Similar to a patient's bill of rights, these are key elements participants should be aware of when asked to use a digital health product.

5. [FAQs for Digital Health Measurement Product.](#) A list of questions and answers that participants may have for digital health products.

6. [FAQs for End User Privacy & Security.](#) A list of frequently asked questions (FAQs) and answers explaining privacy and security elements participants should be aware of before agreeing to use a digital product.

7. [Learning About Context of Daily Life.](#) This document is intended to help participants alert the research team to things that might affect their participation in a clinical trial or use a digital health product.

8. [Plain Language Checklist for Lay Brief Summaries](#). Utilize this checklist to confirm that study materials are inclusive.

9. [Questions to Ask - Patient/Participant Perspective.](#) This tool suggests questions that participants should ask the research team when they are first asked to use a digital health product.

10. [ResearchMatch.](#) ResearchMatch is a research registry funded by the National Institutes of Health (NIH). Those interested in participating in research are connected to research studies across the U.S.

11. [Sample End User License Agreement.](#) A sample end user license agreement (EULA) with descriptions and plain language explanation of each clause.

12. [Smart Patients](#). An online community for patients and their families to learn from each other's experiences with clinical trials.

13. [US National Institutes of Health Clinical Research Trials and You](#). Basic information, volunteer stories. and educational materials for children and seniors. Spanish language materials are also provided.